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THE CONTRIBUTION OF PATIENT REPORTED OUTCOME MEASURES
TO SHARED DECISION-MAKING IN RADIATION ONCOLOGY
AT A MIDWESTERN COMPREHENSIVE CANCER CENTER

A Dissertation

Presented to

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The George Washington University

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Doctor of Philosophy in Translational Health Sciences

by

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Keywords: Shared Decision-Making, Patient Reported Outcomes, Radiation Oncology,

Medical Management

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ABSTRACT

Background. Chronic diseases, such as lung cancer, require a provider-patient relationship developed over time. This relationship fosters shared decision-making (SDM), a collaborative, dynamic information exchange and analysis between provider and patient regarding treatment and desired outcomes. Established benefits to SDM include an improved quality of life and decreased anxiety and depression. Despite established benefits, recent research suggests radiation oncologists are not engaging in SDM. A decision-aid tool utilizing patient reported outcome measures may increase SDM between radiation oncologists and patients with lung cancer. Patient-reported outcome measures, wherein the patient provides direct assessment of their health and quality of life, can inform and initiate SDM. This study investigated the design and implementation of a collaborative decision-aid tool for patients with lung cancer at a Midwestern cancer center as informed by stakeholders, practice considerations, and the evidence base.

Objectives. The primary objective was to develop a collaborative decision-aid tool, using patient-reported outcome measures, that can be implemented in an academic radiation oncology clinic. Secondary objectives then assessed the tool's impact through surrogates of shared decision making (add-on oncology visits, concomitant medication prescriptions), medical management (adverse events, radiation therapy compliance, chemotherapy compliance) and emergent care and its costs (emergency room visits and estimated costs,

inpatient admissions and estimated costs). The hypothesized result was a decision aid designed to increase collaborative communication between radiation oncologists and patients will result in improved shared decision making, yielding better medical management and patient outcomes and reducing emergent care costs. Lastly, an implementation roadmap provided information on experienced barriers, facilitators, and considerations for performance objectives.

Materials and Methods. A sequential exploratory mixed methods design was employed. The qualitative strand explored how stakeholders, practice considerations, and the evidence base informed the design and installation of an ideal collaborative decision-aid tool. Semi-structured interviews were completed with both patients who completed radiation therapy for lung cancer and their radiation oncologist. Interviews were coded and evaluated for themes. Interviews were transcribed verbatim, coded using Atlas.ti software, and analyzed thematically and visually. The results of this analysis, combined with information from the literature base and implementation stakeholders, was used to inform design of the collaborative decision-aid tool that was installed employing the principles of clinical implementation using the plan-do-study-act (PDSA) implementation cycle model. Simple descriptive analysis was performed on objective measures. Mixed analysis included data display, comparison, and integration.

Results. Six patients and six radiation oncologists participated in the semi-structured interviews. Interviews provided insights that patients did not know what to ask of their radiation oncologists, prioritized survival over reduced side effects, and minimized complaints to their radiation oncologists, often to their detriment. Interviews yielded feedback on commonly used patient reported outcome instruments, identifying context as

important and the recall timeframe as difficult. Commonly patient-identified adverse events of concern were fatigue, dyspnea, vomiting, and dysphagia. Radiation oncologists identified a patient's personality as critical to care and translating responses and symptoms to adverse events of treatment. For this reason, numeric scales were not endorsed as they were seen as ambiguous and lacking context. With this feedback, a collaborative decision-aid tool was designed that focused on adverse events of interest (nausea, vomiting, fatigue, dyspnea, chest pain, weight loss). Rather than numeric scales, responses provided granular context that clued physicians to medical needs (i.e., "I cannot walk to my appointment," "It hurts when I eat," "I am not vomiting but I'm not hungry"). This tool was implemented as a quality initiative project for pragmatic impact. Four patients were assigned the tool during the first PDSA implementation cycle. The first follow-up evaluation meeting identified four critical outcomes for the next implementation cycle: how to identify which consults require the decision-aid, how the need for the decision-aid on doctor visits is consistently provided to scheduling, how unplanned visits/special complaints are addressed with regard to the decision-aid, and what actions are necessary if the patient leaves prior to the decision-aid being reviewed. Mixed analysis provided direction for next steps in implementation, tool design, and quantitative data measures. The primary concern, increase in time expended per clinic visit, was not supported by the limited data available from the first implementation cycle.

Conclusion. Implementation of collaborative decision-aid within the radiation oncology clinic is feasible without disruption of the on-treatment visit time. Radiation oncologists can use the tool as a guide for routine on-treatment visit review, so that it is harmonized with their routine practice. Care should be taken during implementation to ensure all

stakeholders are included in the tool's implementation and that desired outcomes are appropriately identified to truly capture what impact the tool has, if any, on clinical outcomes. Focusing on the patient with the goal of improving their experience will guide collaborative decision-aid tool adaptation, implementation, and uptake.

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My father, Richard Wagener, continually encouraged me and empowered me to be whatever I set my mind to. My sister Leslie Dearborn, who took me out for breakfast and dinner and listened to me prattle on, so I could have some level of social engagement. My husband, who added *housekeeper, maid, and cook* to his already long list of tasks and his professional career...and did so without a single complaint. My children who continually supported me through every extreme emotion imaginable. Thank you for putting up with me during this journey.

The boss who has supported me through brutal honesty and critical thinking.
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DEDICATION

This work was completed during the SARS-CoV-2 outbreak and pandemic of 2020 and 2021. At the start of the pandemic, healthcare workers did not have access to personal protective equipment yet chose to put themselves in jeopardy daily to treat those infected with a disease that did not have a treatment let alone a cure. After long hard hours, they then self-isolated to protect their families and loved ones. More than 3600 healthcare workers perished in 2020 while caring for those with SARS-CoV-2. As I conducted my research, I witnessed the impact the 2020 pandemic had on the healthcare staff as well as on oncologic healthcare and the inpatient units at an academic medical center. I saw the stress. I witnessed the fatigue. I heard the pain in their voices as they expressed the frustration that there was often little they could do except provide comfort.

This work is dedicated to all healthcare heroes and their families.

Thank you for caring for us.

“It is not the critic who counts; not the man who points out how the strong man stumbles or where the doer of deeds could have done better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood, who strives valiantly, who errs and comes up short and short again and again, because there is no effort without error or shortcoming, but who knows the great enthusiasms, the great devotions, who spends himself for a worthy cause; who, at best, knows, in the end, the triumph of achievement, and who, at the worst, if he fails, at least he fails while daring greatly, so that his place shall never be with those cold and timid souls who knew neither victory nor defeat.”

President Theodore Roosevelt

“I am only one, but still I am one.

I cannot do everything, but still I can do something.

And because I cannot do everything, I will not refuse to do the something that I can do.”

~ Edward Everett Hale

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CHAPTER 1

1 INTRODUCTION

1.1 Overview

Shared decision-making (SDM) is described conceptually as a collaborative, dynamic information exchange and analytic process between the healthcare provider and the patient (Charles et al., 1999). Essential elements of SDM include openly discussing the risks and benefits of possible therapies as well as the patient's preferences and their understanding of the healthcare problem (Hughes et al., 2018). Incorporating the patient's desires and values into the treatment decision is a hallmark of successful SDM (Noonan et al., 2017). For patients with chronic disease, such as those with cancer, SDM should not be a singular event but should occur often throughout the course of their illness (Peek et al., 2014). Chronic diseases require a provider-patient relationship developed over time and, for this reason, educating patients about cancer and its treatment options can be time-consuming but yields rewards through an enhanced relationship developed through the process (Morrow, 2016).

Potential benefits to SDM include improved quality of life, decreased anxiety and depression, reduced psychological distress, and increased satisfaction (Shabason et al., 2014). Patients with cancer who perceive concordance between preferred and actual treatment decision roles have higher vitality, less fatigue, less confusion, less anger, and

better overall mood (Atherton et al., 2013). The most significant benefit to SDM is one that is not easily measured: respecting the patient's autonomy (Beers et al., 2017).

Respecting a patient's independence and individual values and preferences adds a layer of complexity because not all want to engage in SDM. While the majority of patients prefer to be asked regarding their choice; some prefer to rely on their doctors' professional opinion (Beers et al., 2017).

Patients with lung cancer are often referred to radiation oncology from an outside clinic or after a primary treatment recommendation from a multi-disciplinary oncology board (Golden et al., 2017). As one of the three primary therapeutic modalities, radiation is administered curatively, alone or in combination with other therapies, or as a palliative treatment to provide a better quality of life for patients. Radiation treatment requires a weekly on-treatment visit (OTV), comprised of a personal discussion visit and an examination by the radiation oncologist to monitor for treatment-emergent side effects and symptoms of the cancer. Toxicities from radiation therapy not only include skin erythema (i.e., radiation burn) but subjective symptoms of fatigue, nausea, diarrhea, and anorexia. Patients with lung cancer have the highest rate of medical comorbidities and as such have additional concerning treatment toxicities including dyspnea, sore throat, and dysphagia (Sogaard et al., 2013). Each of these symptoms requires management to continue radiation treatment as well as reduce morbidity. Radiation oncologists rely on the patient's exchange of information during the OTV to identify and manage these symptoms and gauge response to radiation. Thus, SDM for radiation oncologists includes not only the initial decision to undergo radiation treatment but a continued process to adjust concomitant medications for symptom management, potentially modify the

radiation therapy plan, consider instituting a break from the daily radiation treatment, or even discontinue radiation therapy if necessary.

A disparity has been identified between a patient's reported side effects and the oncologist's determination of adverse events. In general, oncologists report adverse events to be less severe than as described by patients—even subjective symptoms such as fatigue and nausea (Atherton & Sloan, 2006; Basch, Deal, et al., 2016; Cirillo et al., 2009; Falchook et al., 2016). This, coupled with other recent research, suggests radiation oncologists are not optimally participating in SDM during their OTVs (Fromme et al., 2016; Golden et al., 2016; Golden et al., 2017). Identified barriers to SDM include time-constraints, the education gap between provider and patient, and the patient's concern of being labeled 'difficult' (Frosch et al., 2012; Legare et al., 2008; Woodhouse et al., 2017). Additionally, and more specifically, research from Fromme and colleagues (2016) identifies poor communication between patient and radiation oncologist regarding treatment side-effects and symptoms of disease. While communication has been identified as a key facilitator to SDM and to patient-centered medicine, interventions to improve communication are typically time intensive, require intervention away from clinic, and have a short-effect window (Beers et al., 2017; Golden et al., 2017; Pollak, Alexander, et al., 2010; Pollak, Arnold, et al., 2010; Pollak et al., 2007; Tulskey et al., 2011).

In their 2017 review of the current research literature, Noonan et al. stated patient-reported outcome measures (PROMs) can increase communication between providers and patients and utilizing PROMs positively impacted SDM and overall patient outcomes. The United States Food and Drug Administration (FDA) define PROM as:

Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. The outcome can be measured in absolute terms (e.g., severity of a symptom, sign, or state of a disease) or as a change from a previous measure.

(2009, p. 2)

Patient-reported outcome measures should be validated for sensitivity to change over time, focused on the outcomes or concepts being measured, and for those outcomes to be impactful toward the intended use for the medical condition (FDA, 2009). The FDA requires the PROM be evidence-based to document it is measuring the right thing in the right way in the specified patient population so that the score accurately and reliably provides information to be interpreted clinically (i.e., provides benefit to the providers and patients) (FDA, 2018). When a new drug or device is approved utilizing a PROM-based endpoint, FDA also reviews the recall period, response burden, and number of items for the patient to complete (FDA, 2009). Current criticisms from FDA include a significant burden of questions and time-points as well as a misalignment between known drug toxicities, PROM questions and instruments, and the lack of investigation as to the impact of a side-effect or symptom on a patient's life (FDA, 2018). In 2016, the 21st Century Cures Act mandated patient-focused drug development (PFDD) and oncology excellence, requiring the patient's voice to be incorporated into drug design as early as the pre-clinical development phase (FDA, 2020a). This federal requirement provides a new opportunity to investigate the impact of PROMs in the radiation oncology clinic as well as strategize methods to make PROMs easy, fast, and meaningful for both provider and patient.

A logical application of the electronic health record (EHR) would be to utilize it as a central repository for PROMs. Initial research suggests this alone does not prompt patient-provider communication or resolve the disconnect between provider and patient regarding adverse events (Fromme et al., 2016). Thus, the next step is to create a tool that stimulates effective information transfer for radiation oncologists and patients without increasing burden to either. Information from the tool would be stored in the EHR, providing a foundation for radiation oncologists to identify trends between their assessments and the patient's assessments, thereby increasing SDM.

1.2 Statement of the Problem

Patient-reported outcome measures can facilitate communication and SDM (Noonan et al., 2017). To date, there is a lack of research evaluating the use of PROMs in clinical radiation oncology practice, including which PROMs should be used, when they should be used, and how they impact clinical measures (Fromme et al., 2016; Gracie & Ford, 2016; Hawley & Jagsi, 2015). Additionally, a disparity exists between the oncologists' and patients' assessments of adverse events and, as a result, a knowledge gap translating the two perspectives has emerged (Atherton & Sloan, 2006; Basch, Deal, et al., 2016; Cirillo et al., 2009; Falchook et al., 2016; Sneeuw et al., 1998; Sneeuw et al., 2002).

With required weekly OTVs, radiation oncology has both unique potential and unique demands for SDM. Radiation oncology presents the opportunity to investigate the relationship between PROM, SDM, and clinical outcomes. Prior work investigating PROM and radiation oncology did not incorporate PROM into the medical record, did not evaluate time expenditure, and had a limited review of clinical outcome measures (Fromme et al., 2016; Golden et al., 2016). Without consistent and clear clinical benefit,

it is difficult to gain buy-in from stakeholders for SDM implementation. Extending prior work to include objective measures—such as time spent in weekly examinations, number of add-on visits, or healthcare expenditures during radiation therapy—would provide foundational evidence to support SDM implementation.

A collaborative decision-aid using PROMs as an intervention could align the importance of specific adverse events between provider and patient, harmonizing evaluation. This collaborative decision-aid would be used at each radiation oncology OTV to review side effects common to the patient and adverse events that are important to the physician. An ideal decision-aid would not only enhance communication but focus it on those side effects most concerning to the radiation oncologist or patient. This discussion should then spur a dynamic discussion about provider and patient treatment goals, increasing SDM.

This would enable trends to be measured over time, empowering the provider to implement interventions earlier and avoid inpatient hospitalizations or breaks in radiation therapy. Most importantly, the decision aid tool could help enforce the importance of treatment and medication compliance, resulting in reduced side effects and thereby reduce the potential for emergency room visits, admissions, or breaks in therapy.

To be useful, the decision-aid would need to be clear, simple, and easy to understand. A decision-aid adding time to a hectic clinical schedule will challenge implementation. The decision-aid should create collaboration between the provider and patient toward the patient's ultimate goals, whether it is palliative or definitive.

1.3 Purpose and Research Questions

This study will develop a decision-aid using PROMs as an intervention tool to promote collaborative communication between radiation oncologists and their patients. First, the study will employ an interpretivist paradigm to determine key factors and considerations from stakeholders to create the decision-aid. Next, a pragmatic paradigm will be used to evaluate the implementation and impact of the decision-aid in a radiation oncology clinic. The overarching hypothesis is a decision-aid designed to increase collaborative communication between radiation oncologists and patients will result in improved SDM, yielding better medical management and patient outcomes and reducing emergent care costs. The primary objective is to develop a collaborative decision-aid tool, using patient-reported outcome measures, that can be implemented in an academic radiation oncology clinic. Secondary objectives then assess the tool's impact through surrogates of SDM (add-on oncology visits, concomitant medication prescriptions), medical management (adverse events, radiation therapy compliance, chemotherapy compliance), and emergent care and its costs (emergency room visits and estimated costs, inpatient admissions and estimated costs). To examine this hypothesis, the following research questions will be addressed:

How do the stakeholders, practice considerations, and evidence base inform the ideal design and implementation of a collaborative decision-aid tool?

What is the impact of the collaborative decision-aid on the medical management of patients actively undergoing radiation treatment for lung cancer?

How does the impact of the collaborative decision-aid tool inform recommendations for future designs and implementation ?

1.4 Translational Nature of the Study

Patient reported outcome measures have been established in clinical research but have not been routinely translated to practice (T3 chasm) or implemented in the oncologic population (T4 chasm) (Drolet & Lorenzi, 2011; Khoury et al., 2007). Additionally, the lack of PROM in routine assessments and medical care impact bench science and discoveries by diminishing the effectiveness of the overarching T4 to T1 feedback loop. Bench science is starved of key feedback about how treatments affect patients, robbing investigators of potential discoveries only evident through the important lens of patient tolerance and preference rather than solely focusing on tumor cell killing. A core facet of translational medicine in oncology is not being robustly addressed, resulting in a translational knowledge deficit in patient-focused drug development, patient-centered medicine, and individualized cancer care.

1.5 Statement of Potential Impact

Rather than a single-point treatment decision, patients with lung cancer undergoing radiation treatment make continual collaborative decisions with their oncologist. Treatment options for these patients include different radiation delivery strategies (i.e., daily for 6-7 weeks, every other day for 1-2 weeks, or even a single treatment alone), concurrent chemotherapy and/or immunotherapy options, or declining aggressive care and transitioning to palliative radiation or medical therapy to reduce symptoms. Additional decisions are made regarding supportive care to get through therapy, for example when a gastrostomy tube should be placed (e.g., prophylactically or only if weight loss is greater than a certain percent). Many patients with lung cancer undergo multiple courses of radiation: first to treat the primary disease and then

additional rounds to treat metastases. Despite weekly OTV for up to nine weeks per course, recent research suggests shared decision making with radiation oncologists diminishes longitudinally (Ernstmann et al., 2012).

Currently, there is a lack of a systematic approach to evaluate radiation oncology patients' symptoms or quality of life. Researchers have not identified what patient reported outcomes to measure in which patient base, how to measure them, nor how to analyze them (FDA, 2018). Without foundational research, oncologists do not understand benefits from PROMs and how to implement them in their clinic. Ultimately, this impacts the oncology patients, whose voice and perspective are reduced or removed entirely in their treatment plan. A lack of real-world evidence limits a patient's ability to understand a treatment's effects in the context of their priorities and treatment goals.

The collaborative decision-aid tool has the potential to not only improve patients' medical management but also provide foundational information about how patients prioritize treatment goals and symptomatic adverse events and how these change over time. This would provide real world evidence to propel patient-centered medicine and patient-focused drug development in oncology. If successful, this research will provide key information on PROM implementation into a radiation oncology clinic as well as for patient-focused cancer research, enabling a new clinical outcome and scientific strategy for subsequent oncology research (FDA, 2018).

1.6 Theoretical Foundation or Conceptual Framework

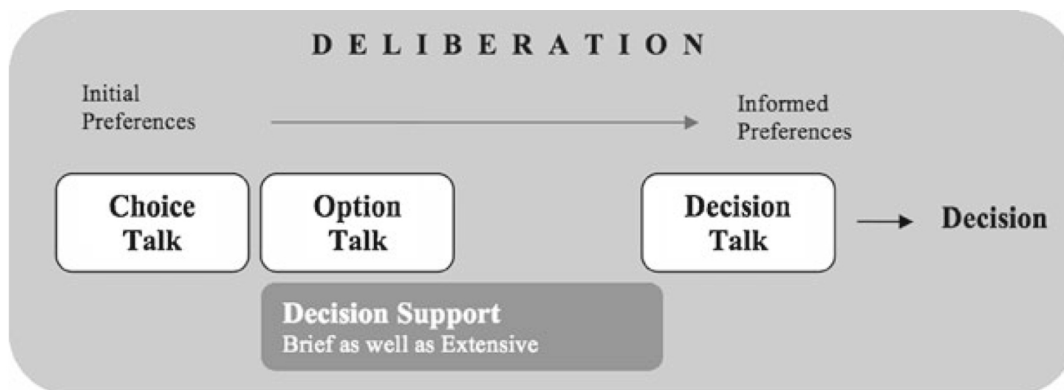
Perpetual research into antineoplastic therapy has shifted cancer away from a fatal disease toward a chronic healthcare condition. While these treatments prolong life they also present different risk profiles. Shared decision-making becomes a logical process

between oncologist and patient to determine which treatment matches a patient's lifestyle and value system.

Shared decision-making describes a knowledge-transfer between the provider and patient at critical timepoints in medical care (Charles et al., 1999). The SDM model identifies three key phases to the model: choice talk, option talk, and decision talk (Elwyn et al., 2012). Choice talk reminds the provider to offer choices, justify the patient's choice by emphasizing the consideration of their personal preferences, and gauge the reaction of the patient before continuing forward. Opinion talk focuses on assessing the patient's foundational knowledge, providing a list of options and their descriptions, and then providing support. Choice talk combined with opinion talk guides patients to informed preferences through deliberation of pros and cons. Patients can then make their decisions

Figure 1

Model of Shared Decision Making Process as Designed by Elwyn et al. (2012)



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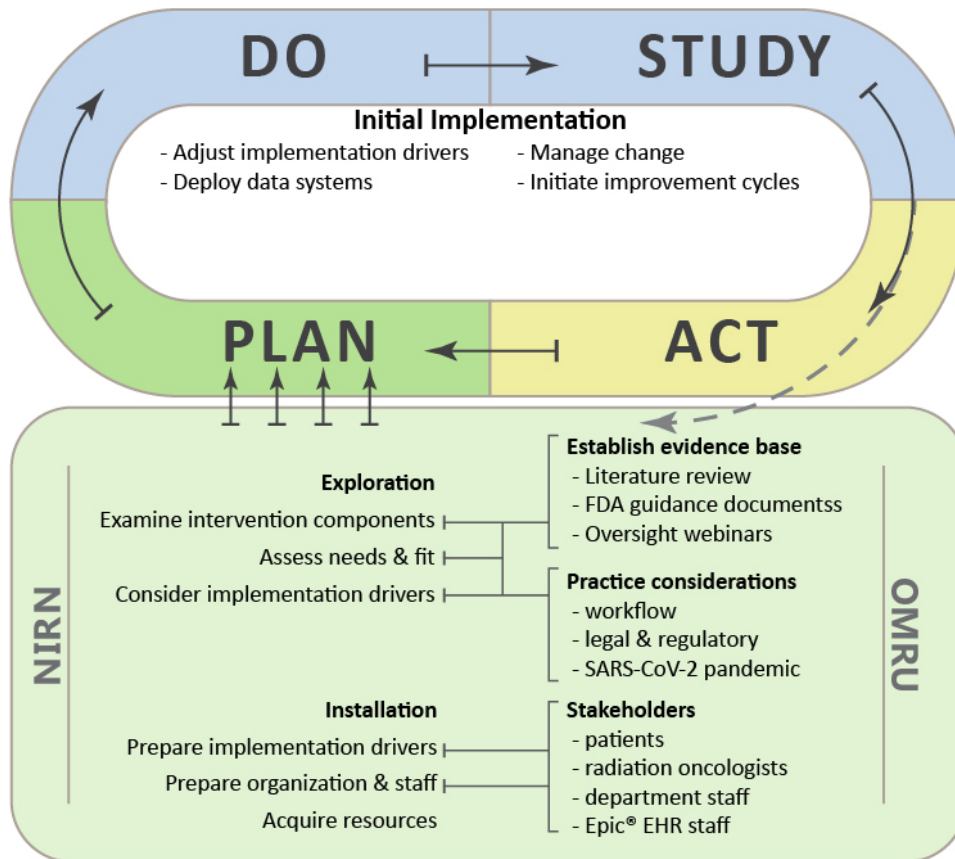
and review them with their provider; the provider may or may not agree with the patient's decision (i.e., decision talk).

This idealized model will be adapted to address the radiation oncology OTV because of the varied levels of decision making (Figure 1). Radiation treatment does not represent a singular treatment decision but a continued processes between the radiation oncologist and the patient. Together, patients and their radiation oncologist decide to continue radiation therapy, determine which side effects are problematic and need intervention, and if further tests or evaluations are required. In early therapy no intervention may be needed. In contrast, in the final weeks of radiation therapy a physician may need to adjust medications several times a week to counter the side effects. Thus, choice talk translates to prioritizing goals and symptoms of therapy while option discussion is the radiation oncologist reviewing and confirming the patient's preferences for treatment and medical management. The decision is then collaborative management, with PROMs providing the critical information for deliberation by both patient and radiation oncologist.

Research shows SDM is not occurring consistently in radiation oncology (Fromme et al., 2016; Golden et al., 2016; Golden et al., 2017). A collaborative decision-aid will need to be developed and implemented in a radiation oncology clinic in hopes of initiating SDM. The Ottawa Model of Research Use (OMRU) provides a framework for implementation of evidence-based innovations by assessing barriers and supports, monitoring the intervention, and evaluating the outcomes (Graham & Logan, 2004). The OMRU documents the interactions between the evidence-based innovation, potential adopters, and the practice environment when assessing the barriers, facilitators, and

Figure 2

Graphical Depiction of the Guiding Conceptual Frameworks.



Note. The Ottawa Model for Research Use provides granularity for the NIRN stages *Exploration* and *Installation*, which flow directly into the PLAN segment of the Plan-Study-Do-Act implementation model (Bertram et al., 2015; Graham & Logan, 2004; Langley et al, 2009). The NIRN stage *Initial Implementation* includes improvement cycles and managing change; this aligns with the DO and STUDY segments of the PDSA cycle. The dotted arrow represents a return to the OMRU and NIRN stages *Exploration* and *Installation* to broaden the implementation, assess for newly identified facilitators or barriers, or to adopt an amended workflow due to an unforeseen event.

environment. It also highlights a feedback loop from implementation, adoption, and outcomes to enable adaptation and fit as required (Graham & Logan, 2004).

The Plan-Do-Study-Act (PDSA) cycle begins by addressing the considerations for implementation (i.e., PLAN segment) (Langley et al., 2009). Although the elegance and

flexibility of use for the PDSA cycle lies within its simplicity, greater detail is needed to guide implementation planning within the healthcare setting—thus the OMRU framework and the National Implementation Research Network’s (NIRN) framework are relied upon to provide further details for the PLAN segment (Figure 2). The OMRU describes the initial decision-aid tool design, from assessing the stakeholders and practice considerations to identifying key barriers and workflow concerns (Figure 2). The key domains of the OMRU (assess, monitor, evaluate) interleaf with the stages of the NIRN Framework, which in turn provides needed detail for the PDSA PLAN segment (Figure 2) (Bertram et al., 2015). The NIRN framework has three stages of interest: exploration, installation, and initial implementation (Bertram et al., 2015). Exploration describes needs assessment, reviewing intervention components and implementation drivers, and assessing fit. *Exploration* aligns with the PDSA’s PLAN segment and also the OMRU’s *Establish Evidence Base* and *Practice Considerations*, providing more granularity for these concepts. *Installation* aligns with the OMRU *Stakeholders* except for one key aspect: the NIRN framework describes acquiring the resources which is not addressed in the OMRU (Bertram et al., 2015). The NIRN stage of *Initial Implementation* outlines managing change, deploying data systems, and adjusting implementation drivers, aligning with the PDSA segments DO and STUDY (Bertram et al., 2015; Langley et al., 2009). The PDSA cycle continues from an initial implementation to subsequent cycles, for improvement, expansion, or adaptation (Langley et al., 2009). In contrast the NIRN implementation framework is linear and the OMRU, although having a feedback loop, is not designed for purposeful iteration of implementation and ramp-up of the intervention.

Although other SDM research has suggested using the Theoretical Domains Framework, this framework is most useful for creating theory-informed behavior change (French et al., 2012). The purpose of this collaborative decision-aid will not involve behavior change as measured by PROM but clinical behavior change as the radiation oncologist and patient form a partnership by using PROM as a tool to achieve identified treatment goals. This nested framework incorporating implementation of evidence-based practice with shared decision making will provide strong conceptual guidance.

1.7 Summary of the Methodology

A sequential exploratory mixed methods study will be employed because resolving the disconnect between research, practice, and population requires a pragmatic ontology (i.e. constructing real-world solutions) with an overall pragmatic epistemology (i.e., objective and subjective knowledge) (Creswell & Plano Clark, 2011). Mixed methods research synergizes the strengths of the single method strategies (i.e. qualitative or quantitative), thereby addressing an individual method's weaknesses and providing additional credibility, completeness, and context to the study (p.12, Creswell & Plano Clark, 2011).

The qualitative strand of the study will provide insight to the design and implementation of the collaborative decision-aid tool. Briefly, a literature search and a review of existing decision-aid tools will provide the initial insight for tool design as well as identifying known barriers and facilitators to SDM and PROM. Once reviewed, semi-structured interviews with patients will inform on communication, the radiation oncology experience, how a collaborative decision-aid tool could be designed, and how it could work. After the patient interviews are initiated, radiation oncologists will also be

Figure 3

Examples of Items for Fatigue from PRO-CTCAE™, PROMIS®, and EORTC

PRO-CTCAE™

As individuals go through treatment for their cancer they sometimes experience different symptoms and side effects. For each question, please check or mark an ☒ in the one box that best describes your experiences over the past 7 days...

In the last 7 days, what was the SEVERITY of your FATIGUE, TIREDNESS, OR LACK OF ENERGY at its WORST?				
<input type="radio"/> None	<input type="radio"/> Mild	<input type="radio"/> Moderate	<input type="radio"/> Severe	<input type="radio"/> Very severe
In the last 7 days, how much did FATIGUE, TIREDNESS, OR LACK OF ENERGY INTERFERE with your usual or daily activities?				
<input type="radio"/> Not at all	<input type="radio"/> A little bit	<input type="radio"/> Somewhat	<input type="radio"/> Quite a bit	<input type="radio"/> Very much

PROMIS®

In the past 7 days...	Never	Rarely	Sometimes	Often	Always
I was too tired to do my household chores.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I was too tired to leave the house.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I was frustrated by being too tired to do the things I wanted to do.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

EORTC

	Not at All	A Little	Quite a Bit	Very Much
Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
Do you need to stay in bed or a chair during the day?	1	2	3	4

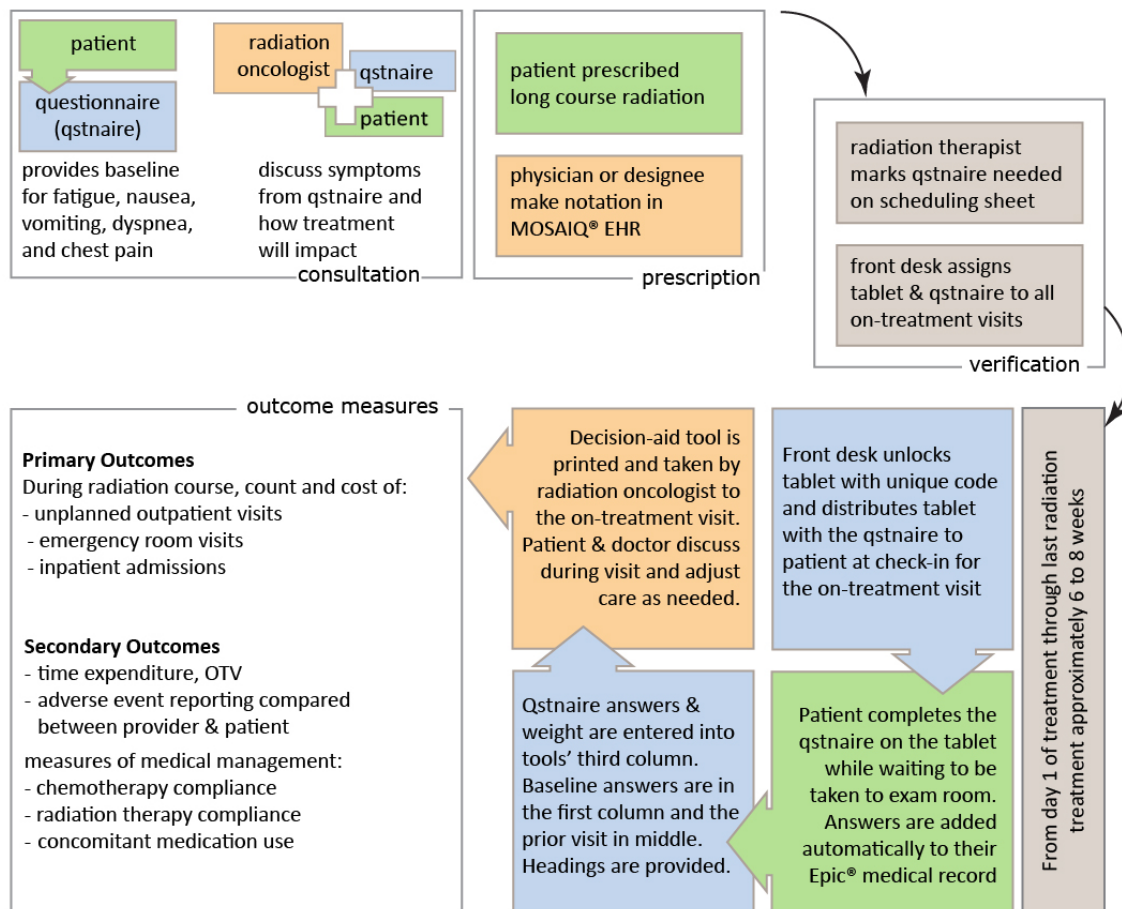
Note: PROMIS® is ©2006-2017 PROMIS Health Organization; EORTC ©1995 EORTC Quality of Life Group.

interviewed to regarding the collaborative decision-aid tool design and implementation. This is an iterative process: information and knowledge obtained from interviews with patient participants and treating radiation oncologists informs future interviews. Similarly, radiation oncologists will be contacted for clarifications about OTV workflows, patient’s treatments, or their clinic workflow. Upon completing the interviews, the tool will be designed to contain PROMs of interest to the patient and radiation oncologist. Items measuring the side-effects/symptoms of interest will be drawn

from validated item banks: the Patient Reported Outcomes–Common Terminology Criteria for Adverse Events item library (PRO-CTCAE™, National Cancer Institute), the Patient-Reported Outcomes Measurement Information System (PROMIS® , Department of Health & Human Services, U.S.), and the QLQ-C30 quality of life questionnaire (European Organization for Research and Treatment of Cancer (EORTC, Brussels) (Figure 3). These three item banks were selected based on the work presented at the 2018 FDA Public workshop *Clinical Outcome Assessments in Cancer Trials*. During this webinar, experts demonstrated how to utilize the validated items from the EORTC, PROMIS® , and PRO-CTCAE™ in a mix-and-match strategy to achieve fit-for-purpose (FDA, 2018). Additionally, the EORTC, PROMIS® and PRO-CTCAE are item banks that contain common cancer symptoms recommended by the Center for Medical Technology Policy as important for comparative effectiveness research in oncology (Basch et al., 2012).

Planning the implementation of the collaborative decision-aid tool will extend the qualitative research from the patient/physician dyad to encompass Epic® EHR information technology specialists as well as key stakeholders within the radiation oncology clinic. After their feedback is provided and a strategy for implementation determined, the study transitions from the qualitative strand to the quantitative strand.

The quantitative stand is rooted in the principles of quality improvement yet is not a formal quality improvement project. Within the U.S., research focusing on improving the quality of patient care or collecting patient or provider data for clinical, practical, or administrative purposes is termed ‘quality improvement,’ and is generally exempted from Institutional Review Board oversight (U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections, 2021). Although the term *quality*

Figure 4*Concept Schema of the Clinical Implementation*

improvement project may be misleading in the context of a formalized quality improvement plan, for the purposes of this work's IRB exemption it was used. This work is designed to pragmatically evaluate the impact of the collaborative decision-aid outside of a formalized clinical trial structure (Figure 4). Data obtained from the tool's clinical implementation will be compared to a historical baseline of patients treated in the same facility for lung cancer. Patients recommended for long course radiation therapy for non-small cell lung cancer will have the collaborative decision-aid tool assigned to their OTVs. Both the radiation oncologist and patient will be provided the opportunity to review the questions prior to the collaborative decision-aid being implemented.

The initial concept is that a set of six to eight patient-reported outcome items could be provided to a patient at their OTV (Figure 4). The workflow exploits two EHR: Epic[®] and MOSAIQ[®]. Whereas Epic[®] is a systems-wide EHR used in the UIHC care system, MOSAIQ[®] is a record-and-verify EHR unique to radiation oncology, enabling radiation oncology-specific notations in designated areas regarding a patient's care plan. MOSAIQ[®] could be utilized to communicate the need for the decision aid for each patient. Because MOSAIQ[®] is not house-wide, Epic[®] was targeted for collection and dissemination of patient reported outcome measures. Thus, the PROM responses are entered into Epic[®] EHR through a direct data input function utilizing a computer tablet. The PROMs would then be transferred into a collaborative decision-aid tool, printed, and provided to the radiation oncologist. The radiation oncologist would take the collaborative decision-aid tool to the OTV for review with the patient. The collaborative aid-design tool informed from the qualitative strand should be easy to understand, free from medical jargon, and provide trends over time. The tool should be flexible in design to accommodate changes in patient or radiation oncology priorities. Outcome measures include number of emergent visits, costs of emergent care, treatment compliance, changes to medical management, and time expenditure for the OTV.

This research will be conducted as a single-site study at the University of Iowa Hospitals and Clinics. Ethics approval will be obtained from the institutional review board (IRB) of record (University of Iowa IRB-01, biomedical) as well as an IRB Authorization Agreement (IAA reliance) executed with George Washington University IRB prior to the initiation of any human subjects research. The study did not require registration on www.ClinicalTrials.gov per federal regulations (42CFR§11).

1.8 Limitations and Delimitations

This study is designed as a single-site study recruiting only English-speaking individuals who have already decided to undergo radiation therapy for the treatment of their lung cancer. This delimitation of the study population then impacts generalizability, limiting the findings. By approaching this established patient base, a significant treatment decision has already been undertaken: the patients have opted to seek treatment rather than comfort care or watchful waiting. Therefore, the results of this study will most likely not be meaningful to those patients. Additionally, the lung cancer patient base at University of Iowa currently has only two primary radiation oncologists for that clinic, limiting the richness and depth of understanding a radiation oncologist's perspective as to the ideal decision-aid tool and its ideal workflow. Another limiting factor is the use of a 'covering' radiation oncologist if the treating radiation oncologist is out of office. This can cause disruption and affect internal validity of this pilot study. Lastly, the University of Iowa serves a rural, midwestern region of the nation. While the coverage area includes the state of Iowa as well as the neighboring bordering communities, the socioeconomic status, agrarian economy, and shared culture of the patient population are markedly different compared to other geographic regions of the United States (e.g., higher socioeconomic status, metropolitan areas).

1.9 Definition of Key Terms

Adverse event (AE). Any untoward medical occurrence whether or not considered related to the treatment or study, often colloquially termed side-effect or symptom.

Clinical outcomes assessment (COA). As defined by the FDA-NIH Biomarker Working Group (2021) this is an assessment of a clinical outcome made through report

by a clinician, a patient, a non-clinician observer or through a performance-based assessment. There are four types of COAs: (a) clinician-reported outcome (ClinRO), (b) observer-reported outcome (ObsRO), (c) patient-reported outcome (PRO), and (d) performance outcome (PerfO). It should be noted that all COAs are considered measures but do not contain the “M” within their acronym denoting “measure.”

Clinician-reported outcome (ClinRO). A type of clinical outcome assessment that is a measurement based on a trained health-care professional’s report after observation of a patient’s health condition and involve objective measures or observable manifestations of the condition or treatment. ClinRO do not include symptoms that can only be known by the patient (FDA-NIH Biomarker Working Group, 2021).

Common Terminology for Adverse Events (CTCAE). A matrix categorizing adverse events by a harmonized naming structure (term) and the associated severity (grade). The CTCAE is used to standardize adverse events for reporting to the Food and Drug Administration for drug and device approval.

Covering radiation oncologist. Herein, a covering radiation oncologist is considered to be a faculty radiation oncologist who is not the treating radiation oncologist but sees the patient for an on-treatment visit because the treating radiation oncologist is not available.

Epic[®] Electronic Health Record (EHR). Epic[®] is a commercial medical record system utilized by roughly one-third of the medical institutions within the United States and throughout the University of Iowa Healthcare system. Epic[®] contains clinic and hospitalization notes, vital signs, medication administration records, procedure and imaging results, and pathology results (e.g., blood counts, metabolic panels, cultures).

Epic[®] also serves as a filing repository for scanned paper records that are received from outside medical facilities. Epic[®] is sold by Epic Systems Corporation, Verona, Wisconsin, USA.

Functional Assessment of Chronic Illness Therapy (FACIT). A collection of quality-of-life questionnaires that are validated as a measurement system for patient reported outcome measures.

Functional Assessment of Cancer Therapy (FACT). A subset of FACIT, these quality-of-life questionnaires were designed to focus on cancer and its therapies.

Health-related quality-of-life (HRQL). Defined by the International Society for Quality of Life Research (ISOQOL) (Mayo & McGill, 2015) as:

A term referring to the health aspects of quality of life, generally considered to reflect the impact of disease and treatment on disability and daily functioning; it has also been considered to reflect the impact of perceived health on an individual's ability to live a fulfilling life. However, most specifically HRQL is a measure of the value assigned to duration of life as modified by impairments, functional states, perceptions and opportunities, as influenced by disease, injury, treatment and policy.

Industry. A jargon term referring to for-profit companies who design, create, or study drugs, biologics or devices for profit. This term also include PhRMA, the Pharmaceutical Research and Manufacturers of America.

MOSAIQ[®]. A commercial electronic health record for radiation treatments that contains the radiation prescription, the treatment plan, contours, radiation to target, and elapsed treatment time by field and completion time by field. Unlike Epic[®], MOSAIQ[®]

access is limited to only authorized radiation oncology staff due to radiation compliances. MOSAIQ® is sold by Elekta Solutions AB, Stockholm, Sweden.

National Institutes of Health (NIH). Comprised of 27 institutes and centers, with each focusing on research within a specific organ class or a healthcare condition. The NIH is funded by the U.S. government with an annual budget of over 40 billion U.S. dollars, serving as a key source of funding for academic medical research. The NIH is based in Bethesda, MD, USA.

National Cancer Institute (NCI). One of the largest NIH centers, the NCI was first established in 1937 and currently has a budget of over 6.5 billion U.S. dollars. The NCI is the primary funding source for academic oncologic research and is a significant influence on research priorities and strategies in oncologic treatments and preventions. Like NIH, the NCI is based in Bethesda, MD, USA.

New drug application (NDA). The application package submitted to a regulatory oversight agency for consideration and ultimately legal approval to market and sell a new drug or biologic. Within the United States, the NDA is submitted to the Food and Drug Administration.

Observer Reported Outcome (ObsRO). A type of clinical outcome assessment measuring observable signs or behaviors related to a patient's health condition by someone who observes the patient in daily life (other than the patient or a health professional). This measure does not include medical judgment or interpretation (FDA-NIH Biomarker Working Group, 2021).

On-call radiation oncologist (on-call). An on-call radiation oncologist is a radiation oncologist who is assigned to consult and plan emergent or add-on patients who

cannot be scheduled through routine workflows. When on-call, the radiation oncologist accepts patients outside their standard clinical focus and, unless care is transitioned, typically is considered their treating radiation oncologist.

On-treatment visit (OTV). A weekly exam required within the United States for patients undergoing radiation therapy.

Patient reported outcomes (PRO). Defined as “aspects of a patient’s health status directly reported by the patient” (p.2, van der Wees et al., 2019).

Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™). A measurement system developed by the National Cancer Institute to capture patient’s assessments of symptomatic adverse events.

Patient-Reported Outcomes Measurement Information System (PROMIS®). An NIH-funded measurement system that evaluates and monitors physical, mental, and social health.

Patient reported outcome measure (PROM). A type of clinical outcome assessment that is a measurement of a PRO based on the patient’s direct report without amendment or interpretation of the response by a third party. The PROM can be measured by self-report or by interview only the patient’s response is recorded without interpretation. Symptoms or other unobservable concepts known only to the patient can be measured only by PROM (FDA-NIH Biomarker Working Group, 2021).

Performance Outcomes (PerfO). A clinical outcome assessment measuring task(s) performed by the patient following standardized instructions. The assessment may be administered by trained personnel or directly by the patient (FDA-NIH Biomarker Working Group, 2021).

Quality-of-life (QoL). Defined by the International Society for Quality of Life Research as:

A term often used erroneously to refer to health-related quality-of-life or health status, but is broader than just health and includes components of material comforts, health and personal safety, relationships, learning, creative expression, opportunity to help and encourage others, participation in public affairs, socializing in leisure. (Mayo & McGill, 2015)

Quality-of-life questionnaire, cancer-30 questions (QLQ C-30). A validated questionnaire developed and maintained by the European Organization for Research and Treatment of Cancer (EORTC) to measure the quality-of-life for cancer patients. It is not disease-site specific and is comprised of 30 questions covering five functional scales (physical, role, emotional, social and cognitive), three symptom scales (fatigue, nausea & vomiting and pain) and a global health status/QOL scale and six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties).

Radiation oncology. The medical discipline encompassing all aspects of cancer treatment using radiation.

Radiation oncologist. A physician who has completed post-graduate training in using radiation to treat disease, including cancer. Radiation oncologists are board certified to treat all cancers using a variety of methods (e.g., external beam, brachytherapy, or nuclear medicine).

Shared decision making (SDM). A collaborative information exchange between the healthcare provider and the patient (Charles et al., 1999).

Treating radiation oncologist. The board-certified physician specializing in therapeutic radiation who prescribes, creates, and approves the radiation plan for a patient. While the treating radiation oncologist is typically the physician that sees the patient for an on-treatment visit a covering radiation oncologist can also cover the visit.

CHAPTER 2

2 LITERATURE REVIEW

2.1 Introduction

The Agency for Healthcare Research and Quality (AHRQ) states SDM can improve health outcomes, including decreasing anxiety, reduced recovery times, and increasing compliance with treatment regimens (AHRQ, 2020). Despite these potential benefits, research suggests radiation oncologists do not participate in SDM (Fromme et al., 2016; Golden et al., 2016; Golden et al., 2017). Radiation oncology is a unique discipline which mandates a minimum of weekly visits (i.e., OTV) for patients undergoing active treatment (American College of Radiology (ACR), 2018); radiation oncologists routinely see patients more frequently to address treatment emergent health issues. It is possible SDM may not be employed during these visits due to the absence of a significant medical choice (e.g., radiation *versus* surgery). Shared decision making as described by Elwyn et al. (2012) employs three steps (i.e., choice talk, option talk, decision talk) but does not address identifying the antecedent need. Patient reported outcome measures can identify this need, detecting unrecognized issues and initiating SDM (Greenhalgh et al., 2018; Greenhalgh et al., 2005). To further investigate SDM and PROM for patients actively receiving radiation therapy, they must be explored through the lens of a treatment requiring frequent healthcare decisions. A literature

review was undertaken to understand and elucidate the path forward to understand the interrelationships between SDM and PROM for application within radiation therapy. This chapter summarizes literature from this search with focus on SDM, PROM, and considerations for implementation within a radiation facility.

2.2 Shared Decision-Making

Shared decision making between physician and patients was initially introduced to provide an ethical balance, reduce risk of medical malpractice, preserve individual dignity, and restore justice (Brody, 1980; Veatch, 1972). It is described as the middle ground between a paternalistic approach, where the physician makes all therapeutic decisions for the patient, and the informed decision model, where the physician is simply a source of information and the patient solely makes the decision (Charles et al., 1997; Gafni et al., 1998).

Identified benefits to SDM include improved quality-of-life, decreased anxiety, reduced psychological distress, increased satisfaction (Atherton et al., 2013; Joosten et al., 2008; Shabason et al., 2014; Sondergaard et al., 2019), and improved treatment adherence (Coulter & Collins, 2011). Research has revealed patients engaging in SDM were more likely to report higher quality of care, even if their preference aligned with the paternalistic model (Kehl et al., 2015).

Hughes et al. (2018) analyzed two databases created and maintained by the AHRQ to explore the fiscal impact of SDM. Data were mined from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and the Medical Expenditure Panel Survey (MEPS) and then analyzed to determine how patient-perceived SDM impacted not only patient-reported outcomes and healthcare quality but also

healthcare utilization (Hughes et al., 2018). Shared decision making was described as ‘patient-perceived’ and derived from the CAHPS survey results by assigning Likert values to answers. The composite scores ranged from four (worst) to twelve (best); poor SDM was considered a score between four to eight points where optimal was a score of twelve (Hughes et al., 2018). Results suggest optimal SDM decreased the incidence of two or more emergency room visits but was not associated with a change in inpatient hospital stays (Hughes et al., 2018). While not statistically significant, there was a trend in the mean annual healthcare expenditure between optimal SDM (\$6,238) and poor SDM (\$5,862) ($p=0.60$) (Hughes et al., 2018). The trend in healthcare expenditures against SDM and inpatient hospital stays in days invites further exploration. The findings of this research are limited in generalizability to the oncologic SDM due to its retrospective nature as well as poor context (e.g., provider, service, established rapport). The crux of SDM is individuality, not generality.

In 2012, Elwyn and colleagues were the first to fashion a model for SDM (Chapter 1, Figure 1), based upon prior published work that described the concept of SDM but did not describe its process. The model provided a simplified path for SDM, beginning with *choice talk* which transitions to *option talk* and then ends with *decision talk*. Choice talk is the conversation stating options are available, that a decision will need to be made, the patient will have an active role in that decision making process. Elwyn et al. (2012) discourage paternalism and suggest if the patient defers to the physician that the physician agrees to provide perspective but also to review options in more detail so a decision can be made. Option talk is then the transition to identifying all available options and then describing the pros and cons of those options (Elwyn et al., 2012). Options

should be provided as a clear list, preferably in a format conducive to discussion between the patient and provider. After deliberation, the final step is decision talk, which encourages the patient to make a decision but also can provide the iterative process of reviewing the options in brief and then identifying the selected option (Elwyn et al., 2012). Within *choice talk*, the first step of the model, Elwyn et al. (2012) suggest a guiding opening statement of “Now that we have identified the problem, it’s time to think what to do next” (p. 1363). This reveals a key assumption: a problem has been identified. Thus, a barrier to SDM may be lack of acknowledgement that a problem exists.

A qualitative synthesis of 40 articles describing SDM models identified 24 SDM components relevant to healthcare (Bomhof-Roordink et al., 2019). The incidence of these components was identified according to disciplines of care (e.g., oncology, chronic care, emergency medicine) and expressed as a percentage of the total SDM models for that discipline (p. 8, Bomhof-Roordink et al., 2019). Components with highest incidence (76% to 100%) in oncologic care overlapped somewhat with the chronic care discipline, sharing *describe treatment options* and *deliberate* in high incidence (Table 1). The SDM components of *make the decision*, *patient preferences*, *determine the next step*, and *provide information* are more commonly associated with the discipline of chronic care (Figure 8) but *provide neutral information*, *offer time*, *support decision making process*, *advocate patient views*, and *learn about the patient* have a high incidence in oncologic care but are absent from SDM models in chronic care (Table 1). This is interesting as many malignancies are transitioning from terminal illnesses to chronic healthcare conditions, transitioning the SDM model from oncologic care to chronic healthcare. Not

Table 1*SDM Comparison between Chronic Healthcare and Oncologic Care*

Component	Chronic Healthcare	Oncologic Care
Describe treatment options	≥ 76%	≥ 76%
Deliberate	≥ 76%	≥ 76%
Make the decision	≥ 76%	50 – 75%
Patient preferences	≥ 76%	50 – 75%
Determine next step	≥ 76%	50 – 75%
Provide information	≥ 76%	50 – 75%
Tailor information	50 – 75%	≥ 76%
Learn about the patient	—	≥ 76%
Advocate patient views	—	≥ 76%
Support decision making process	—	≥ 76%
Offer time	—	≥ 76%
Provide neutral information	—	≥ 76%

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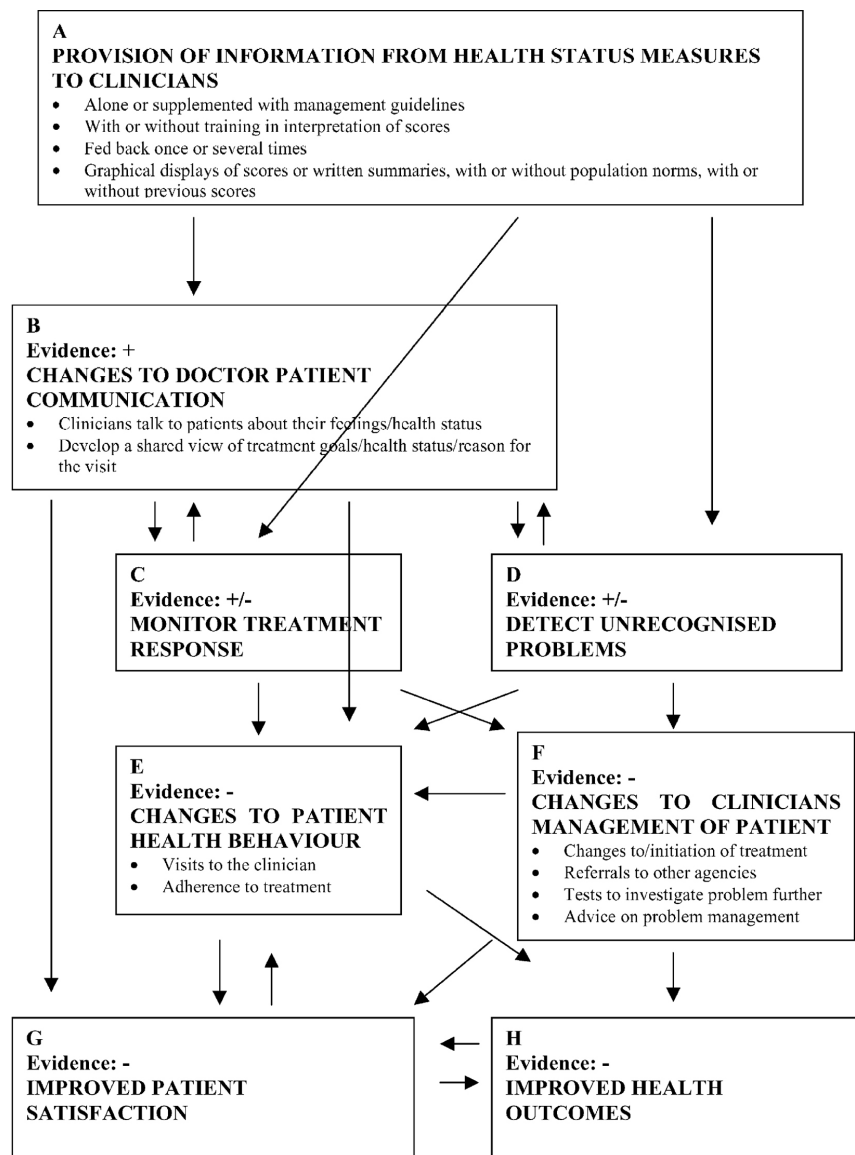
listed as an identified SDM component is identification of the problem/issue requiring a decision (Bomhof-Roordink et al., 2019). Without it, SDM cannot occur.

A solution to identifying the problem can be found in work by Greenhalgh et al. in 2005, which explored through a thought exercise why there were differences in treatment and healthcare outcomes when utilizing HRQL in the clinic. In the review, points and paths critical to impact of HRQL within the clinic were identified and discussed (Figure 5). Prior work was deemed simplistic in its approach for a complex

phenomenon with a multitude of confounding factors influencing the path of HRQL instruments changing care within a clinic. Greenhalgh et al. (2005) identified concerns within the information flow such as identifying the appropriate clinical provider to receive the HRQL (e.g. nurse *versus* physician), if a single collection is adequate or if

Figure 5

Outcomes and hypotheses in the trials evaluating the impact of health status measures on clinical decision making (Greenhalgh et al., 2005)



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trends over time should be provided, and if the information is provided in a format to maximize its value and interpretation. The model from Greenhalgh (Figure 5) visually depicts a significant portion of proposed work, especially panels D (detecting unrecognized problems) and F (changes to clinician management of patient). The authors concluded further research needed to be conducted.

In 2018, Greenhalgh and others reviewed the published peer-reviewed literature on HRQL and impact on the healthcare clinics, including oncology clinics, to create a realist synthesis. The synthesis yielded two theories: (a) completing HRQL supported patient to clinician communication regarding issues, and (b) the reported HRQL scores brought the patient's problems to the clinician's attention (Greenhalgh et al., 2018). Some physicians raised concerns that HRQL questions could be upsetting or distressing to patients, but this was minor compared to the opinion HRQL instruments gave patients permission to discuss concerns, including issues they may have felt awkward raising independent of the instrument (Greenhalgh et al., 2018). Similar to prior work, communication became key to HRQL and its impact on the patient-physician treatment dyad. In general, utilization of an HRQL instrument increased a patient's awareness of their health as well as of their care by their physician. The authors acknowledged not all patients want to discuss these issues with their physicians or that it may be contextually dependent (Greenhalgh et al., 2018). In their oncology literature review, Greenhalgh et al. (2018) noted the physicians commonly treated HRQL answers consistent with another lab result or test, focusing on the specific symptom rather than its impact on the patient's functioning and/or quality-of-life. Greenhalgh et al. (2018) concluded, "Exploring how and why patients answer PROMs in the ways that they do, in addition to understanding

how clinicians and patients interpret the score itself, can expand our knowledge of how patients understand their condition and its impact” (p. 24).

Golden et al. (2016) explored the patient’s perception of SDM when deciding between surgery or stereotactic radiation therapy (SBRT) for definitive treatment for early stage non-small cell lung cancer. Both treatments are accepted as best practice for this patient population and meet the definition of equipoise. The authors used a patient-centered communication model to guide the study questions (Golden et al., 2016). Enrollment continued until thematic saturation was reached. Thirteen patients were enrolled, with six deciding to receive SBRT. Roughly 25% described a complete absence of SDM, describing their experience as being “...completely uninformed about other possible treatment options” (p. 1364, Golden et al., 2016). The authors identified trust, and not simply information exchange, as a significant factor in SDM and that it served as both a facilitator and a barrier. As a facilitator, trust enabled patients to be comfortable with their provider and rely upon clinicians’ information. Conversely, trust became a barrier if it created such a security as to instill acquiescence and cause the patients to take a passive role (Golden et al., 2016). This is echoed in a qualitative study by Smith et al, which identified that patients perceived the decision making process as agreeing with the treatment team and, when the team did not align or contradicted itself, trust was negatively impacted (Smith et al., 2017). Recommendations from the patient participants included to use numbers, written materials, and tailored information. Patient participants recommended providers reinforce important points about the treatment at each encounter (Golden et al., 2016).

Poor understanding of decision points was reflected in work examining SDM and maintenance chemotherapy for patients diagnosed with lung cancer (Sztankay et al., 2017). Maintenance therapy is a cytotoxic chemotherapy regimen designed to keep the disease and its symptoms stable, shifting the cancer to a chronic healthcare condition. Patients were interviewed when initiating maintenance chemotherapy as well as at its end (Sztankay et al., 2017). In review, there was a discrepancy between the physician and the patients (n=84) as to why therapy was initiated and why it was ended. Sztankay et al. (2017) posited the inclusion of PROM would strengthen identification of treatment emergent side effects and toxicities. This is consistent with other research identifying differences between anticipated side effects of therapy as well as their severity (Pilote et al., 2019; Shaverdian et al., 2019).

From 2018 forward, work in shared decision making in oncology, including radiation oncology, has included patient decision aids and their impact on shared decision making (Agin et al., 2018; Leech et al., 2020; Raphael et al., 2020; Treffers & Putora, 2020). Decision aids can be videos, graphical/cartoon, paper, or electronic (Agin et al., 2018; Berman et al., 2016) but should provide steps 1 and 2 in the SDM model as described by Beers et al. (2017): informing the patient there is a decision to be made and providing information in a medium that is useful to the patient. What remains critical, and are most likely tied to the success of a decision aid and its outcomes, are steps 3 and 4 of the work by Beers et al. (2017): identify the patient's preferences for treatment and goals for therapy and then make the decision by summarizing preferences, points, and potential problems.

Steps 3 and 4 of Beers et al. (2017) were echoed in findings from Rocque and colleagues (2019). This work explored what was considered important by patients when making treatment decisions for metastatic breast cancer (Rocque et al., 2019), using a qualitative design with the Ottawa Framework as the guiding model (Graham & Logan, 2004). Researchers interviewed patients (n=20), community oncologists (n=6), and academic oncologists (n=5). Thematic findings identified physicians considered the treatment efficacy and side effects at the expense of patient preference (Rocque et al., 2019). Patient participants expressed trust in their doctor but also expressed frustrations with communication and listening. Rocque et al. (2019) provided the following poignant quotes which clearly illustrate the chasm in shared decision making within oncology:

Patients wanted oncologists to ask them about their preferences and wanted to be heard. One woman stated “I know doctors have a busy schedule, but making time to ask questions and listen is the main thing” (patient 12). One woman expressed frustration that her concerns were dismissed. “I do think that the doctor should take out a little more time to kind of, ask you questions...my doctor be ‘oh, you gonna be all right.’ That ain’t what I want to hear” (patient 17) (p. 1318).

For example, when asked about intolerable side effects, one participant identified ‘not being able to focus and think’ (patient 4) as unacceptable. In contrast, another patient commented ‘I would rather accept the chemo brain than not have an aggressive treatment’ (patient 8) (pp. 1317-1318).

The authors present rich quotes from patients in a point/counter-point fashion regarding side effects (physical, emotional, cognitive), personal responsibilities such as work, logistics and convenience, financial, and impact on activities of daily life (Rocque et al.,

2019, Table 2). The quotes provide clear imagery of diametric opposition, highlighting the spectrum of opinions and preferences within this patient population. When reviewing the marked differences in patient preferences, the scope of work for SDM in the field of oncology is highlighted by a quote from an oncologist in Rocque et al. (2019):

I feel like their goals are my goals, which is to live as long as possible with least toxicity. I feel like they all have the same goal, pretty much...which would be to have as long a life with as good a quality-of-life. (p. 1318)

When an oncologist believes their goals are the same as the patient's information transfer is foundationally flawed and SDM fails (Beers et al., 2017; Herrmann et al., 2018). Other discussed contributing factors to problems in SDM implementation include trust in provider, lack of treatment consensus, time constraints, and poor communication (Agin et al., 2018; Ankolekar et al., 2019; Covvey et al., 2019; Legare & Thompson-Leduc, 2014). It is reasonable to extend these findings to patients diagnosed with lung cancer as well as their treating radiation oncologist.

2.2.1 Communication

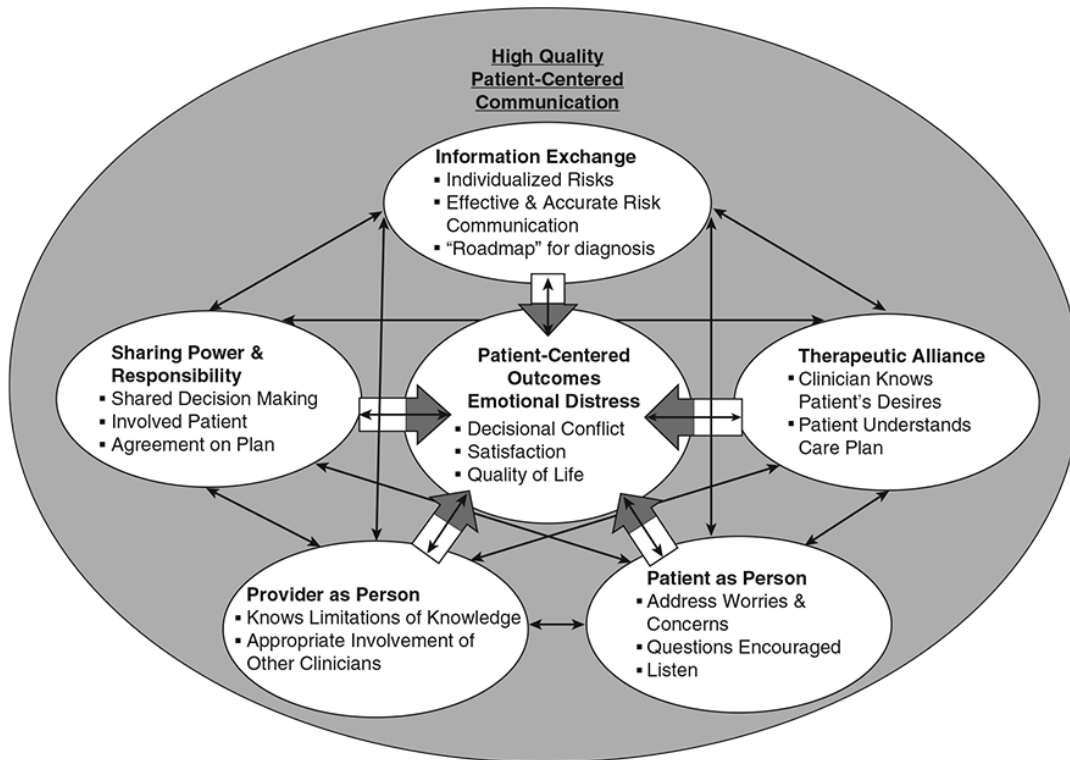
Communication serves as a foundation to shared decision making, a co-factor in each step of the SDM model as posited by Beers et al. (2017): informing, explaining identifying, and summarizing. Not only is communication key for SDM, it is critical for accurate diagnosis and proper medical care; unfortunately, communication between the physician and patient is not only complex but problematic (Palmieri & Stern, 2009). In addition to health literacy, medical jargon, and tight clinical schedules, known problems in patient-provider communication also include provider-pleasing behavior, so-called "white lies," (a falsehood to spare pain, discomfort, or emotional distress), and 'nudging,' (a

strategy for changing a patient's behavior or decision without impinging on autonomy) (Avitzour et al., 2019; Palmieri & Stern, 2009). Standards for communication typically include readability, ease of interpretation, and the patient's comprehension; regardless, simply *discussing* a diagnosis, prognosis, or treatment options with a patient does not align with the quality of communication necessary for SDM. In addition to this rote exchange of information, the National Cancer Institute (NCI) identifies quality communication in oncology as one that has a *dynamic* to promotes healing, that *engages* in emotional discussion and displays empathy, and *asks* patients for their preferences to aid them in being proactive in their care (Epstein & Street, 2007). Factors influencing the communication dynamic include information preferences and emotional state/climate of the visit whereas the patient-provider dyad is commonly impacted by pre-existing factors (e.g., socioeconomic, communication style, personality) (Siminoff & Step, 2005).

In 2017, Golden and colleagues examined the provider's perspective on the quality of patient-provider communication. This qualitative study extended prior work (Slatore et al., 2015) by exploring the experiences of 20 clinicians (eight radiation oncologists, seven thoracic surgeons, four pulmonologists, and an oncology nurse) using a patient-centered communication model (Figure 6) to guide qualitative questions and analysis (Golden et al., 2017). The model has five domains to help explain communication strategies: information exchange, sharing power & responsibility, therapeutic alliance, provider as person, patient as person. Golden and colleagues (2017) focused on information exchange, patient as person, and sharing power & responsibility to guide their work. The clinicians expressed uncertainty as to how to frame treatment goals for each individual patient. While all clinicians described the importance of information sharing, only thirteen (80%) believed all

Figure 6

Patient-Centered Communication Model as Adapted by Golden et al. (2017).



Note. Reprinted from *Patient Education and Counseling* with permission from Elsevier ©2017.

treatment options should be discussed with the patient. The clinicians concurred the patient made the final decision regarding their treatment but noted a treatment recommendation or decision was made prior to the consult with radiation oncology. This treatment recommendation could be made by the multi-disciplinary oncology board, the pulmonologist, or the referring surgeon (Golden et al., 2017). When patients are distressed, the clinicians responded by providing more information rather than exploring the reasons for the distress. Similarly, the clinicians did not query patients for their preferences or values – thus limiting SDM engagement and instead simply providing a rote information

exchange (Golden et al., 2017). The authors concluded that oncologists should continue to provide clear and accurate information, but this should be framed by patient values and preferences (Golden et al., 2017).

The differences in recall over what has been communicated between oncologist and patient ('recall disparities') have been documented regarding treatment goals and purpose (Chen et al., 2021; Gabrijel et al., 2008; Lee et al., 2018; Linford et al., 2020; Temel et al., 2011). To address this, Linford et al. (2020) recommended a caregiver be present for discussions and that this should be prioritized by the provider. This is consistent with the findings of Smith et al. (2017) in their research on SDM. Exploratory work done in India identified that not only was the family/caregiver instrumental in support, but key to communication (Datta et al., 2017). This work reflects cultural norms – such as the family providing diagnosis rather than the provider as well as making treatment decisions independent of the patient (Datta et al., 2017; Kim et al., 2007; Lee et al., 2018). These findings further emphasize the first step of healthcare communication should be to ascertain the patient's and caregivers' preferences (Beers et al., 2017; Datta et al., 2017; Herrmann et al., 2018; Siminoff & Step, 2005).

Another factor for communication in oncology is creating a dynamic to encourage conversations about diagnosis and prognosis as well as the psychological and emotional strain accompanying the disease (Epstein & Street, 2007; Siminoff & Step, 2005). Creating this dynamic and providing appropriate support requires empathy, which can be provided by the provider providing support by sitting silently or leaving the room to allow the patient and caregivers to collect their thoughts prior to further discussion (Back et al., 2005; Martin et al., 2019; Tulsy et al., 2011). Difficult conversations in oncology, such as diagnosis,

prognosis, or relapse, are often guided by the N.U.R.S.E. mnemonic: *Name* the emotion, *Understand* the emotion, *Respect* the patient/family, *Support* the patient/family, *Explore* (i.e., tell me more) (Martin et al., 2019; Tulsy et al., 2011). Historically, communication strategies have not been included as a formal educational program within medical school and residency in radiation oncology (Martin et al., 2019). Education for communication strategies can be viewed as costly as well as time intensive (Tulsy et al., 2011) and results of interventions have been mixed (Paladino et al., 2019).

2.2.2 Documentation

A source of clear communication should be the written record, including the patient's electronic medical record. The medical record serves as the reference document, the prime information source for the patient's general healthcare as well as for the condition under treatment. Inadequate documentation as well as erroneous information negatively impact SDM by providing a false foundation for choice (Elwyn et al., 2012). Practice parameters for the field of radiation oncology recommend documents are prepared contemporaneously and in a useful format, reviewed to minimize errors, and that it documents appropriate medical decision making (Schechter et al., 2020). Revised approximately 9 times since its initial release in 1990, the ACR-ASTRO practice principles outline the need to clearly state the treatment options, the intent of treatment, the risks / benefits that were discussed with the patient as well as anticipated toxicities, and the anticipated treatment region (American College of Radiology (ACR), 2018; Schechter et al., 2020). Despite a curated national guideline, documentation errors are consistent within radiation oncology (Blakaj et al., 2017). A review of the incident reporting system sponsored by the national radiation oncology

group ASTRO identified 4617 safety-related events over 5 years; of these, 1002 directly involved communication (Blakaj et al., 2017). Based on a random sample, 20% of the events were considered potentially serious and 39% of the events were related to poor documentation from radiation oncologists (Blakaj et al., 2017).

In 2019, Dana Farber Cancer Institute published findings from a cluster randomized controlled trial targeting improved documentation for patients with lung cancer (Paladino et al., 2019). The goal of the research was to improve documentation such that covering physicians or outside medical facilities could quickly and completely understand critical information, rather than the often fragmented and scattered information within the electronic health record (Paladino et al., 2019; Walker et al., 2018). The intervention was a 2 ½ hour training for clinicians on serious illness conversations as well as a template for the electronic medical record notes (Paladino et al., 2019). Results demonstrated documentation regarding goals/values increased significantly (<0.001) as well as goals of care (<0.001) and life-sustaining procedures ($p=0.004$) (Paladino et al., 2019). A subsequent study by the same research team confirmed the findings, this time by adding audio recordings of the clinician's visit to serve as the gold standard for the documentation (Geerse et al., 2021). Unlike the 2019 study, documentation that did not use the EMR template, but written by trained clinicians, was also reviewed (Geerse et al., 2021). When utilizing the EMR template verbal information was 62% concordant with documentation with 10% not documented whereas when not using the template, documentation was 13% concordant and not documented 77% (Geerse et al., 2021). These findings suggest an EMR template, and not necessarily the communication training, are responsible for better documentation practices.

2.3 Patient Reported Outcome Measures

Definitions of patient reported outcomes (PRO), patient reported outcome measures (PROM), quality-of-life (QOL), health-related quality-of-life (HRQL), and patient reported experience measures (PREM) vary based upon the researcher, the organization, and the regulatory agency (Bottomley et al., 2016; Bottomley et al., 2019; Gensheimer et al., 2018; Haraldstad et al., 2019; Karimi & Brazier, 2016; Mayo & McGill, 2015; Snyder et al., 2012; U.S. Food and Drug Administration (FDA), 2020d; van der Wees et al., 2019). All agree that a patient providing information directly, without edit by a third-party, is a patient reported outcome; from there, opinions vary based on inclusion of distal domains (e.g., emotional constructs, social impact), global health vs. discrete symptoms, statistical planning and analysis as well as prime category vs subset (e.g., HRQL as an umbrella for QOL and PROM; PROM as an umbrella for QOL and PROM) (Fiero et al., 2019; Kluetz, O'Connor, et al., 2018; U.S. Food and Drug Administration (FDA), 2007). Valderas and Alonso (2008) suggested the FDA relies heavily on the *source* of the information rather than the information's *content*. A model differentiating concepts of patient reported outcomes (i.e., symptom status, functional status, general health perceptions, and health-related quality-of-life) was synthesized from work-to-date to help classify PROM (Valderas & Alonso, 2008). The model is positing a linear, unidirectional pathway from symptom status to functional status to general health perception and ending in health-related quality-of-life (Figure 1, Valderas & Alonso, 2008). Despite this model, inconsistency in terminology continued. As Bottomley et al. (2016) stated succinctly:

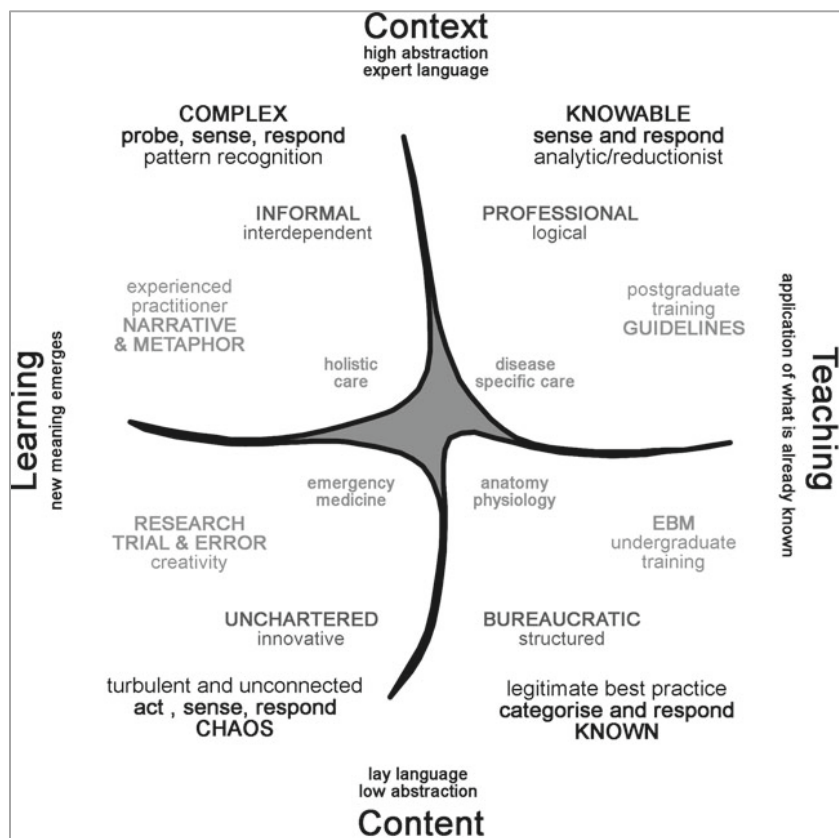
The terms ‘patient -reported outcome’ and ‘HRQOL’ have, at times, been used interchangeably, leading to confusion in terminology. However, patient-reported outcome and HRQOL are two distinct terms that complement each other... This distinction between patient-reported outcomes and HRQOL implies that, on the one hand, patient-reported outcomes can be used to measure constructs other than HRQOL (e.g., adherence and experiences of care), and that, on the other hand, HRQOL can be measured by means other than a patient-reported outcome (e.g., observer or proxy reports). (p. e510)

This inconsistency, as well as the interchangeable use of PRO, PROM, QOL, and HRQL, limits the application of the research (Bottomley et al., 2016; Burke et al., 2008; Fiero et al., 2019; Haraldstad et al., 2019; Karimi & Brazier, 2016; Kluetz, Kanapuru, et al., 2018; Valderas et al., 2008). As an example, in their 2019 review of quality-of-life literature, Haraldstad et al. identified that of the papers reviewed (n=163), only 13% provided a definition of QOL and only 25% provided the rationale for the choice of instrument. The reasons for the lack of inclusion could include poor manuscript standardization strategy as well as word count limitations, the findings could also suggest a lack of realization that QOL should be defined and the instrument should be fit for purpose.

Due to the variability, for the purposes of this discussion, default definitions are those provided previously (Introduction: Definition of key terms). If the reviewed literature utilizes a different definition the difference and context will be highlighted within the text as appropriate.

Regardless of the term selected, patient reported outcome measures (including the patient-assessed health-related quality-of-life measures) address a concept of health that

includes the social, somatic, semiotic, and psychological (Sturmberg, 2013). Patients provide direct measures regarding an amalgamation of a complex system, the interactions between the disease, the treatment, comorbidities, demographics, activities of daily life, and many others. Direct report and measure from the patient based on their experience is markedly different than the standard within the United States. Current medical practice within the United States is rooted in a didactic and apprenticeship educational structure passed down through generations of physicians, resulting in an alignment of assessments and knowledge. To maintain their license, physicians must meet continuing medical education requirements, further harmonizing the knowledge base across regions within the U.S. It is this paradigm and knowledge base on which current medical care is based. Incorporated patient experience data creates a spectrum of information: the rote physician's assessment to a patient's reported outcome of an objective symptom (e.g., emesis or stooling frequency, weight loss) to health-related quality-of-life, a fully subjective patient reported outcome. Translation of this information currently follows the Cynefin model (Figure 7), transitioning from the *Known* (structured, categorize and respond) to the *Knowable* (sense and respond, disease specific care) to the *Complex* (probe, sense and respond; holistic care) (Sturmberg & Miles, 2013). When in the Complex realm, the brain is overwhelmed in sense-making, attempting to predict and organize in the current moment; however, knowledge is only gained in retrospect as the pattern and experience is viewed in its entirety. This phenomenon, in which the mind attempts to create predictive models based on past experiences and prior knowledge, is termed 'predictive coding' (Clark, 2013; Sturmberg & Miles, 2013). The brain's sensemaking through this predictive modeling can cause misinterpretation and blind spots

Figure 7*Medical Knowledge and Healthcare Intertwined in the Cynefin Framework*

Note. Predictable knowledge, such as a physician's routine assessments, lies in the known whereas in the complex realm, patterns can only be identified in retrospect. Health related quality of life falls within this realm as an integrated compilation of multiple confounding factors. Reprinted/adapted by permission from Springer Science+Business Media, LLC, part of Springer Nature: *The Complex Nature of Knowledge* by Joachim P. Sturmborg and Andrew Miles ©2013.

by viewing the world through a singular lens with linear logic (Sturmborg & Miles, 2013). Upon realizing this phenomenon, the threads of predictive modeling become identifiable in the peer-reviewed literature, is from seeking to align physician and patient reported outcomes (Atkinson, Reeve, et al., 2018; Atkinson et al., 2017; Atkinson et al., 2016) to cost-justification of patient reported outcome measures rather than

acknowledging them as key medical information (Grewal & Berman, 2019; Hsiao et al., 2019; Kotronoulas et al., 2014). Adapting to, and learning from, a complex adaptive system such as HRQL requires dynamic assessment and adaptation; all available knowledge should be used to adapt care to the patient (Sturmberg & Miles, 2013). With that framing the question then becomes how to translate the experience and patterns identified from the Complex realm of HRQL into the Knowable, contributing to a knowledge base that is generalizable to other patients. Around 2005, research into patient reported outcome measures beyond HRQL gained momentum in oncology; in 2016, the U.S. FDA passed legislation patient reported outcome measures must be included in the new drug application package or 510k application for new devices (U.S. Food and Drug Administration (FDA), 2020a). This shifted PROM from the realm of research and use within the clinic to also include drug and device development. With FDA's current emphasis on pragmatic and real world trials, as well as the 505(b)(2) application mechanism allowing approval of drug indications based upon peer-reviewed literature, PROM performed for academic research as well as for clinical use became a focus for industry and, with it, regulatory oversight including FDA and EMA.

2.3.1 Research Use

Initial work in oncology clinical trials utilized instruments such as the EORTC QLQ-C30 and the FACT-L (Haraldstad et al., 2019; Minasian et al., 2007). The National Cancer Institute (NCI) funded initial work to create the PRO-CTCAE™ as well as compare PROMs against ClinRO of treatment emergent adverse events (Basch et al., 2005; Basch et al., 2006). The trial randomized participants to complete the PRO-CTCAE™ prior to or after a physician visit. Physicians did not review the completed

PRO-CTCAE™ but did complete a matched CTCAE assessment sheet. Disparity was noted with as much as a 59% discordance (Basch et al., 2006). This finding is consistent with other studies utilizing other PROM, with other research teams reporting a disparity between oncologists grading adverse events to be less severe than how the patients perceive them to be (Atherton & Sloan, 2006; Basch, Deal, et al., 2016; Cirillo et al., 2009; Falchook et al., 2016; Sneeuw et al., 1998; Sneeuw et al., 2002).

In 2007, the NCI held a clinical trials planning meeting to set priorities for the upcoming calendar year (NCI, 2016a). It was decided PROs were a priority for cancer research and should be adopted in future clinical trials. This position was further strengthened by FDA's draft (2006) and then final (2009) guidance documents (Burke et al., 2006; U.S. Food and Drug Administration (FDA), 2009). In 2010, the NCI endorsed PRO-CTCAE™ as a validated instrument for cancer research and released it for use free of charge (National Cancer Institute (NCI), 2010, 2016d). A website was created for the instrument download, with instructions provided as well as citations (NCI 2010, 2016a). Factors promoting translation of this NCI-endorsed instrument to clinic include the NCI's extramural 2010 budget of just under 4 billion US dollars, NCI-directed intramural research with a budget of 1.1 billion US dollars, control of the national cancer-therapy cooperative group programs (e.g., Alliance, NRG, ECOG-ACRIN), and the NCI-designated Cancer Center program (National Cancer Institute (NCI), 2015, 2016b, 2016c). Through these mechanisms, NCI has a monopoly on research use of PROM instruments on several levels: unfunded investigator-initiated research, extramural funded research, pivotal phase III studies, and even pharmaceutical-sponsored research through academic-industrial funding (through the SBIR/STTR mechanism). NCI's endorsement PRO-CTCAE™ should have

initiated a seamless transition to implementation and adoption. To date, this has not occurred and implementation of PRO-CTCAE™ remains spotty, as evidenced by a lack of presence in the peer-reviewed literature (<30 articles yearly for the past 3 years), poor uptake of the instrument in NCI's national protocols (Howell et al., 2021), and an absence of requirement for its use in clinical trials to obtain extramural funding from the NCI.

The Center for Medical Technology Policy (CMTP) developed an effectiveness guidance document (EGD) regarding the PROs in comparative effectiveness research (Basch et al., 2012). The CMTP solicited input and feedback from multiple stakeholders, including Patient Advocates in Research and PatientsLikeMe (Basch et al., 2012b). This guidance evaluated various PRO-assessment instruments, including the QOL-C30, PROMIS, FACT, and PRO-CTCAE™. Of those evaluated, PRO-CTCAE™ was one of three evaluation instruments that captured 12 key cancer symptoms (Basch et al., 2012b, Table 2). Fifteen recommendations were made for incorporating PROs to clinical research; of note, electronic capture was preferred, and the questionnaire should be limited to only taking 15 minutes of time (Basch et al., 2012). Other recommendations included statistical considerations for missing data, power calculations, and to include an assessment of health-related quality-of-life (Basch et al., 2012). This article served as a summary of a longer EGD available online and sought to improve and promote PROs in clinical effectiveness research.

In a study by Wood et al., patients undergoing a bone marrow transplant completed a customized PROM (PRO-CTCAE™) at 24 hours post-procedure as well as seven days post-procedure (Wood et al., 2015). The purpose of this study was to determine concordance between these two timepoints; the authors concluded the data

suggested a weekly assessment was preferred but that further research was needed (Wood et al., 2015). This small feasibility study investigated frequency of assessment for a specific cancer population but was not powered (n=32) for validation. Although the study investigated use of PRO-CTCAE™, it did not use the questionnaire as an instrument to assess patient outcomes in therapy.

Falchook and others investigated disparity between healthcare provider CTCAE assessment and PROs (2016). For this study, participants enrolled in a phase II therapeutic clinical trial for oropharyngeal cancer (NCT01530997) were invited to complete PRO-CTCAE™ customized questionnaires weekly during therapy and then at study-designated follow-up (Falchook et al., 2016). Unlike similar studies (Basch et al., 2006), PRO-CTCAE™ evaluated a combined treatment modality (radiation therapy, chemotherapy, surgical excision) compared to a chemotherapy-only regimen (NCT01530997, Falchook et al., 2016). The authors found a substantial disagreement between PROM and ClinRO during treatment (Falchook et al., 2016). Disagreement also occurred at initial presentation, such as participants reporting dry mouth or hoarseness as a baseline symptom whereas providers reported no symptomology (Falchook et al., 2016). The implications for this disagreement are significant: in general, adverse events occurring during therapy are defined only if they increase above baseline or if the etiology is known to change. If a patient has baseline moderate dry mouth, reporting this as a drug-related adverse event could be considered over-reporting as the event may not be a valid drug-related side effect. More concerning was the provider's inaccurate assessment of fatigue during the six weeks of therapy (mean agreement 28%, range 12 to 49%) (Falchook et al., 2016). Fatigue is a check-point assessment for many

chemotherapy regimens, with required dose reductions (or treatment interruptions) for grades 2 or 3 fatigue. Despite being a subjective assessment, the three fatigue categories have been parsed out as objectively as possible: relieved by rest (grade 1), interfering with instrumental activities of daily life (grade 2), and limiting self-care (grade 3) (Cancer Therapy Evaluation Program (CTEP), 2010). Instrumental activities of daily life and limiting self-care are clearly defined and provide specific examples (CTEP, 2010). Despite this, providers rated ~83% of participants as having mild to no fatigue at week six of therapy whereas all participants reported some fatigue, with only 14% reporting mild fatigue (Falchok et al., 2016).

Work from Fromme and colleagues (2016) suggests poor communication between patient and radiation oncologist to be a factor regarding reporting disparity of treatment side-effects and symptoms of disease: of 211 patient-identified adverse events (e.g., side-effects, symptoms) only 19 were discussed with the radiation oncologist. In clinical trials, the often-used model to treatment emergent adverse events as well as symptoms of disease are for physicians to examine the patient, document their findings in a clinical note, and have that information mined and abstracted by a research coordinator (Trotti et al., 2007). Oncology often utilizes the Common Terminology Criteria of Adverse Events (CTCAE), which categorizes the event (e.g., fatigue, nausea, pain) and then grades its severity. In general, a grade of 0 equates to the symptom not being present whereas a grade 5 means the patient died from that event. Grade 1 is mild (no treatment indicated or over the counter only), grade 2 is moderate (prescription indicated, non-urgent medical intervention required), grade 3 is severe (urgent medical intervention required, two or more prescriptions, inpatient admission) and grade 4 is life-threatening or emergent care needed.

This standardized system enables physicians to communicate to other physicians what they diagnosed and what level of care or intervention was necessary in its management. Dose reductions and delays of antineoplastic therapy are triggered by these events; for example, grade 2 nausea may trigger a dose reduction and grade 3 fatigue may cause a dose delay. The accuracy of assessing adverse events for severity becomes paramount for consistent and safe oncologic treatment between cancer clinics and amongst providers.

As mentioned, Basch and colleagues published work documenting a disparity between physicians' documented adverse events and the patients' reported events (Basch et al., 2006). Patients diagnosed with lung cancer (n=200) were provided questionnaires prior to examination with their oncologist; the oncologist then completed an assessment using CTCAE version 3 for the same symptoms immediately after the exam (Basch et al., 2006; Trotti et al., 2003). Resultant data demonstrated poor alignment between the patient/provider dyad, including discrepancies in pain assessment (40%), fatigue (59%), dyspnea (48%), and anorexia (34%) (Basch et al., 2006). Of the symptoms assessed, the only assessment found to be significantly different was fatigue ($p < 0.01$), yet pain grading was different by at least *two grades* from the clinical assessment 7% of the time. This discrepancy translates to a moderate pain being present (i.e. pain or analgesics interfering with functioning but not interfering with activities of daily life) where the oncologist did not identify it *or* severe pain was present (i.e. pain or analgesics severely interfering with activities of daily life) but the oncologist considered it to be mild (Basch et al., 2006; Trotti et al., 2003). Similarly, there was a 17% incidence of the patient judging the nausea to be more severe by at least one grade and vomiting 9%. As graded by CTCAE, severity of vomiting is graded by the episodes of emesis per 24 hours: grade 1 vomiting is defined

by 1 episode only, grade 2 vomiting has 2 to 5 or a need for outpatient intravenous fluids, and grade 3 vomiting lists an incidence of 6 or more emesis episodes *or* a requirement for hospitalization *or* a requirement for total parenteral nutrition (TPN) (Rao & Faso, 2012; Trotti et al., 2003). Grading the severity of nausea is more subjective as mild nausea described as lack of appetite but without a change in eating habits (Trotti et al., 2003). However, as severity grading increases, the criteria become more objective and align to vomiting: grade 2 lists qualifying criteria as non-significant weight loss *or* outpatient intravenous fluids and grade 3 the requirement for tube feedings *or* TPN (Trotti et al., 2003). Given the objective data used to grade nausea and vomiting severity, it is unclear why the discrepancy exists. Chemotherapy-induced nausea and vomiting (CINV) often spurs dose modifications or treatment delays, ultimately impacting treatment compliance and outcomes (Rao & Faso, 2012). Independent of cytotoxic regimens, radiation therapy to the thorax and/or gastrointestinal tract also causes vomiting and resultant treatment-associated comorbidities such as odynophagia, esophagitis, and gastrointestinal pain causing inpatient admission for pain control (Abdelsayed, 2007; Feyer et al., 2015; Ganesh et al., 2018; McKenzie et al., 2019; Rowbottom et al., 2016; Salvo et al., 2012). It is reasonable differences in grading, and the exchange of information these differences represent, could impact prescribed therapy as well as adjust concomitant care to prevent admissions.

To further explore adverse event discrepancies, DiMaio et al. (2015) compared physician grading of adverse events compared to PROMs collected utilizing the EORTC's QLQ-C30 in two randomized clinical trials managed by the National Cancer Institute (Gridelli et al., 2012; Gridelli et al., 2007). Three trials representing 1459

participants were reviewed; two of the trials focused lung cancer treatment and contributed 1160 participants (79.5%) (Di Maio et al., 2015). The authors compared patient and physician reported adverse events across 2482 cycles of treatment (Di Maio et al., 2015). The authors translated the PROM survey responses to a binary response: the symptom was reported by the patient (yes/no) and the symptom was reported by the oncologist (yes/no) (Di Maio et al., 2015). The design is elegant in its simplicity by focusing on data trustworthiness: (a) if a patient is reporting an adverse event, did the physician capture it, and (b) if a physician captures an adverse event, is it real or a copy / paste error (Di Maio et al., 2015; Gridelli et al., 2012; Gridelli et al., 2007). Although nausea was not reviewed, six other core adverse events were reviewed and the interrater reliability revealed poor reliability of data (McHugh, 2012). The symptoms with the highest Cohen's kappa were diarrhea ($\kappa = 0.45$) and vomiting ($\kappa = 0.41$); this translates roughly to an estimated 15 to 35% of data that are reliable (McHugh, 2012). Nausea and constipation were considered to have a minimal level of agreement resulting in an estimated data reliability of 4 to 15% and with a Cohen's kappa of 0.15, anorexia was considered to have a reliability of $\leq 4\%$ (Di Maio et al., 2015; McHugh, 2012).

According to DiMaio et al. (2015) "When examining only patients who reported 'very much' toxicity in any cycle, the proportion of under-reporting by physicians was 50.0% for anorexia, 25.8% for nausea, 13.0% for vomiting, 44.2% for constipation, 24.1% for diarrhea" (p. 912). The authors' conclusions suggest that physician discrepancy may, in part, be explained by their focus on toxicities that would necessitate a treatment modification as well as that patient self-reporting has a relatively minimal role in clinical care as well as clinical trials. DiMaio et al. (2015) believed the findings to be

generalizable to the larger cancer population and suggested:

[F]indings emphasize the need for modifying the current system of toxicity assessment in clinical trials. Specifically, a collaborative reporting approach, where the patients directly report symptomatic toxicity information, which is then provided to clinicians to inform their CTCAE reporting, could improve the efficiency of reporting, and modern technologic supports (e.g., tablets) could be used to facilitate patient reporting. (p.914)

Although dated, the clinical trials' data reflect a problem with currently conducted clinical trials: there is not an integration between patients' assessments and clinicians' assessments. Data from PROMs (e.g., PROMIS, QLQ-C30) are frequently not considered for adverse event reporting; this has resulted in the 21st Century Cures Act mandating COAs, including PROMs, in drug development (FDA, 2020a).

2.3.2 Regulatory Use

The U.S. FDA finalized a guidance in 2009 regarding the use of PROM for the labelling of medical products. Patient reported outcome measures (PROM) were brought to the forefront of drug and device development within the United States by the passing of the 21st Century Cures Act in 2016 under U.S. Public Law 116-255 (U.S. Food and Drug Administration (FDA), 2020a). This law prioritized the patients' perspectives (creating the acronym PFDD for patient focused drug development) as well as modernizing trial design to incorporate real-world evidence (FDA, 2020a). The FDA has held a series of workshops for study designs (e.g., mixed methods, qualitative studies) as well as how to incorporate those results into new drug applications (U.S. Food and Drug Administration (FDA), 2020c).

Of note, the FDA considers PFDD to utilize Clinical Outcome Assessments (COAs), of which only one is PROM – the remaining are observer-reported outcome (ObsRO) measures, clinician-reported outcome (ClinRO) measures, and performance outcome (PerfO) measures (FDA-NIH Biomarker Working Group, 2021; Schultz-Knudsen et al., 2021; U.S. Food and Drug Administration (FDA), 2020b). Thus, to comply with the 21st Century Cures Act, the supplied data may be obtained from observers or objective measures rather than PROM (U.S. Food and Drug Administration (FDA), 2020a). Of the new drug applications approved between 2011 through 2015 (n=182), 18 were for malignancies but none had patient reported outcome data submitted to support the filed indications (Gnanasakthy et al., 2017). Similarly, of the 2019 new drug approvals, 11 were for anti-neoplastic indications but none had COA listed as a primary objective but two utilized PROM: darolutamide (NUBEQA[®], Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ, USA) and fedratinib (INREBIC[®], Impact Biomedicines, Inc., Celgene Corporation, Summit, NJ, USA) (Schultz-Knudsen et al., 2021). Both provide case studies in the use of PROM in drug development and highlight the necessity of proactively selecting the instrument and the rationale for its use.

Darolutamide was a new molecular entity approved in 2019 as a treatment for patients diagnosed with non-metastatic castration resistant prostate cancer (Bayer HealthCare Pharmaceuticals Inc., 2021). Of the tested secondary endpoints, one tested time to pain progression, which was measured by question 3 of the Brief Pain Index – Short Form (BPI-SF) (Cleeland & Ryan, 1994; U.S. FDA Center for Drug Evaluation and Research, 2018). It should be noted that this question was the only one deemed fit-for-purpose by the FDA out of the 4 questionnaires which utilized a total of 95 questions that

were administered every 16 weeks (U.S. FDA Center for Drug Evaluation and Research, 2018). Time to pain progression was deemed both clinically relevant and statistically significant and thus was listed as a benefit to the new drug. The FDA reviewer had this comment regarding the PROM choices used for the pivotal study:

Interpreting the impact of the various composite scores analyzed on the safety and tolerability of darolutamide is difficult due to methods of assessment that include reports of emotional state and functionality that can be influenced by non-drug factors. Therefore, these measures may not be truly reflective of the effects of the drug being evaluated. Although the prostate cancer subscale of the FACT-P was used in this trial the items are more relevant in assessing symptoms associated with disease and treatment in the early prostate cancer setting as opposed to patients with castration-resistant disease. (p. 142)

The pivotal JAKARTA trial evaluating fedratinib utilized only a single patient reported outcome questionnaire – the Myelofibrosis Symptom Assessment Form – as did the phase 2 open label trial JAKARTA2 (ClinicalTrials.gov, 2016a, 2016b). The questionnaire had only six assessments (night sweats, pruritus, abdominal discomfort, early satiety, pain under the ribs on left side, and bone/muscle pain) which mirrored symptoms common to the disease under study (U.S. FDA Center for Drug Evaluation and Research, 2019). The pre-specified test for the secondary outcome was the number of participants who responded to treatment (i.e., investigational medical product or placebo), where a responder was a participant who had a reduction of $\leq 50\%$ of symptoms burden by end of cycle 6 (U.S. FDA Center for Drug Evaluation and Research, 2019). Data demonstrated a significant statistical difference, with 34 – 40% (dose dependent)

achieving the pre-defined response compared to 8% in the placebo control (U.S. FDA Center for Drug Evaluation and Research, 2019), p.16. These data were accepted by the FDA to support the outcome of symptom reduction on the prescribing information (Impact Biomedicines Inc. a subsidiary of Celgene Corporation, 2019). The FDA's multidisciplinary review of fedratinib noted:

[S]ponsors should carefully consider the study design and its effect on PRO data interpretation. FDA recommends that if a claim of treatment benefit is sought, there is a clear endpoint definition and formal statistical testing with adjustment for multiplicity, as well as an appropriate pre-specified statistical analysis plan (SAP) with a plan to control the type 1 error rate. In the SAP, there should be details on the statistical analysis methods, procedures for handling missing values, justification for the endpoint definition and procedures for what constitutes meaningful within-patient change. (p.148).

These comments from the FDA's Center for Drug Evaluation and Research regarding the new drug approvals using patient reported outcomes highlight a current chasm in patient focused drug development: a lack of fit to purpose when implementing PROM and a lack of a statistical analysis plan when using PROM as a primary or secondary endpoint to support labelling for a drug or device, representing one use for PROM.

The FDA considers five elements when evaluating patient reported outcome measures: (a) identification of claim(s); (b) utilization of an appropriate conceptual framework; (c) appropriately document content validity; (d) establish the definition of a response; and (e) reassessment after modification to a PRO instrument (Burke et al., 2008). The elements follow a typical strategy but include qualitative techniques,

including focus groups with cognitive interviewing until saturation (Burke et al., 2008). FDA encourages the PROM to focus on the symptom or side effect that is experienced by the patient and not objectively quantifiable by the physician, as a difference in opinion is expected between the two (Kim et al., 2018). The measurement should be fit-for-purpose, sensitive to change over time, and be able to capture the toxicity over time through longitudinal assessments (Burke et al., 2008; Kim et al., 2018; Kluetz, Kanapuru, et al., 2018; Kluetz, O'Connor, et al., 2018). For example, FDA defines 'tolerability' as a patient-generated concept, that the symptom or toxicity burden is tolerable and does not interfere in day to day activities (Kluetz, Kanapuru, et al., 2018). FDA encourages trials to focus on the symptom that could be used to inform tolerability. This becomes exceedingly important as maintenance treatments are extending the lives of patients with cancer but at the cost of continuing side effects (Addario et al., 2020).

Despite the FDA's stance on tolerability as a PROM, integration of PROM to assess tolerability within the U.S. drug approval process remains unclear – as it does for most instruments deemed to be HRQL or QOL (DeMuro et al., 2013; Kluetz, O'Connor, et al., 2018; Rock et al., 2007). For example, the FDA stresses that reviewing responses to HRQL is incumbent upon investigators to protect the safety of clinical trials participants (Kim et al., 2018). This elevates HRQL to a safety endpoint (Kim et al., 2018; Kluetz, O'Connor, et al., 2018). Yet HRQL responses are often not reviewed as a part of the safety assessment during a clinical trial nor are they used to define the adverse event profile for the prescribing information. This is only one example of the confusion created by nebulous direction from U.S. regulatory oversight for new drug and device development (DeMuro et al., 2013; Kluetz, O'Connor, et al., 2018).

In a 2013 review article comparing the types of PRO approvals between FDA and the EMA, DeMuro et al. used Soliris™ (eculizumab, Alexion Pharmaceuticals, Inc., Cheshire, CT, USA) as an example of the discordance between the U.S. FDA and the EMA. Soliris™ received approval for paroxysmal nocturnal hemoglobinuria (Alexion Pharmaceuticals Inc.; U.S. Food and Drug Administration (FDA), 2007). Supporting pivotal trials utilized both the EORTC QLQ-C30 and the FACIT-F instruments (U.S. Food and Drug Administration (FDA), 2007). During its medical review, FDA stated that although statistically robust, the "...FACIT-F QOL tool has not been validated for patients in the hematology oncology setting. Therefore, the results... should not be included in labeling..." (p. 72). Data from the EORTC QLQ-C30 were filed as exploratory and, as such, were not considered by FDA for efficacy or labeling. In contrast and based upon the same data, the EMA approved Soliris™ for claims based on data from both the FACIT-F and QLQ-C30 instruments. The EMA-approved labelling states "74% of the patients without a history of transfusion and treated with Soliris™ experienced clinically meaningful improvements in FACIT-Fatigue score (i.e., increase by 4 points or more) and 84% in EORTC fatigue score (i.e., decrease by 10 points or more)" (European Medicines Agency (EMA), 2009).

Approval reviews suggest the U.S. FDA grants the majority of new drug approvals based upon symptoms; whereas, EMA is more likely to approve based on 'higher order constructs'—ostensibly HRQL (DeMuro et al., 2013). In 2018, selected representatives from the FDA, the EMA, and Health Canada's Therapeutic Products Directorate authored an article identifying differences in PROM guidelines and policies for drug approval (Kluetz, O'Connor, et al., 2018). In it, EMA deems HRQL an important

primary outcome measure for oncology clinical trials, citing their reflection paper providing instructions for claims of improving HRQL, such as the use of a validated instrument and that all domains must be robustly impacted (EMA, 2005; Kluetz, O'Connor, et al., 2018). In comparing PROM guidelines, FDA's Paul Kleutz writes "discordance is particularly notable with regards to the acceptability of the more global domains of health-related quality-of-life (HRQL), which can be viewed as being affected by non-drug contributors (i.e., external influences not directly related to the study medication)" (p.e267, Kleutz et al., 2018). The article further clarifies that FDA's perspective is HRQL should focus on core symptoms of disease under study, treatment emergent adverse events, and quantifiable physical function assessments. Because emotional and/or social interactions impact HRQL in the absence of the drug or therapy being examined, FDA requests HRQL measures be supplemented with functional and well defined symptom data (Kluetz, O'Connor, et al., 2018). Reviewing lung cancer clinical trials from 2007 through 2017 supporting new U.S. drug approvals underscores FDA's stance (Fiero et al., 2019). Common PROM instruments within the trials included the EORTC QLQ-C30, FACT-L, and the LCSS, yet individual symptomatic domains (e.g. dyspnea, pain, fatigue) were the FDA's outcomes of interest rather than the composite HRQL score (Fiero et al., 2019). The statistical analysis for the PROM utilized in the lung cancer trials was not systematic nor justified, especially when determining clinical relevance for the composite scores (Fiero et al., 2019). Fiero et al. conclude the impact of HRQL as an instrument to inform both clinicians and patients is hampered due to poor planning and implementation and, for this reason, FDA should be contacted early and often to effectively utilize PROM in trial design with the end-goal of including the results in marketing applications.

2.3.3 Clinical Use

Oncologic practice within the United States is significantly influenced by the U.S. FDA through the drug approval cycle: oncologists treat based upon newly approved indications but are influenced as well as by Industry with its perpetual clinical trials regime to obtain those new marketing approvals. Secondary influences include research based upon prior trials, so that if an earlier trial utilized a specific PROM instrument, subsequent trials may incorporate that instrument. Similarly, investigator initiated trials may copy instrument use from Industry clinical trials they have participated in. Academic physicians may incorporate PROM instruments to provide data for chart review research or quality improvement projects at later dates. Regardless of the cause, PROM instruments have become part of the oncology clinic, with some clinics implementing and adapting better than others.

Incorporating patient-reported outcome measures (PROMs) into the electronic health record (EHR) seems the logical strategy to create patient-centered care as well as harmonize communication between patient and provider and patient but initial work has met with varied success (Basch et al., 2005; Basch, Rogak, et al., 2016; Boyce & Browne, 2013; Chen et al., 2013; Gensheimer et al., 2018; Hsiao et al., 2019; Kotronoulas et al., 2014; Kozlov & Benzon, 2020; Kyte, Ives, et al., 2013; Lavallee et al., 2016; Nestle et al., 2020; Olde Rikkert et al., 2018; Snyder et al., 2012; Snyder et al., 2017). A randomized controlled trial of the Patient Reported Outcomes Measurement Information System (PROMIS) evaluated adding this PROM as an electronic survey in an adult gastrointestinal clinic (Almario et al., 2016). The PROMIS-GI questionnaire was completed by patients using an electronic portal one-week prior to their visit. Results

showed no statistical difference between measures of patient satisfaction, assessments of the providers' interpersonal skills, and shared decision making (Almario et al., 2016). Limitations include the single-visit structure of the study as well as the general GI-patient population, rather than a GI-cancer population. Fromme et al. (2016) created an electronic questionnaire based upon the Memorial Symptom Assessment Scale (MSAS) Short Form and the EORTC's QLQ-C30 quality-of-life questionnaire. Participants completed this questionnaire on a Windows-based PC with results provided to the radiation oncologist as a color-coded printed report showing change over time (Fromme et al., 2016). Results suggest a continued inconsistency between patient-reported adverse events and adverse events discussed with the radiation oncologist despite the intervention. The study did not investigate shared decision making, patient communication preferences, or measures of communication between provider and patient. Limitations include not including the PROMs in the EHR, not evaluating consultations (e.g., occupational, physical, nutritional), and not stratifying by tumor or treatment type (e.g., chemoradiation, radiation only) (Fromme et al., 2016).

In contrast to much of the literature, the results of a multi-center, pragmatic clinical trial funded by the National Institutes of Health (NIH) did not identify positive results from incorporating the NIH's own Patient Reported Outcomes Measurement Information System (PROMIS) gastrointestinal (GI) instrument into clinic workflow (Almario et al., 2016; Gracie & Ford, 2016). The trial employed the PROMIS GI instrument approximately one week before the clinic visit through an electronic portal (Almario et al., 2016). The primary study endpoint was patient satisfaction with secondary endpoints including provider interpersonal skills and shared decision making

(the 9-item shared decision making questionnaire, SDM-Q-9) (Almario et al., 2016). The trial used alternating deployment of the PROMIS GI instrument, with one week on and one week off for the clinic; this created the concurrent control group for comparison. With over 200 patients in the GI PROMIS arm and 150 in the control arm, neither statistically significant differences – or even trends – were detected between the groups (Almario et al., 2016). A significant limitation to the work is the intervention occurred for only one clinic visit compared to consecutive uses over the duration of the patient’s care. Additionally, despite the authors discussion about the ‘extraordinary burden of gastrointestinal illnesses,’ the exact diseases being cared for are not described (Almario et al., 2016). Inclusivity is key to pragmatism but, in this instance, impacts internal validity given the wide range of symptoms triggering gastrointestinal consults. Other recent studies also report a lack of improvement in patient experience measures when using patient reported outcome measure instruments, including PROMIS (Keulen et al., 2018; Kroenke et al., 2018).

A key reason for the heterogeneity of findings could be the context of PROM use. A 2008 systematic review of the literature explored the impact of use of PROMs in clinical care (Valderas et al., 2008). In their review of 28 applicable studies, Valderas and colleagues (2008) found the most significant impact occurred on the process of care (e.g., education, diagnosis, referrals). The authors described consistent methodologic concerns with PROM investigation and attributed these issues to the varied results. However, this review had a broad scope, ranging from primary care (n=19) to dental offices (n=1) to cancer clinics (n=2). It could be that the context of the medical discipline, as well as context of use, impacts PROM functionality within the clinic. The authors

concluded upon their review that methodologically stronger trials were required to provide direction, context, and insight for clinicians regarding how to incorporate PROM into clinical use.

Five years later, a systematic review found PROMs were often used in outpatient specialized healthcare settings (Boyce & Browne, 2013). Inclusion criteria for this review were restrictive, requiring an eligible study to utilize a randomized control with clinical use of PROM being the sole intervention. Of the final cohort of 17 studies, only one was an oncology study investigating the impact of PROM on pain management in patients with cancer (Boyce & Browne, 2013). In conclusion, Boyce and Browne (2013) identified consistent methodologic issues with the work to date, suggesting future research focus not only on hypothesis driven quantitative research but also qualitative work to provide a richer understanding of problems implementing PROM as well as understand if PROM affect the decision-making process and, if so, how.

That same year, a systematic review by Chen and colleagues (2013) identified 27 publications evaluating the routine use of PROM in the oncologic setting. Outcomes evaluated from PROM implementation included patient-provider communication, monitoring treatment response, and changes to patient management (Chen et al., 2013). Of the publications reviewed, 16 were randomized controlled trials (RCTs), two were before/after studies, and 11 were observational studies. Identified limitations to the work included simple-randomization strategies, which do not address contamination of the system, failure to utilize a comprehensive model and/or framework, and all studies occurring at a single site (Chen et al., 2013). Of the 27 studies reviewed, 23 reported on the impact on patient-provider communication; 21 reported a positive effect. All of the 11

studies reporting on monitoring treatment response found a positive impact, typically on monitoring chemotherapeutic toxicity. Of the 16 studies describing the problem of unrecognized problems, 15 reported a strong or moderately positive impact on detection. The authors concluded the evidence base was weakest for PROM impact on changes to patient management as well as improved health outcomes. None of the studies examined changes to patient health behavior, quality improvement, or better health care system performance (Chen et al., 2013). In their conclusions, the authors state that simple feedback alone provided by adding PROM to the clinic may not improve patient management or health outcomes. Additional resources, such as an implementation and assessment plan, may be required to obtain benefit from incorporating PROM into the oncology clinic (Chen et al., 2013).

A review by Kotronoulas and colleagues (2014) investigated the value of routinely incorporating PROM into oncology clinics. Whereas Chen et al. evaluated the impact of PROM on patients, providers, and healthcare organizations, Kotronoulas et al. focused on if any improvement occurred in discrete patient outcomes, processes of care, or health service outcomes (Chen et al., 2013; Kotronoulas et al., 2014). Seventeen of the 24 articles reviewed were also reviewed by Chen et al. (2013); perhaps for this reason, the results were similar. Overall, a positive effect was observed on physical symptoms, including psychological distress and greater satisfaction with emotional support and communication with the healthcare team were observed with PROM use (Kotronoulas et al., 2014). Despite these findings, Kotronoulas and colleagues (2014) stated evidence was weak regarding the effectiveness of PROM in improving quality of care for patients undergoing antineoplastic therapy. Like the previous reviews, the authors conclude with a

need for rigorous research that would provide the context and guidelines for PROM implementation to result in not only an effective use but a fiscally efficient use as well (Kotronoulas et al., 2014).

To perhaps help with identified weaknesses, systematic guidance on how to incorporate PROMs into clinical practice was drafted and provided by The International Society for Quality of Life Research (ISOQOL) as well as others (International Society for Quality of Life Research et al., 2015; Kyte, Draper, et al., 2013; Lavalley et al., 2016; Olde Rikkert et al., 2018; Snyder et al., 2012; Snyder et al., 2017). Basch and colleagues guidelines propose core symptom assessments for oncology clinics and trials using PROM (Basch et al., 2012; Basch, Rogak, et al., 2016). Other guidelines include setting goals for PROM use, identifying the method for capture (patients, setting, timing), and deciding how to report and address results (ISOQOL et al., 2015; Snyder et al. 2012). The guidelines omit the patient perspective, not including them in goal setting, instrument design, or how they would like the results presented (ISOQOL et al., 2015; Snyder et al. 2012). This is in contrast to recent publications that recommend including patients in the care-planning process as well as regulations requiring goal setting for patient-centered care (Addario et al., 2020; Baker et al., 2001; Olde Rikkert et al., 2018; van Dulmen et al., 2015). This becomes key, as inviting patients to participate in setting goals of treatment bridges a gap, identifying PROMs as an instrument in SDM.

2.4 Frameworks and Implementation

As mentioned previously, capturing PRO as well as initiating PROM instruments have met with mixed success for both implementation and outcomes. Recently, key opinion leaders have proposed standardized strategies. The majority of

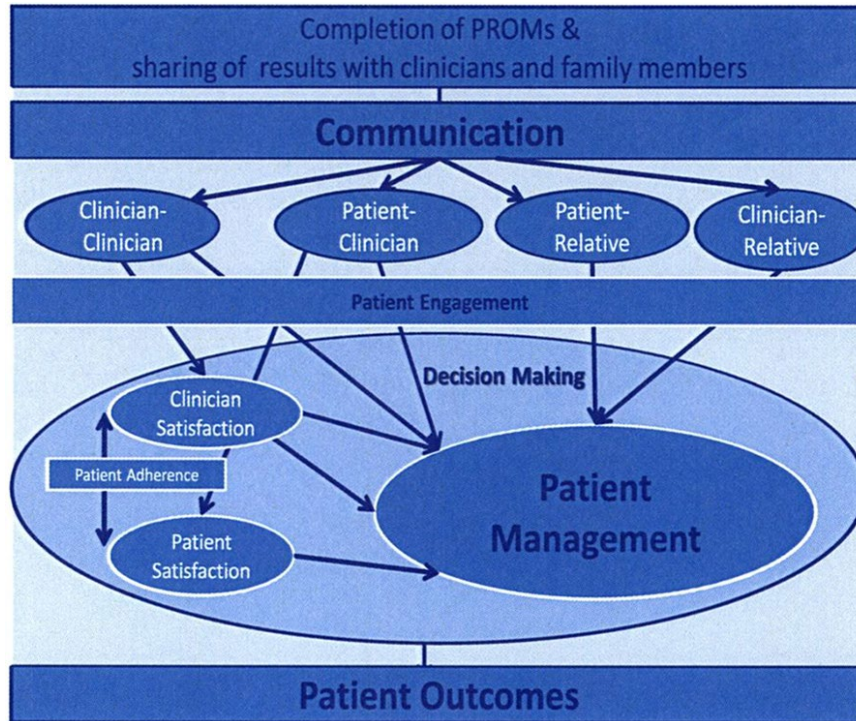
the leaders agree on the need to prospectively identify the PRO to measure, select the instrument to measure the PRO, ensure the measurement is fit for purpose, confirm the instrument is sensitive to change, define how often PROM are collected, how the PROM are collected, and that analysis is well-defined prior to implementation (Basch, Rogak, et al., 2016; Burke et al., 2008; Gensheimer et al., 2018; Kluetz, O'Connor, et al., 2018; Snyder et al., 2012; U.S. Food and Drug Administration (FDA), 2009, 2018). In addition to these considerations, there are others that may have not yet been identified or may be identifiable only in context. When introducing a new instrument or communication strategy into a complex adaptive system (such as multidisciplinary oncologic care), frameworks should be reviewed if not utilized.

2.4.1 Frameworks

Theories, models, and frameworks become key when considering creation of an instrument, its implementation, or its uptake. The FDA has listed identifying and utilizing a conceptual framework as one of the five key criteria for successful PROM use and evaluation (Burke et al., 2008). A framework provides a visual depiction of factors, influences, and their interactions and may outline key steps that should be considered for concept or phenomenon of interest (Nilsen, 2015). Frameworks for implementation, termed *determinant frameworks*, can serve as a mediator for change by proactively identifying barriers and facilitators (Nilsen, 2015). A framework does not specify causality, but simply provides the implementation concepts or foundational constructs. When used appropriately, frameworks provide structure to implementation, can decrease poor fit, and increase uptake. Frameworks that were incidentally identified through the search of the peer-reviewed literature PROM and SDM were reviewed; of these, three

Figure 8

Conceptual Framework Identifying Potential Downstream Effects of PROM for Patients with Chronic Health Issues



Note. Reprinted by permission from Springer Science+Business Media, LLC, part of Springer Nature: Rapid Communications of Oxford, Ltd. *Quality of Life Research*. Framework to assess the effects of using patient-reported outcome measures in chronic care management by M. J. Santana and D. Feeny. ©2014

were identified as relevant to a shared decision making / communication instrument in radiation oncology utilizing patient reported outcome measures.

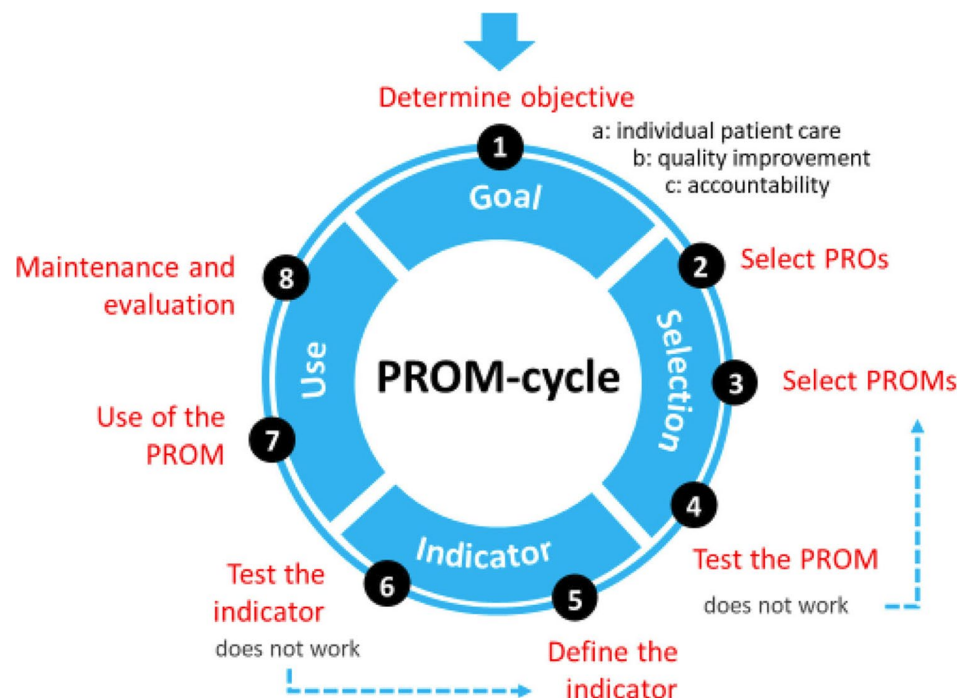
Santana and Feeny (2014) proposed a framework for patient reported outcomes and communication for clinical use for patients with chronic healthcare problems (Figure 8). The framework elegantly conveys the cascading effect of the PROM and downstream communication between patient, caregiver, and physician (Santana & Feeny, 2014). When considering implementation of the PROM, the first downstream effect is patient engagement followed by decision making and outcomes (Figure 8). Increased patient

engagement could stem from the PROM instrument establishing a foundation of items for discussion, deeming them to be ‘acceptable’ for discussion with physicians (Greenhalgh et al., 2018).

In 2019, van der Wees et al. developed a framework (Figure 9) which was then evaluated in its preliminary format at an ISOQOL workshop. The framework provides a stepwise strategy for thoughtful implementation and use of a PROM instrument (Figure 9). The framework aligns with the requirements underscored by FDA: define the objective, select the PRO, select the PROM to ensure appropriate measure, identify the metric to be used as an indicator of quality, and then maintain the PROM implementation

Figure 9

The Goal-Selection-Indicator-Use Framework



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(van der Wees et al., 2019). The framework reminds that a patient reported outcome is not a patient reported outcome measures, that quality strategy must be applied to PROM instruments as another clinical assessment, and that the use of the PROM instrument must be assessed for uptake and fit (van der Wees et al., 2019).

2.4.2 Implementation of SDM and PROMs

The proposed work relies heavily on three implementation frameworks and models: the National Implementation Research Network as described by Bertram and colleagues in 2015, the Ottawa Model of Research Use (OMRU) as written by Graham and Logan in 2004, and the Plan-Do-Study-Act implementation cycle model originally described by W. E. Deming in the 1920s (The W. Edwards Deming Institute, 2021). As discussed in Chapter 1, the framework and models create an needed granularity when integrated, providing details and considerations for implementing a decision-aid.

Despite known benefits, research demonstrates oncologists, including radiation oncologists, do not participate in SDM (Amundsen et al., 2018; Glatzer et al., 2020; Hopmans et al., 2015; Jabbour et al., 2018; Mokhles et al., 2018; Smith et al., 2017; Sztankay et al., 2017). Research by Shabason et al. (2014) suggests only one-third of patients at an academic center in the U.S. endorsed shared decision making with their radiation oncologist. This is consistent with research from Australia, which suggests incidence of SDM ranging from 33 to 37% in general oncology practice (Herrmann et al., 2018; Jabbour et al., 2018).

Within generalized oncology practice (i.e. the radiation, surgical, or medical specialties), barriers to SDM have been identified as time-constraints, a generalized feeling of being rushed, lack of applicability of SDM to the current situation, an

education gap between provider and patient, and the patient's concern of being labeled 'difficult,' a lack of a treatment consensus between oncology disciplines (e.g., medical, surgical, radiologic), patient concern over adverse effects, poor physician communication, and the oncologist's understanding of the patient's preferred decision making preference (Agin et al., 2018; Ankolekar et al., 2019; Covvey et al., 2019; Frosch et al., 2012; Legare et al., 2008; Legare & Thompson-Leduc, 2014; Woodhouse et al., 2017).

A common concern is that SDM increases time per clinic visit and time commitment for quality communication then becomes a significant barrier (Martin et al., 2019; Paladino et al., 2019). A qualitative study from Australia explored patients' first consultations with their oncologist (radiation or medical). The consults were audio-recorded were transcribed, coded, and compared between the two specialties. Results revealed radiation oncologists spent less time with their patients (23.1 minutes vs. 36.7 minutes) and allowed less time for the patient to speak (6.2 minutes vs. 10.6 minutes) (Dimoska et al., 2008). Although a partial explanation for this could be radiation oncology is a referral service, with medical oncology providing initial diagnosis, prognosis, and indications for therapy, in this work the visits were independent (Dimoska et al., 2008). Radiation oncologists invested an average of 9 seconds during the consult to confirm patient understanding and engaged only 25 seconds in communication that was considered rapport building (Dimoska et al., 2008). The same study demonstrated patients took a total of 62 seconds to reveal the problem/intention; this is less than other studies which have found patients average 90 to 120 seconds to provide their rationale for their visit and/or concerns (Langewitz et al., 2002; Rabinowitz et al., 2004; Singh Ospina et al., 2019). Prior work has identified the

majority of general practice physicians interrupt during their patient's initial monologue, with time-to-interruption ranging from 11 to 23 seconds (Singh Ospina et al., 2019). It is reasonable to extrapolate this to radiation oncologists, as Martin et al. (2019) describe the radiation oncologists' communication style as, "...less patient-centered, more hurried, and less clear" (p. 294).

Beers et al. (2017) state that approximately 75% of oncology patients seek an active or collaborative role with their oncologist(s) in decisions about their. Similarly, Zeng et al. (2017) evaluated decision-making preference (active *versus* passive) of patients with metastatic cancer to the brain and all participants requested an active SDM role. Patients who seek a passive role tend to have poorer coping skills and are more fatalistic (Beers et al., 2017). Herrmann et al. (2018) identified five categories of decision making within oncology: patient only, predominantly patient, collaborative, predominantly doctor, doctor only. A cross-sectional survey querying the patient's preferred involvement the patient's perceived involvement was sent to adult cancer patients treated at medical or radiation oncology units. Of the 423 respondents, a third reported a discordance between their preference and their perception and roughly 55% reported being asked about their preference for decision making (Herrmann et al., 2018). Reasons cited for not asking patients their preference for involvement in decision making include additional time constraints or burden in an already hectic clinic and also the perception that patients prefer not to be responsible for their treatment decisions (Herrmann et al., 2018).

With this research, Herrmann et al. (2018) adds a significant first step to the SDM in oncology framework that was described by Beers et al. (2017). Whereas Beers outlined 4 steps: (1) informing patients, (2) explaining the treatment options, (3) identifying patients'

values and goals, and (4) making the decision, Hermann et al. (2018), define the critical first step as asking the patient to identify their preferred decision making method, rather than assuming the patient's preference. Failing to identify a patient's preference has been coined, "preference misdiagnosis," and can result in anxiety, stress, depression, and patient dissatisfaction with care (Mulley et al., 2012) as well as create a crack in the foundation of patient-centered care, which is defined by the AHRQ and the National Academy of Medicine as "Providing care that is respectful of and responsive to individual patient preferences, needs, and values" (Agency for Healthcare Research and Quality, 2018, 2020; Institute of Medicine, 2001).

This is noteworthy, as radiation oncology is—perhaps—the most patient-centered oncologic discipline. Rather than a simple, binary treatment decision (i.e., radiation yes, radiation no), radiation therapy techniques demand an individualized plan designed to the sub-millimeter, customized to the patient's unique anatomy, tumor type, treatment strategy (e.g., palliative, definitive, adjuvant) and even medical comorbidities (Berman et al., 2016). However, a metric to determine the success of SDM within radiation oncology has not yet been identified much less agreed upon (Berman et al., 2016; Leech et al., 2020).

Radiation treatments vary in dose, schedule, technique, and modality; some may not have a clear superiority and can be recommended based on provider preference or technological capability of the radiation oncology facility (Woodhouse et al., 2017). When such clinical treatments meet equipoise, or if patients express uncertainty or confusion over treatment options, clinical decision-aids can serve as instruments to help identify the best treatment path for the patient (Woodhouse et al., 2017). A decision-aid instrument can promote shared decision making in situations where patient preference is

influential, creating a collaborative dynamic where factors including treatment burden, financial stressors, and therapy goals are incorporated into the treatment decision.

Decision-aids should be tailored for the patient (to the extent feasible) and provided to the patient for retention. This not only encourages the patient to share information with family and caregivers, but also to review the information provided after the initial consultation, when patients report poor information retention (Charles et al., 1997).

Unfortunately, tailored patient information in radiation oncology, and thus a decision aid instrument, includes discussion about a technically complex medical discipline. Radiation oncology requires high-resolution imaging, assessment of tumor motion, hundreds of contours of normal tissues as well as target tissues (i.e., tumor tissue or tissue at risk), constraining doses to organs to reduce radiation damage, peer-review, a medical physics plan check, and daily quality assurance. The American College of Radiology-American Society for Radiation Oncology (ACR-ASTRO) *Practice Parameter for Communication: Radiation Oncology* explicitly outlines information to be communicated to the patient as well as information to be documented in the medical record (Schechter et al., 2020). Direct communication between the radiation oncologist and patient should be bidirectional, collaborative, supportive, and should include treatment options (Schechter et al., 2020). The recommendations do not include discussing the technical aspects of the radiation plan or documenting them in the patient's notes (Schechter et al., 2020).

A study in 2017 explored a radiation decision aid for patients diagnosed with lung cancer metastases who could have either of two radiation therapy strategies: whole brain radiation with stereotactic radiosurgery (WBRT + SRS) or SRS alone (Zeng et al., 2017). The decision-aid outlined differences in potential neurocognitive toxicities, treatment

duration, and risk of recurrence for both treatments but did not provide differences in survival, side effects, or quality-of-life – simply stating that they were ‘equal’ (Zeng et al., 2017). After evaluating the decision aid, twenty-one of participants (91%) selected SRS alone as their therapy. Participant responses to surveys suggested maintaining QOL and functional independence was of greater importance to patients than disease recurrence, development of new metastases, or the number of trips to the treatment center (Zeng et al., 2017). Of concern, the peer-reviewed literature Zeng et al. cited in their work did not support the information on the decision aid instrument. One of the two studies cited was halted by its data and safety monitoring committee due to the severe neurocognitive adverse effects of SRS+WBRT (Chang et al., 2009). Chang et al. state that QOL was not the same for the SRS and SRS+WBRT cohorts as measured by the FACT-BR instrument. Quality-of-life was not defined within the article or within the decision aid instrument

Figure 10

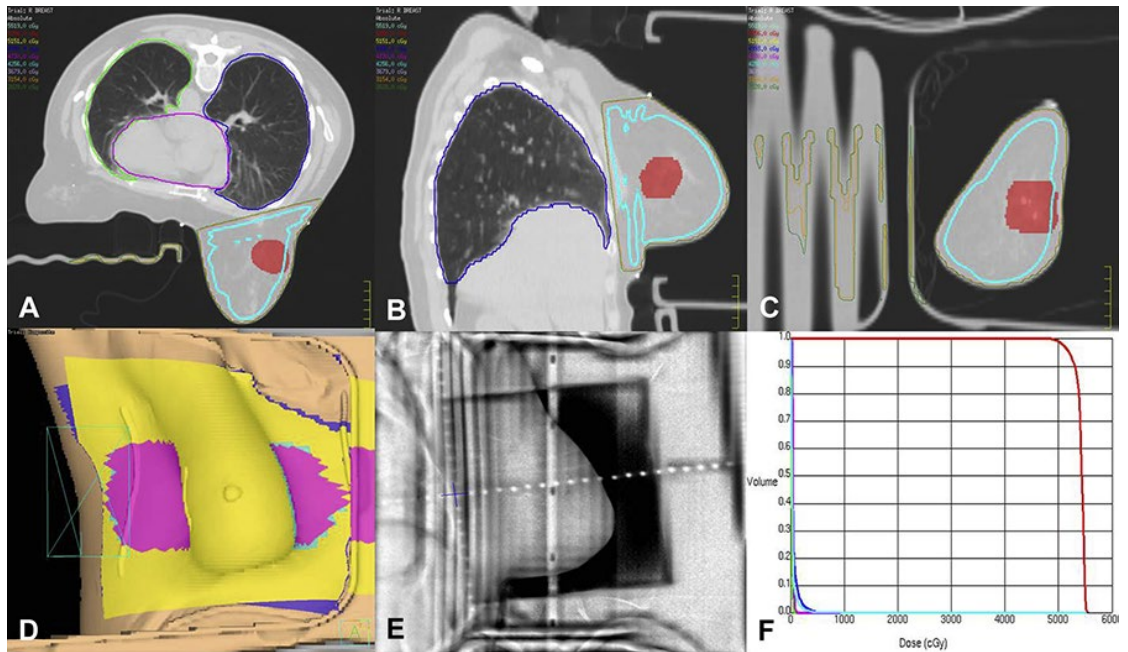
Decision Aid for SRS Alone or SRS Combined with WBRT

Summary	<ul style="list-style-type: none"> ◆ No overall survival differences; ◆ No quality of life differences; ◆ No differences in side effects; ◆ No difference in functional independence ◆ But ◆ Differences in neurocognition; ◆ Differences in probability of developing other brain metastases; ◆ Differences in local control
Given these similarities and differences, which Treatment Plan do you prefer?	

Note. SRS: stereotactic radiosurgery, WBRT: whole brain radiotherapy. This figure is adapted from a figure within an open access article distributed under the terms of the Creative Commons CC BY license, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. Copyright information provided by AME Publishing Company, publisher of *Annals of Palliative Medicine*. Patient preference for stereotactic radiosurgery plus or minus whole brain radiotherapy for the treatment of brain metastases by Zheng et al. ©2011.

(Zeng et al., 2017). Zeng et al. (2017) wrote, “but also the quality-of-life during that period (in this case, possible worsening neurocognitive function)” (p. 159). This quote highlights the discrepancy within the article: how does experiencing significant neurocognitive decline not influence QOL? It seems illogical to suggest otherwise, but this is what is stated within the decision aid drafted by Zeng et al. (2017) (Figure 10). This study further highlights how the ambiguous use of the term HRQL can stifle research trustworthiness and usability, as it is unclear how QOL is not impacted and side effects are the same but deficits in neurocognition (which are a side effect of radiation) are significantly different (Zeng et al., 2017).

Dyer and colleagues explored sharing technical details of an RT plan in a randomized clinical trial (2019). Patients diagnosed with breast cancer requiring adjuvant radiation were randomized prospectively to standard review *vs.* a detailed review which included the radiation treatment plan, tissue doses, organ constraints, and the radiation beam arrangement (Figure 11) (Dyer et al., 2019). As shown, the information provided for the detailed review is technical with poor readability, with X-ray imaging for target alignment (Figure 11, panel E) and dose volume histograms, which provide the normalized volume to receive a specified radiation absorbed dose measured in centigray (cGy) (Figure 11, panel F). Despite the heavy technical details, overall satisfaction scores were increased at baseline for patients increased for patients undergoing the detailed review; however, these equalized to the control arm by week 1 of radiation and remained consistent with the control by completion of radiation treatment (Dyer et al., 2019). With an average increase of 4 minutes for the plan review, the work by Dyer does not support implementing a detailed technical review to increase overall satisfaction, including the FACIT subdomains

Figure 11*Sample Radiation Therapy Plan Shared with Patient for SDM*

Note. Sample radiation therapy plan to treat a lumpectomy for a patient with breast cancer. This figure is an example of the plan shared with patients for a detailed review of their treatment (Dyer et al., 2019). **A, B, C.** Images from the radiation therapy planning system showing contours for organs as well as the target (solid red area). **D.** Three-dimensional representation of patient's breast and where the radiation enters (e.g., pink overlay). **E.** Positional imaging to ensure the radiation aligns with the target. **F.** Dose volume histogram showing the volume of tissue receiving specified radiation doses. Reprinted from *Practical Radiation Oncology*, volume 9, Dyer et al. Prospective, randomized control trial investigating the impact of a physician-communicated radiation therapy plan review on breast cancer patient-reported satisfaction, pages e487-e496, ©2019, with permission from Elsevier.

of confidence & trust, physician communication, and technical competency (Dyer et al., 2019). It could be study utilized the wrong endpoint, as FACIT scale has a 1 to 3 numeric scale and not designed for radiation therapy. The normalization could reflect a patient's passing interest in the technical information regarding the radiation plan. It could also

reflect a patient's lack of recall due to information overload or simply the stress of their diagnosis. This would be consistent with earlier findings that found over half of patients with lung cancer could not recall information about goals of therapy and treatment options provided to them (Gabrijel et al., 2008) and 15% of patients believed they were receiving radiation therapy to cure their cancer when it was palliative (Mackenzie et al., 2018).

2.5 Summary

Peer reviewed literature to date supports the use of SDM and identifies multiple benefits. Despite the potential benefits, research suggests radiation oncologists are not participating in SDM. Patient reported outcome measures prompt both quality communication as well as SDM. Implementation of PROM, including HRQL, has met with difficulty due to overlapping definitions, poor fit for purpose between the instrument and the patient reported outcome, and a lack of planned statistical analysis. Clinical outcome assessments include both PROM and ClinRO which often demonstrate a disparity. Inclusion of COA, including PROM, is legally required for new drug and device approvals within the U.S.; this creates additional pressure for oncology clinics to proactively implement PROM. Frameworks should be used when implementing PROMs and SDM within the radiation oncology clinic, as the literature suggests work to date has been contradictory and inconsistent. Within radiation oncology, knowledge gaps remain regarding design of decision aids, how to measure SDM effectiveness, and best practice to increase incidence of quality communication.

CHAPTER 3

3 RESEARCH METHODOLOGY

3.1 Overview

The aim of this study was to explore the impact of a collaborative decision-aid tool, informed by stakeholders, the evidence base, and the practice considerations, when used for weekly on-treatment visits for patients with lung cancer undergoing radiation therapy. This is addressed through the following research questions:

1. How do the stakeholders, practice considerations, and evidence base inform the ideal design and implementation of a collaborative decision-aid tool?
2. What is the impact of the collaborative decision-aid on the medical management of patients actively undergoing radiation treatment for lung cancer?
3. How does the impact of the collaborative decision-aid tool inform recommendations for future designs and implementation ?

The primary objective was to develop a collaborative decision-aid tool, using patient-reported outcome measures, that could be easily implemented in an academic radiation oncology clinic for patients undergoing radiation therapy for lung cancer.

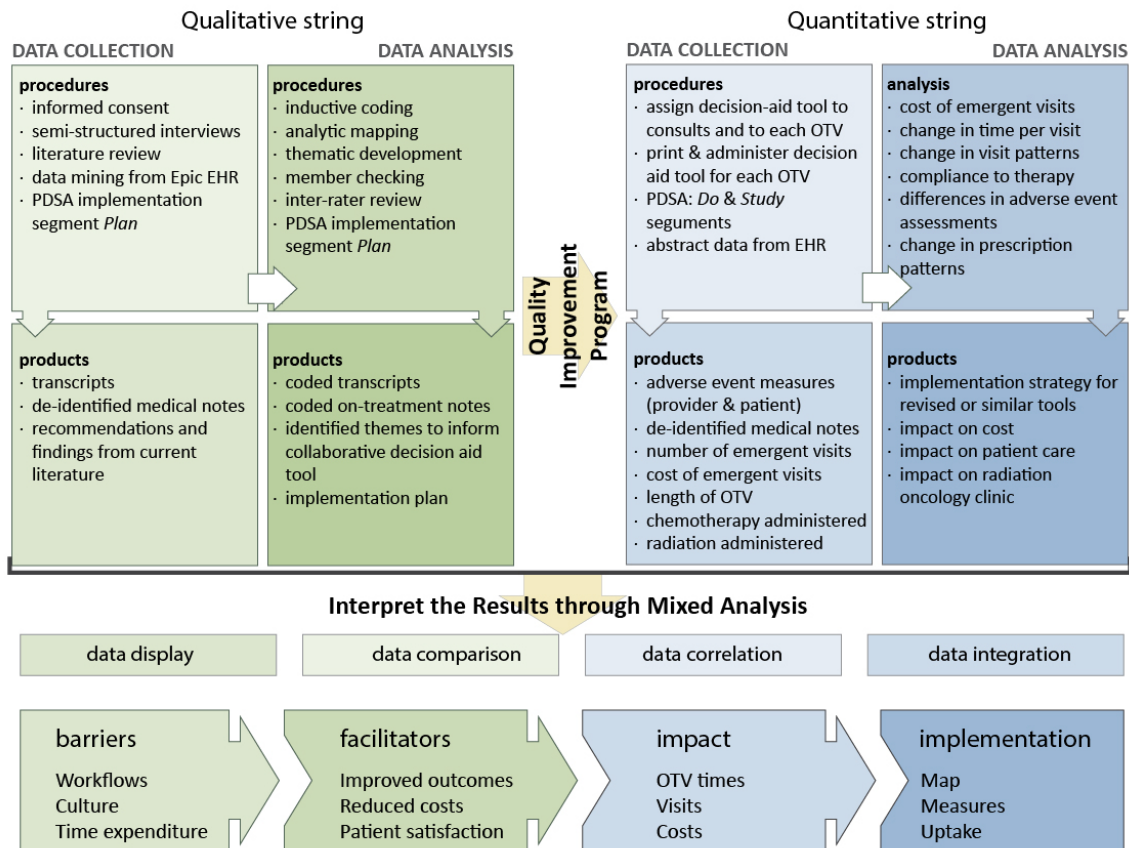
Secondary objectives were indicators of impact: surrogate measures for SDM (unscheduled oncology visits, concomitant medication prescriptions), indicators of medical management (assessed adverse events, radiation treatment compliance, chemotherapy compliance), and

emergent care visits and fiscal costs (emergency room visits and estimated cost, inpatient admission frequency, length of stay, and estimated cost). The hypothesized result was improved shared decision making, yielding better medical management and patient outcomes and reducing emergent care costs.

A dualistic epistemology was employed, with both pragmatic and interpretivist points of view utilized to obtain knowledge. The interpretivist paradigm was woven throughout the study with the key stakeholder insights (i.e., patients, radiation oncologists) contributing to the design and implementation of the collaborative decision-aid, its potential use, and their experiences with shared decision making. The pragmatic

Figure 12

Sequential Exploratory Mixed Methods Design



Note. Adapted from Creswell & Plano Clark (2011).

approach was highlighted within the mixed methods by examining how the evidence base and the practice inform the design and implementation of the decision aid, employing the Plan-Do-Study-Act to iteratively adapt it for use within an academic radiation oncology clinic, and provide mapping and guidelines for future design and implementation within the real-world setting.

This design approach (i.e., sequential exploratory mixed methods case study) was utilized to create and evaluate a decision tool yet enable flexibility through an iterative research process (Figure 12). Challenges to this multiphase design included both a significant time requirement and a high resource investment as well as practical focus on implementation strategy and context (Creswell & Plano Clark, 2011). Although time intensive, the design exploits the qualitative research strategy through interviews with patients and radiation oncologists to inform the tool's design and implementation and then employ a clinical implementation initiative to implement the collaborative decision-aid tool in a pragmatic, real-world fashion and then evaluate the tool's initial impact (Creswell & Plano Clark, 2011).

3.2 Research Setting

The study took place in Iowa City, Iowa within the University of Iowa Health Care system (UIHC) which is a combination of the University of Iowa Hospitals and Clinics, the University of Iowa Children's Hospital, and the Roy J. and Lucille A. Carver College of Medicine, serving as both the state's only academic medical center and as the only NCI-designated comprehensive cancer center, the Holden Comprehensive Cancer Center. For its electronic health record, the UIHC utilizes Epic[®] as well as Care Everywhere[®] and MyChart[®] (Epic Systems Corporation, Verona, Wisconsin, USA).

3.2.1 University of Iowa Health Care System

This academic center has over 1,000 beds (190 pediatric, 860 adult) in a geographic footprint of 17 acres. In fiscal year 2020, UIHC had 50,468 emergency room visits, received just under 1100 patients by air transport, and had 32,872 acute inpatient admissions. UIHC has more than 200 outpatient clinics which coordinated over one-million outpatient clinic visits, 550 organ transplants, 32,000 major surgeries, and 150,000 minor/routine surgical procedures. UIHC employs over 1800 physicians and dentists, 3200 nurses, 3200 allied health staff, and 3100 non-patient care professionals. The UIHC is also supported by a tremendous volunteer staff, which provides more than 82,000 hours – roughly 225 volunteer hours daily.

3.2.2 The Department of Radiation Oncology

Located in the Center of Excellence in Image Guided Radiation Therapy, a facility of over 40,000 ft², the department has cutting edge technology including three Versa linear accelerators, a Gamma-Knife, and one of only three MRI-guided linear accelerators within the United States. The department has multiple national accreditations and is known for treating difficult cases that other radiation oncology centers cannot. Staffing includes nine radiation oncologists, four outreach radiation oncologists, one nurse practitioner, seven radiation oncology residents, 14 licensed medical physicists, three medical physics residents, eight clinical nurses, four research nurses, fifteen radiation therapists, six dosimetrists, and five front desk staff responsible for scheduling and check-in. Radiation Oncology utilizes Epic[®] EHR but the radiation planning, prescription, and delivery systems utilizes a second EHR system, MOSAIQ[®] (Elekta Solutions AB, Stockholm, Sweden). The system enables notes to be placed by staff about the patient or their radiation treatment.

On average, the department treats approximately 20 new patients per month for lung cancer. The department has two radiation oncologists who specialize in lung cancer; each radiation oncologist has a unique day of the week designated for their OTVs. The clinic treats an average of 90 to 100 patients per day with a radiation oncologist seeing 15 to 20 patients during their scheduled on-treatment clinic day.

3.2.3 Workflow for Patients with Lung Cancer Prescribed Long Course Radiation

Patients with lung cancer typically undergo a scheduled consultation with their treating radiation oncologist. At this consult, acute and chronic side effects of radiation therapy are discussed as is the expected treatment outcome (e.g., cure, prolongation of life, palliation). The patient then returns for a scheduled *simulation* visit, in which the patient is positioned on a computed tomography (CT) scanner as they will be for their daily radiation treatment. The treatment plan is then created from this CT scan, taking approximately 5 to 7 business days to complete dependent upon the plan's complexity. The patient then returns for *verification*, a practice run of their radiation treatment. Typically, radiation begins the next business day. For patients with lung cancer undergoing definitive treatment, a typical fractionated radiation regimen is 30 to 34 fractions with one fraction administered per business day. This long course of radiation for patients being treated for lung cancer will involve approximately 7 OTVs and one end-of-treatment visit (i.e., *fini*).

Standard of care for these patients requires concomitant or consecutive cytotoxic chemotherapy. Chemotherapy is prescribed and managed by the Division of Medical Oncology, located directly above the radiation oncology center. Chemotherapy is administered in the infusion center, located two floors directly above the radiation

oncology center. Of note, at UIHC radiation oncologists do not have hospital privileges to admit patients. Thus, patients requiring inpatient medical management must be referred to the medical oncology clinic or directly to the emergency room for consideration of hospital admission.

3.2.4 The State of Iowa's COVID-19 Center

Unfortunately, in 2020 the workflow at the academic center shifted dramatically, as the UIHC and the UICH were designated as the State of Iowa's COVID-19 center. As such, protocols were put into place in early March to accept the first case of SARS-CoV-2 (COVID-19) and develop an in-house diagnostic test to address the shortage. The academic center housed more than 1860 adult inpatients and 116 pediatric; 575 of these patients were transferred in from other hospitals. As the designated center, UIHC provided 87,195 telehealth screenings and over 112,000 respiratory illness clinic visits. To prevent community spread, as well as accommodate the increasing demand for beds and medically licensed personnel, everything within the University of Iowa Health Care system was dramatically altered.

3.3 Research Adaptation due to the SARS-CoV-2 Pandemic

The pandemic irrevocably altered the study as designed by making it impossible to obtain three key sources of information to address the research questions: audio recordings of on-treatment visits between the radiation oncologist and the patient, non-participant observation of the clinic's workroom, and SDM-Q-9/SDM-Q-DOC questionnaires. Brief information is provided to acknowledge they were considered and had to be omitted from the study. Further details regarding the impact of the pandemic on this study is provided in Appendix A.

3.3.1 Audio Recordings

The study sought and obtained permission from the UIHC's legal department to allow on-treatment visits to be recorded in secret. Ethics approval from the IRB was also obtained and patients provided written consent to have a recording completed during the fourth, fifth, sixth, or seventh OTV. The treating radiation oncologists provided verbal consent to have the OTV recorded and were the individuals who obtained consent from the patients. Neither the patient nor the radiation oncologist were aware of when the recording was completed as the recorder was hidden in the examination room or by attending staff. Recordings were to be obtained prior to the collaborative decision-aid tool was implemented and then post-implementation. These recordings could serve as a golden truth to evaluate shared decision making, if the collaborative decision-aid instrument was being used as intended (i.e. fidelity), and how it could be improved. The audio recordings were to be transcribed verbatim, coded inductively, and compared (pre-implementation vs. post-implementation). The rich detail the recordings were anticipated to have provided was significant. Due to the concern for fomite transmission of the SARS-CoV-2 virus, no extraneous items were allowed within the examination room (including the recorder) and this potential source data was terminated.

3.3.2 Non-Participant Observation

Academic training of radiation oncology residents employs an apprenticeship model with milestone requirements for each of the four years of their specialized training. A critical portion of the training is 'giving report,' wherein the resident provides the information obtained from their interview with the patient as well as their findings of a preliminary exam before the attending physician examines the patient. The attending

radiation oncologist and their clinic nurse will correct, query, and address oversights in the communal workroom before all three go into the exam room and then finish the training post-exam in the same workroom. This process was identified as a possibly causing communication confusion but most significantly identifying how experienced radiation oncologists train new physicians in observations and communications with patients. To capture this information, four sessions of 4-hour non-participant observation of the communal workroom was planned prior to implementation and after implementation. Non-clinical personnel were banned from clinic through June 2020 and remain discouraged from remaining in clinical areas for prolonged periods of time. Residents gave reports by phone or by using computer conferencing (e.g., Zoom, Skype). The communal workroom was identified as a problem for SARS-CoV-2 transmission and, for this reason, its use has changed and continues to change as the pandemic waxes and wanes. For this reason, the non-participant observation of the communal workroom has been removed from the research strategy.

3.3.3 SDM-Q-9 and SDMC-Q-DOC

The key data to be captured were from questionnaires completed by the patient-participant (SDM-Q-9) and by the radiation oncologist (SDM-Q-DOC) were to be obtained prior to implementation (as the baseline data) and post-implementation (investigational data). Comparing the answers in a pre/post fashion would provide information about the communication aid's impact within the radiation oncology clinic. Both questionnaires are five-point Likert-styled scales requiring a balance of nonparametric and parametric review. Nonparametric procedures (e.g. median, range, frequency) were to be used to describe the scores of the pilot study participants, the

historical controls, and the treating radiation oncologists (both historical and pilot phases). An independent t-test was to be used to evaluate significance. It was recognized there was debate regarding use of a parametric test for Likert-scaled data, but publications indicated this testing was the most robust to assess these data (Norman, 2010; Sullivan & Artino, 2013). These data would be assessed using a student's t-test to determine the statistical difference (if any). The questionnaire results would also be compared to the qualitative data obtained from the OTV recordings. In attempts to reduce community spread of SARS-CoV-2 and reduce risk to UIHC staff, paper and writing implements were removed from the clinic and it was emphasized passing of documents between patient/provider should not occur with the exception of obtaining written consent. These prohibitions remain in place and the questionnaires discontinued.

3.3.4 Communication Patterns

An incidental impact was the shift in communication patterns. Prior to SARS-CoV-2, numerous caregivers, family, and friends were allowed to be in attendance during the on-treatment visit. Given large farm families, it was not uncommon to have 4 or more individuals in a small exam room to discuss the current therapy. These third parties provided additional information as well as an additional lens the radiation oncologists had utilized as an information source for their practice. To date, caregivers have not been allowed to return to the radiation oncology clinic unless there is clear medical need. The radiation oncologists have noted this has changed their communication strategy, causing them to query further to try to obtain the information necessary at the visit. The difference between the baseline communication recordings (caregivers, family) and the peri/post-

pandemic recordings (no third parties in attendance) causes an irrevocable shift for comparison purposes to assess shared decision making.

3.3.5 Amended Design

The overarching hypothesis (i.e., a decision aid designed to increase collaborative communication between radiation oncologists and patients will result in improved shared decision making, yielding better medical management and patient outcomes and reducing emergent care costs) and aims (i.e., create a collaborative decision-aid tool, implement it, and assess its impact) remain unchanged. Triangulation was only minimally impacted, as the original research design did not rely on the audio recordings of the OTV as assessments of SDM because it was a legal issue with the UIHC. Based on prior requests, it was suspected the UIHC legal department would decline and one of the treating thoracic radiation oncologists also objected. Data for triangulation were the comprehensive literature review, contemporaneous review of new recommendations regarding PROMs (e.g., new peer-reviewed literature, guidance from FDA regarding PROM, webinars from oversight / regulatory authorities regarding PROM), patient interviews, radiation oncologist interviews, and review of medical record notes to compared to the interview and provide additional detail. Thus, the quantitative strand—although altered—was still considered to have appropriate design to obtain the patients’ and providers’ insights regarding the collaborative decision-aid tool and its implementation as well as providing data for triangulation for the qualitative strand.

Because the SDM-Q-9/SDM-Q-DOC could not be obtained, the quantitative strand had to be amended slightly. These data were to address, in part, the quantitative research question *What is the impact of the collaborative decision-aid on the medical*

management of patients actively undergoing radiation treatment for lung cancer?

Although quantitative measures of SDM had been selected for this strand, it was only one measure of many that could be used to address the question. In addition to improved quality-of-life (Absolom et al., 2021; Grewal & Berman, 2019), research indicates improved healthcare resource utilization – particularly emergency room visits (Barbera et al., 2015; Basch, Deal, et al., 2017; Geerse et al., 2018; Howell et al., 2020). Although a systematic review suggests variability in results of PROM-based interventions (Kotronoulas et al., 2014), work by Howell et al. (2020) suggests this is due to implementation and not the intervention. This is supported by the findings of a scoping review, which identified the most efficacious PROM and SDM interventions as those which involved active communication and not passive interpretation (Kirkland et al., 2020; Kotronoulas et al., 2014) In 2016, Basch and colleagues published the results of a randomized clinical trial which demonstrated the use of PROM decreased emergency room visits and hospitalizations and improved both chemotherapy compliance and survival (Basch, Deal, et al., 2016). Data as cited by Basch et al. (2016) (i.e., ER visits, inpatient admission, and chemotherapy compliance) are easily obtained from Epic® EHR and can be compared to the pre-implementation metrics. Estimated healthcare expenditures for these visits can also be evaluated as can unplanned visits to oncologic outpatient clinics.

The final issue was the unpredictable impact of the pandemic on the approval and continuance of non-essential human subjects research studies. With research procedures in continual flux based on the spread of the virus and the need for personnel, there was significant concern the quantitative strand would not be approved, enrollment would be

halted, or study procedures limited. It was during this time it was noted the literature reported implementation of PROMs within oncology utilizing a clinical trial / research study strategy. This increases internal validity but diminishes external validity and the likelihood of fidelity during implementation. In contrast, if implemented through the clinic using the PDSA cycle, a research team would not manage the workflow, thereby not pre-emptively solving problems or omitting clinical pathways for research-only pathways. Clinical-only implementation would be pragmatic and provide insights into implementation within a clinic separate from research management. This would, in part, address a knowledge gap in the literature regarding PROM implementation in an academic radiation oncology clinic. Additional advantages of a clinical implementation include all patients within the designated clinic would have the decision-aid applied, and it would be clinical and—as such—not subject to research shutdowns. The departmental chair agreed to implement the collaborative decision-aid tool clinically. The project was then submitted to the University of Iowa IRB for human subjects research determination, which concluded the clinical implementation, did not meet the definition of human subjects research (Appendix B). The model selected for the clinical implementation project was Plan-Do-Study-Act (PDSA) as it has been used with prior success with the OMRU when examining SDM interventions (Graham et al., 2006; Gravel et al., 2006; Langley et al., 2009; Legare et al., 2006; Legare et al., 2008; Legare & Thompson-Leduc, 2014; Reed & Card, 2016; Straus et al., 2013). The qualitative strand addressed *PLAN*, and the quantitative strand addressed *DO* and *STUDY*.

3.4 Qualitative Strand

The objective of the qualitative research strand was to understand how patients and radiation oncologists described the design and implementation of a collaborative decision-aid tool regarding symptoms of lung cancer and side effects of the treatment. A case-study strategy was utilized to explore the phenomenon of side-effects, symptoms, treatment goals, and communication between provider and patients who had either undergone radiation therapy for lung cancer or were finishing their treatment course (Creswell, 2013). The end-products (e.g., key design principles, tool presentation, understanding workflow concerns, barriers and facilitators) were then used to design the collaborative decision-aid tool that was evaluated in the quantitative strand.

The Ottawa Model for Research Use (OMRU) framework provided essential elements to translate research into meaningful clinical use, key for PROM that have failed to cross the T3 chasm (Drolet & Lorenzi, 2011; Graham & Logan, 2004). Contextual elements to be considered in the qualitative strand include attitudes, knowledge, skill, culture, clinic workflow, and facility resources (i.e., documents and storage in the electronic health record). These should be evaluated as both barriers and facilitators to future adoption. The Shared Decision Making Model (Chapter 1, Figure 4 & Chapter 3, Figure 12) also informed this qualitative inquiry. Specifically, the SDM framework graphically depicts the flow of information between provider and patient, transitioning the decision-making process from initial preferences to informed management (Chapter 1, Figure 4 & Chapter 3, Figure 12). It provided insight for communication, discussion, and decision strategies for management of radiation

oncology treatment. Participant interviews and the OTV notes within the medical record were identified as key sources to identify SDM elements.

In addition to insights regarding communication and SDM, the qualitative strand also informed implementation. The first stage of implementation science as described by Bertram et al. (2015) NIRN framework *Stages of Implementation* is *Exploration*. This focused on assessing the community, resources, and needs, evaluating and aligning to desired outcomes and identifying potential barriers to fidelity and sustainability. The PLAN portion of the PDSA cycle was addressed by the NIRN *Exploration* stage by establishing an evidence-base, identifying stakeholder's goals and concerns, and identifying practice considerations (Langley et al., 2009; Reed & Card, 2016; Snyder et al., 2012). The qualitative strand assessed readiness for change at the individual and provider level, identified potential adjustments to support fidelity and sustainability of the program, and provided insight to the appropriateness and potential benefits of the collaborative decision-aid tool (Graham & Logan, 2004). A key consideration for readiness for change also included the adaptability of Epic[®] EHR, the culture surrounding its use, and the clinic's workflow.

The original rationale for targeting Epic[®], the center's EHR, was three-fold: enable radiation oncologists to import the responses into their notes without issue, provide the measures in an easy-to-find format for all healthcare providers, and to create a bank of PROM to further inform the patient experience during clinical research or chart reviews. With the advent of the pandemic, the choice of utilizing the EHR was of even more significance as providing paper was removed from the clinic.

Assessing multiple sources of information (i.e., interviews, EHR, literature) aligned with the case study approach for qualitative inquiry (Creswell, 2013). This approach examines "...a real-life, contemporary bounded system...through detailed, in-depth data collection involving multiple sources of information..." (p. 97, Creswell, 2013). For this study, the unit of analysis was the provider-patient relationship of those patients who have undergone radiation therapy for lung cancer.

3.4.1 Research Question

The central question *How do the stakeholders, practice considerations, and evidence base inform the ideal design and implementation of a collaborative decision-aid tool?* guided the interview, analysis, and tool development. This question served as the anchor to guide and focus the research for the qualitative strand.

3.4.2 Sample Size

Sample size for data collection in qualitative research is dependent upon the richness of the data, the depth and breadth of information sought, and the available time and resources (Patton, 2015). This qualitative strand focused on depth of the interactions between patients with lung cancer and their treating radiation oncologist. The case study was tightly bounded to the interactions in the radiation oncology clinic regarding treatment. The study explored communication patterns, side effects and symptoms, and goals of therapy as well as facets of SDM (e.g., perceptions, barriers, facilitators), so the openness of the inquiry was slightly constrained. Thus, the design is a middle-ground between depth and breadth, reserving time and resources to explore design possibilities for the collaborative aid tool (Patton, 2015). Based on this, the anticipated sample size for the patients treated for lung cancer was between 6 and 30 participants with final sample

size determined by data saturation. The provider sample size was constrained by the number of radiation oncologists at the academic site (n=7).

3.4.3 Participant Selection, Recruitment, and Sampling Strategy

This case study focused on the communication relationship between the radiation oncologist (i.e., provider) and the patient who is receiving, or has received, radiation and chemotherapy for the treatment of lung cancer. The goal was to obtain new knowledge about SDM to create a collaborative decision-aid for patients with lung cancer. Thus, there were two participant pools to consider in study design.

3.4.3.1 Patients

The potential participant pool consisted of adult patients who were in their last few weeks, or had recently completed, chemotherapy in combination with fractionated radiation therapy at UIHC for a diagnosis of lung cancer. A purposeful sampling technique was employed, focusing on typical cases representing patients referred for standard chemotherapy and radiation (Patton, 2015). Selection criteria excluded atypical presentations not representing the general lung cancer population. Medical oncologists were consulted to create eligibility criteria to identify patients representing real-world patients with lung cancer. Utilizing medical oncologists for the selection process minimized the risk of a confounding bias from querying the treating radiation oncologists regarding the patients to approach. The treating radiation oncologists required they review the appropriateness of each potential participant. If the radiation oncologist agreed with enrolling the patient on the study, they approached the patient and, if the patient agreed, obtained consent. A signed copy of the informed consent document was provided to the patient. Patients who appeared to meet eligibility in chart review, but were not

deemed appropriate by the treating radiation oncologist, were either too ill/infirm or unable to provide consent.

3.4.3.2 Providers

During the time of the study, UIHC employed seven radiation oncologists as faculty at the Iowa City clinic. Of these, two had dedicated lung cancer clinics and the remaining radiation oncologists provided coverage for patients with lung cancer. This creates a nested hierarchy of informants based on not only how many patients they treated for lung cancer but if the radiation oncologist had to provide clinic or on call coverage for an unfamiliar patient base. The radiation oncologists with dedicated lung cancer clinics were key informants; it was anticipated these providers were the richest source of information and experience. Both of these radiation oncologists were interviewed. Radiation oncologists who provided only coverage services to patients undergoing radiation for lung cancer were considered tertiary. Of the remaining five radiation oncologists, four agreed to participate in the interviews. They were interviewed in two groups of two group and represented radiation oncologists who could be, or had been, scheduled *ad hoc* to see patients with lung cancer. These radiation oncologists were considered to have important information about managing communication and SDM when covering for a treating radiation oncologist who was out of the office.

Collaborating oncologic specialists, such as surgical oncologists, medical oncologists, and nurse practitioners, were not included in this study. The study's primary focus was on the shared decision-making of the *treating* radiation oncologist, the *covering* radiation oncologist, and the *patient* undergoing radiation therapy for treatment of lung cancer. Nurse clinicians are currently not authorized to independently staff the

OTV at the University of Iowa. Medical and surgical oncologists are separate disciplines and do not contribute to the discrete shared decision-making during the radiation oncology OTV. The influence of these disciplines will be explored in later studies.

3.4.4 Interviewing Protocols

Within the United States, a radiation oncologist's board certification is the foundation for all therapeutic radiation interventions (e.g., cancer, nerve pain, heterotopic ossification). A radiation oncologist may further subspecialize for specific cancers (i.e. lung cancer). Those subspecializing are more familiar with current techniques, concurrent therapies, and common sequelae. Those subspecializing in other malignancies (e.g., brain, head & neck, prostate) do not have the same recall as those specializing in lung cancer. Given the potential for varied knowledge bases, four separate interviewing protocols were developed: one for patient participants (Appendix C), a second for radiation oncologists specializing in lung cancer (Appendix D), and the third for the covering radiation oncologists (Appendix E). A fourth interviewing protocol was developed for radiation oncologists who did not specialize in lung cancer but who served as the treating radiation oncologist for a patient with lung cancer (Appendix F). This situation was not identified by the study (i.e., all patients with lung cancer were treated by radiation oncologists specializing in lung cancer) and thus the interview protocol was not used. An interviewer's journal was maintained for reflection, comments, and considerations during the interviewing phase to provide context and clarity to the interviews.

3.4.4.1 Patient participants

Interviews were scheduled in one-hour time slots at the participant's preference and conducted in a private examination room within the radiation oncologic clinic during routine business hours for the clinic (Monday–Friday, 7 a.m. through 5 p.m.). All interviews were audio-recorded.

A social constructionist interview strategy was employed with semi-structured questions to prompt for previously-identified key topics (Patton, 2015). The social constructionist inquiry method was selected to enable the dexterity and flexibility needed to shift from what a participant knew about a particular topic but to create knowledge through active dialogue (Patton, 2015). Using a constructionist strategy, it was expected the interview questions would evolve over time, to further investigate knowledge created by previous patient participants.

Questions were open-ended and probative to discuss the patient's initial goals for treatment, if the goals changed over time, explore the patient's initial concerns regarding therapy and if those concerns changed over time. Sample questions pulled from PROM validated item banks (e.g., PRO-CTCAE, PROMIS) were reviewed with patients during the interviews to explore not only how easily the items are understood but also how well they fit the side-effect, symptom, or therapeutic goal. Patient were also queried regarding communication with their treating radiation oncologist and—if appropriate—a covering oncologist who covered an OTV. Communication preferences, barriers to communication, and hindsight considerations (i.e., what they wish they would have known) were also examined. Questions also investigated the participant's perception of SDM per their recollection. Patient interviews were extended or shortened depending

upon the dynamic between the researcher and participant; similarly, if clarification was sought, patient participants were asked if they could be contacted again. The reason for a second interview would be documented in the participant's casebook. Sample questions for patient participants are provided (Appendix C).

3.4.4.2 Radiation Oncologists Specializing in Lung Cancer

Interviews with radiation oncologists who specialized in lung cancer (i.e. treating radiation oncologists) were scheduled as their calendars allowed. Interviews were held in a small conference room or in a physician's office to respect privacy and confidentiality for the provider. Interviews were scheduled for between 30 to 60 minutes and were audio-recorded. Unlike patient participant interviews, the interview strategy employed with the treating radiation oncologist was pragmatic, with straightforward questions about issues identified from literature, patient participants, or observation (Patton, 2015). This was considered a best-fit approach to focus on solutions for radiation oncologists, address problems, and be considerate of time and resources while still yielding practical insight. Inquiry focused on the provider's identified toxicity management and treatment goals as well as barriers and concerns to tool design, implementation, and use. Semi-structured interview questions evolved from the patient-participant interview data. In addition, the treating radiation oncologists clarified questions about the patient participants' treatment, adverse events, or workflow/clinical questions arising from the interviews. It was anticipated interviews with treating radiation oncologists would be iterative, with multiple interviews per physician. Lines of inquiry differed between radiation oncologists focusing on lung cancer from the other treating radiation oncologists. This was to obtain knowledge regarding how other radiation oncologists

identified with patients who have lung cancer, if there was a difference between treating patients with lung cancer compared to their standard clinic, and if they perceived barriers or facilitators unique to patients undergoing treatment for lung cancer. This was a perspective radiation oncologists dedicated to lung cancer treatment may not provide. Sample questions are provided for radiation oncologists specializing in lung cancer (Appendix D).

3.4.4.3 Radiation Oncologists Providing *Ad Hoc* Coverage

Covering radiation oncologists are those who do not specialize in lung cancer but who could provide intermittent care for patients with lung cancer by covering absences of the treating radiation oncologist. These radiation oncologists provide on-demand services for patients not directly under their care or within their routine clinical focus. As such, their perspective provided a different lens regarding prioritization of treatment goals, time spent in clinic for each OTV, and interaction with the patient. Here, it is not only interesting to understand the dynamic processes between providers when providing coverage but to provide the opportunity to provide feedback to each other to create additional buy-in to tool design. This interview thus served two purposes: (1) to obtain information and (2) to reduce barriers from a stakeholder that has a reduced likelihood of investment. Four radiation oncologists consented to participate in this portion; interviews were completed as two groups of two. Sample questions unique to this group are provided in Appendix E.

3.4.4.4 Radiation Oncologists (All)

Interview questions common for all radiation oncologists (i.e., regardless of treatment specialty) focused on what information was important regarding patients

undergoing radiation for lung cancer, how that information should be presented, and the common workflow for routine on-treatment visits as well as when addressing coverage.

Radiation oncologists were provided sample questions to review regarding symptoms of fatigue and dyspnea. These two subjective symptoms were selected because they are two of the most common during radiation therapy for lung cancer (Defraene et al., 2019; Vokes et al., 2007). Questions were pulled from the PRO-CTCAE™, PROMIS®, and the QLQ-C30 (Chapter 1, Figure 3; Chapter 4, Figure 15). These sources were selected as they are commonly used in healthcare research and utilized during FDA's conference on patient reported outcome measures in oncology (FDA, 2018). Radiation oncologists were asked to review the questions, provide feedback, and mark their preferred question format.

3.4.5 Implementation: the PDSA's PLAN Segment

The tool was to be introduced to the clinic utilizing a real-world approach, with minimal intervention from the researcher. The PDSA model was selected to guide implementation as it has been used with prior success with the OMRU (Graham et al., 2006; Gravel et al., 2006; Langley et al., 2009; Legare et al., 2006; Legare et al., 2008; Legare & Thompson-Leduc, 2014; Reed & Card, 2016; Straus et al., 2013). An additional benefit to the iterative nature of the PDSA model was it enabled implementation slowly in parts, expanding over time to address long-term goals. This enabled the first implementation cycle to focus on key areas identified by the stakeholders.

The initial key stakeholders were identified as the radiation oncology clinical administrator (overseeing the entirety of the clinic, compliance, and front desk/scheduling) and the two treating thoracic radiation oncologists. After the first meeting, an additional

stakeholder was identified: the chief radiation therapist, who controlled the lynchpin communication of the radiation therapists informing the front desk how to schedule a patient—including assigning the questionnaire for each OTV. A focal point in the meetings with stakeholders was the patients' request for a paper collaborative decision-aid and the radiation oncologists' request for electronic entry into the EHR. Due to the pandemic, collection of PROM using a pen and paper task was not considered as the transfer of paper through multiple hands increased risk of fomite transmission as did pens. Meetings with the stakeholders identified on four points for implementation cycle 1: *who* would distribute the tablet, *how* would that staff know to distribute the tablet, *how* would the responses be reviewed by the treating radiation oncologist, and *how* would the responses be printed for the radiation oncologist to share with the patient. With an initial workflow designed, the second check in was scheduled after the first patients completed the tool questionnaire from baseline through the last day of radiation.

Implementation facilitators and barriers were documented through email communication with the key stakeholders as well as through journaling in field notes. Simplistic implementation mapping was completed employing a program theory logic model (*if/then*) to identify the next steps as well as who was responsible, when it needed to occur, how it would occur, and where (Funnell & Rogers, 2011). The purposeful outcome chain would identify at what steps in the workflow the barriers and facilitators were occurring while the taxonomy of barriers and facilitators as provided by Legare et al. (2006, 2008) provided harmonized terminology and definitions. Attention was paid to the work from Reed and Card (2016) who outlined pitfalls when using the PDSA for implementation, with attention to utilizing program theory, adhering to the original data

collection and analysis plan but also adapting to newly identified data of interest, planning for the ‘who, what, where, when, and how,’ for the implementation, and considering what will happen if there is failure in the logic chain steps (p. 149).

3.4.5.1 Data Collection and Analysis

In addition to interviews, additional data sources included the existing literature, newly published contemporaneous literature, regulatory/oversight guidance documents and webinars regarding PROM and SDM, and the electronic health record (Epic® EHR, Verona, Wisconsin).

The first strategy employed for the qualitative strand was a brief literature review to identify known barriers and facilitators and considerations for current PROM instruments. After this literature was reviewed, a set of sample questions were developed for fatigue and dyspnea as was a mock-up of treatments *vs.* outcomes (i.e., side-effects and disease response). Patient-participant interviews began and then, after those interviews started, the radiation oncologist interviews were started to help inform the patient interviews. Upon conclusion of the interviews, the next step was to meet with the Epic® EHR specialists for installing the questionnaire into Epic®. Once the translation of the collaborative decision-aid tool into Epic® EHR was agreed upon, stakeholders again extended to members of the Department of Radiation Oncology to finalize the implementation plan as well as format of the printed tool. A summary of each step undertaken in the qualitative strand is provided (Table 1, p.48) as well as the products of each step and how they were used in both planning the collaborative decision aid and the *PLAN* segment of the PDSA implementation cycle.

Table 2

Order of Procedure in the Qualitative Strand, the Source Data Obtained from that Procedure, and Its Utilization in the Design of the Collaborative Decision Aid and Implementation PLAN Segment of the PDSA

Step: Data Source¹	Utilization²
<p>First: Literature review</p> <p><i>Literature review provided foundation of current PROM instruments and medium (design) as well as barriers, facilitators, and implementation outcomes (planning). The source is the iterative synthesis over time, archived in MS Word documents as well as the sample PROM questionnaire.</i></p>	<p>Secondary data</p>
<p>Next: Patient interviews²</p> <p><i>Patient interviews yielded transcripts that were then coded and mapped analytically for information on both design and implementation. Source data are archived audio recordings, transcripts, codes, and analytic maps.</i></p>	<p>Primary data</p>
<p>Next & concurrent: Physician interviews</p> <p><i>Physician interviews yielded transcripts that reviewed for key concepts and mined for illustrative quotes. Source data are archived audio recordings and transcripts.</i></p>	<p>Primary data</p>
<p>Last: Stakeholder meetings</p> <p><i>Stakeholder meetings provided information on installing the tool in Epic[®] format, identified key areas of focus/concern for the first implementation cycle, and created a walkthrough. Source data are artifact electronic communication.</i></p>	<p>Secondary data</p>

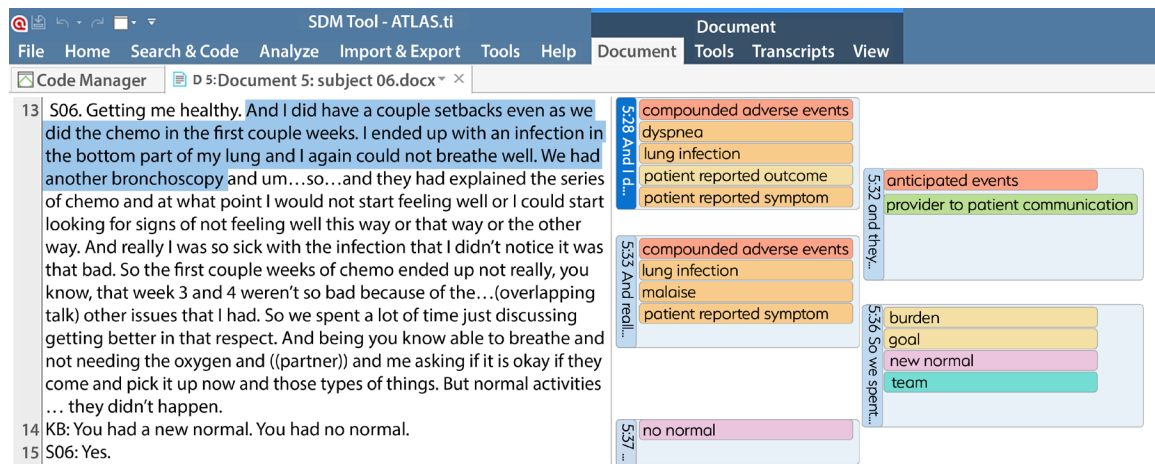
¹ Source data will be archived in compliance with HIPAA and retained for a minimum of six years after closure of the IRB application.

² Utilization refers to the data use for both the decision aid tool design and PLAN segment of PDSA

3.4.5.2 Interviews and the Analysis

Interviews were performed by the student researcher to minimize interview-to-interview variation. This was feasible due to the convenience scheduling of the patient participants and immediate access to the provider participants. Provider interviews began after the first few patient participant interviews were completed. Interviews with a radiation oncologist specializing in lung cancer were completed first (Appendix D). The remaining four radiation oncologists, who provided coverage services for the thoracic radiation oncologists, were interviewed after patient participants (Appendix E). The paired interview setting was selected for the radiation oncologists who provided only covering services for OTV so that their viewpoints were discussed as a group, providing a consensus as to their thoughts, opinions, and considerations for a collaborative decision-aid tool use in a clinic they only cover and do not routinely staff. All interviews were audio recorded and transcribed verbatim.

All interview transcripts were analyzed using a qualitative inductive approach to generate new concepts regarding communication of goals, priorities, and treatment burden (Creswell, 2012; Patton, 2015; Thomas, 2006). An inductive analytic approach identifies patterns, themes, and categories in the data using an open coding strategy. The first step is to prepare the files in a common format for visual consistency and then review the transcripts in their entirety to obtain a generalized understanding of the content (Creswell, 2012; Creswell & Plano Clark, 2011; Thomas, 2006). At the end of the review, the evaluator should be familiar with the text and context, already gaining insight into themes and their descriptions present in the transcript (Thomas, 2006).

Figure 13*Example of the First Level Open Coding Strategy Used*

Note. An inductive open-coding strategy was applied to patient interview transcripts. These first-level codes were designed to be granular and directly based on subject information (i.e., burden, no normal) or used as an index to sort easily through the rich detail provided in the text (i.e., patient reported outcome, anticipated events).

After this initial review, an open-coding process was used to create labels and call-out patterns (Figure 13) (Creswell & Plano Clark, 2011; Saldaña, 2016; Thomas, 2006). Consistent with inductive coding, a pre-defined codebook was not employed, instead codes and categories emerged from the transcripts (Creswell, 2012; Saldaña, 2016; Thomas, 2006). The data coding process divided the text into smaller granular details (i.e., first level codes) but also enabled tagging sentences or sections for quotations and/or future review (indexing) (Creswell & Plano Clark, 2011). The ATLAS.ti qualitative data analysis software (Scientific Software Development GmbH, Berlin, Germany) was used to facilitate this process by enabling code organization as well as maintaining a coding framework (Saldaña, 2016). The resultant codes were then grouped together to further identify patterns or commonality across interviews (Figure 14). The number of times the code was used across the study's documents (i.e.,

Figure 14

Group View with Detail in ATLAS.ti

Name	Grounded	Density	Groups
familiarity with provider~	4	9	[1 Facets Increasing Security and Reassur
frustrated~	1	4	[1 Frustrations Voiced by Patients] [2 Factor
isolation~	5	8	[1 Frustrations Voiced by Patients] [1 Stress
medicine by committee~	7	18	[1 Experience of Diagnosis & Prognosis] [1
multiple providers~	8	12	[1 Experience of Diagnosis & Prognosis] [1
patient repeated communication~	2	3	[1 Frustrations Voiced by Patients] [2 Factor
repeated efforts to contact~	2	6	[1 Frustrations Voiced by Patients] [2 Factor

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Negative connotation regarding the use of multiple providers in providing a single treatment

Note. Screenshot of the qualitative analysis depicting organization capabilities and framework within ATLAS.ti. **(A)** user created second-level groups (red box: code groups), **(B)** the frequency of the code's use (orange box: grounded) and **(C)** the number of linkages to codes, memos, and quotations (green box: density), and **(D)** an area for defining the code and making notations (purple box: comment)

grounding) and the number of times the code was linked to another code, memo, or quotation (i.e., density) is displayed within the group view, enabling an easy assessment of the code's frequency of use (Figure 14). Despite this framework, the interrelationships remained elusive and not apparent to this researcher. For this reason, ATLAS.ti's network analysis (i.e. concept mapping) was utilized to explore the relationships between the codes graphically (Daley, 2004; Pokorny et al., 2018). Similar to mind-mapping, concept-mapping can be used for sense-making of complex systems by placing codes and assigning relationships between them (Conceição et al., 2017; Daley, 2004; Friese, 2020; Kinchin et al., 2010; Pokorny et al., 2018). The ATLAS.ti software serves as a whiteboard, enabling codes to be moved, grouped, and colored to explore how the codes and their quotations are interrelated—similar to piecing together a jigsaw puzzle. This enables the researcher to reflect on the reduced data (i.e. codes), review memos and

interview transcripts for relationships, and explore interconnectedness across subjects. It is this deep dive and its journey that reveal the story (i.e. themes) the data are telling.

An initial concept mapping was performed consistent with prior literature as an explorative technique (Conceição et al., 2017; Kinchin et al., 2010; Pokorny et al., 2018). Concept mapping has multiple forms, including link, chain, network, weighted, and directional (Daley, 2004; Friese, 2020; Kinchin et al., 2010; Pokorny et al., 2018). The initial concept map used the network strategy, identified by Kinchin et al. (2010) as scholarly maps which have linkages that are “often rich and complex showing deep understanding” (p.55). A relational analysis was selected *in lieu* of software-based cluster or weighted analysis (Conceição et al., 2017; Pokorny et al., 2018). The rationale for relational analysis included the small sample size (n=6), the exploratory nature of the research, and the study design, as cluster and weighted analysis are often utilized with grounded theory approaches (Conceição et al., 2017; Kinchin et al., 2010; Pokorny et al., 2018).

This initial ‘test’ analysis resulted in the *Communication* upper level category, a central, downstream concept category created through the relationships of four direct codes and eight categories (Appendix G). This upper level category graphically represented the keystone of the overarching theme, “The shared decision-making tool could address the patient-identified communication barriers of having to repeat information across multiple providers as well as reduce the feeling of isolation while undergoing radiation therapy.”

This graphical method of analysis proved to be a breakthrough and provided the key insights needed for the qualitative string; thus, this method was utilized. The

hierarchy and levels of analysis began with the first level coding (i.e., data reduction), followed by a downstream grouping into *categories* by concept mapping and ultimately ending in a concept category (i.e. *node*). These categories are the upper level, centralized concept categories that represent foundation within the ATLAS.ti software for thematic consideration (Conceição et al., 2017; Pokorny et al., 2018).

Relationships between the codes were defined by the patient participants (by reviewing the transcripts) rather than presumptions from the researchers. These relationships were important in identifying categories, both first level categories and second level categories (i.e., conceptual categories, termed ‘nodes’ by ATLAS.ti). After creating these analytic maps, relationships were further described through analytic memos with example quotations as well as the defined codebooks. The analysis was done in a stepwise fashion, with a single conceptual category being identified through mapping, drafting the supporting information and rationale, and submission to senior researchers. Further analysis was not performed until review and discussion between the research team members. The research team was careful to identify participant defined relationships between emergent data and logically / assumptively driven relationships from the team. Resultant codes, categories, and themes were reviewed by an independent committee to provide guidance as well as confirm codes and themes.

Transcripts were analyzed contemporaneously to inform subsequent patient participant interviews as well as provider interviews. Data were collected from patient participants until saturation was reached. Transcripts from the radiation oncologists underwent the same inductive analysis and compared to patient participant themes. Resultant themes were used to inform the design of the collaborative decision-aid tool.

3.4.5.3 Data Collection *via* Electronic Health Record.

The OTV notes of the patient participants were downloaded, stripped of all identifiers (i.e., de-identified), and loaded into the ATLAS.ti program for thematic analysis. Dates of visit were retained. Information of interest was the length of the note, if a resident was involved, the signature date of the note (if it is contemporaneous with the visit), the number of adverse events, and any prescribed interventions. This provided insight into the provider-patient dynamic during the OTV as well as serve as baseline information for the quantitative phase of the study.

3.4.6 Anticipated Outcomes

The format of the collaborative decision-aid tool was informed on the themes identified from the radiation oncologists' and patients' interviews. Based on the literature review, it was anticipated the tool would be a hybrid presentation of both numeric data and graphical trends over time, most likely a line graph. Similarly, the patients' interviews would provide insight as to what areas to query for prioritization and how many questions are preferred. For example, patients with lung cancer could choose to focus on symptoms of their cancer (e.g., pain, dyspnea), acute side effects of their therapy (e.g., esophagitis, dysphagia), or chronic side effects of therapy (e.g., numbness, dyspnea, fibrosis) and balance these choices against the aggressiveness of therapy. Qualitative data provided insight to prioritization and patients' considerations of symptoms, side effects, and treatment outcomes.

It was anticipated that two templates would be created for the collaborative decision-aid tool. The first would be a prioritization questionnaire. This questionnaire would be distributed to the patient and their treating radiation oncologist, empowering

the patient to prioritize a disease symptom, treatment side-effect, or other outcome. The radiation oncologist would also complete a prioritization questionnaire; however, based on the literature review it was anticipated the prioritization would not routinely vary between patients.

This prioritization would then determine the individual patient-reported outcome elements to populate the collaborative decision-aid tool for the weekly OTV. Individual queries measuring the goal or concern would be drawn from validated, standardized item banks (Chapter 1, Figure 3). Items from the validated banks would be selected based on a symptom (e.g., nausea, pain, appetite), a physical function (e.g., walking, gardening) or a role function (e.g., cooking, grocery shopping, math). By utilizing the available item banks across multiple tools, questions can be identified that focus on the patient's primary concern, fully informing on their experience. If a question was not available from prior evaluation or use, sample questions could be reviewed with the patient participant. In total, there would be seven to ten questions to capture the targeted goals and concerns. The radiation oncologist would then review the tool to verify the information queried reflects the information to be captured. Similarly, on the radiation oncology verification visit, the patient would be asked to review the questions and confirm they are understandable. If the patient did not believe the question adequately captures their prioritized concern, or they did not understand the question, the validated item banks would be reviewed for the patient's preference. If a question was changed, the radiation oncologist would again be consulted to confirm it is acceptable.

Although the PROMs would be queried to, answered by, the patient through Epic® EHR, it was anticipated that the collaborative decision-aid tool would be printed in

paper, distributed to the radiation oncologist for review before the OTV, and then carried in to the OTV to discuss with the patient. The paper document would serve as a communication prompt for the radiation oncologist as well as a visual summary for both the provider and the patient. Prompt reminder questions for the patient and provider could also be included to queue for additional symptoms or concerns. Prompt questions should be simple and based on established healthcare improvement strategies, such as Ask-Me-3 (Institute for Healthcare Improvement (IHI), 2018). The originating digital data, including the trends, would be maintained as source data in the EHR. The data should be viewable, but not alterable, within Epic[®] EHR. Additionally, the data should be able to be mined for future studies as well as be able to be imported into clinician notes or printing groups as desired.

3.4.7 Trustworthiness and Rigor

Several strategies were undertaken to increase trustworthiness of the study results. Triangulation of data sources (i.e., literature review, regulatory/oversight review, review of electronic health record, interviews with patients, and interviews with radiation oncologists) was employed to demonstrate alignment or consistency between sources. Member-checking was employed with summaries of key findings from radiation oncologist interviews (Creswell & Plano Clark, 2011). This reduced risk of investigator bias and enabled clarification of interpretation. A committee of established researchers independently reviewed the codes, themes, and outcomes to provide added trustworthiness. Committee members included a senior researcher trained in both qualitative methodology and patient reported outcome measures as well as a senior physician researcher in oncology who served as a chief medical information officer at a

large academic medical center (Creswell & Plano Clark, 2011; Thomas, 2006). Themes identified from the interviews were cross-verified against themes in the published literature as an available evidence base. Interviews with covering oncologists provided additional cross-checking for interview data with radiation oncologists (Creswell & Plano Clark, 2011). Lastly, disconfirming or contradictory information obtained from the interviews or observations was evaluated and included in the analysis as a divergent perspective (Creswell & Plano Clark, 2011).

3.4.8 Ethical Considerations

The qualitative strand met the definition of human subjects research. Institutional review board (IRB) approval was obtained prior to study initiation with the University of Iowa as the IRB of record (IRB00000099, IRB-01-Biomedical) and under the Federalwide Assurance Number FWA00003007. No elements of consent were waived. Legally authorized representative consent was not allowed, patients had to provide independent consent. Written informed consent was obtained from patient participants and included details regarding audio recording and storage of data for future use. Patients were also asked to allow access to their medical record and mining of data from their radiation therapy visits. A waiver of documentation of consent was obtained the radiation oncologists, as they served as both as participants and as co-investigators in this study.

3.5 Quantitative Strand

The objective of the quantitative strand was to assess the impact of the collaborative decision-aid tool when implemented in a midwestern radiation oncology clinic within an academic medical center (Creswell, 2015). The tool was implemented utilizing a practice initiative to assess clinical, and not research, use. Like the qualitative

strand, this work was informed by the NIRN framework (Bertram et al., 2015), the OMRU (Graham & Logan, 2004), and the Shared Decision-Making (SDM) model as described by Elwyn (2008 and 2012), but also the Plan-Do-Study-Act (PDSA) cycle for implementation (Langley et al., 2009; Reed & Card, 2016; Snyder et al., 2012). The quantitative phase addressed the *Do* and *Study* segments of the PDSA cycle, including barrier identification, adaptation of workflow, and assessing attitudes of providers. The PDSA model provided guidance for the initial implementation cycle at the clinical level where as the SDM model provided guidance for the initial implementation at the patient/provider level, addressing decision support and use of the tool.

3.5.1 Research Question

The quantitative strand addresses the question *What is the impact of the collaborative decision-aid on the medical management of patients actively undergoing radiation treatment for lung cancer?* through the primary objective endpoints **of time expended per OTV and compliance with SDMCQ completion**. Secondary objectives provide insight into the tool's impact on medical management: surrogates of shared decision making (add-on oncology visits, concomitant medication prescriptions), medical management (adverse events, radiation therapy compliance, chemotherapy compliance) and emergent care and its costs (emergency room visits and estimated costs, inpatient admissions and estimated costs).

It is anticipated utilizing a collaborative decision-aid tool employing PROM will reduce the number of unplanned outpatient oncology visits as well as the number of ER visits. This is based not only on prior findings (Barbera et al., 2015; Basch, Deal, et al., 2016; Howell et al., 2020; Kirkland et al., 2020) as well as literature indicating common

causes for emergency room visits for cancer patients, including those that can be addressed in outpatient clinic settings (Caterino et al., 2019; Centers for Medicare & Medicaid Services, 2021; Gallaway et al., 2021; Scholer et al., 2017). The most common reasons for ER visits include pain and nausea; lung cancer patients are the most common patients to seek ER services (Caterino et al., 2019; Panattoni et al., 2018; Scholer et al., 2017). Perhaps most importantly, this expectation is based on the determination by Centers for Medicare and Medicaid Services that nausea, emesis, anemia, neutropenic fever, diarrhea, dehydration, and/or pain are adverse events for which an ER visit is potentially avoidable (CMS, 2021). Potentially preventable ER visits are estimated to account for 20% to 63.5% of cancer-associated visits (Panattoni et al., 2018; Shah & Neal, 2021).

3.5.2 Sample Size

Sample size of patients using the collaborative decision-aid tool was determined by the PDSA cycle length, which was determined by the length of time it took from introduction of the collaborative decision-aid tool into clinic until the first patient's completion of intervention from initial treatment through last day of radiation. This was 8 calendar weeks; during this time, 15 patients had the collaborative decision aid applied to at least one clinical visit.

3.5.3 Participant Selection

Patients referred for radiation therapy for treatment of their primary lung cancer, with/without concomitant cytotoxic chemotherapy had the collaborative decision-aid tool assigned to their clinical visit with their treating radiation oncologist. This provided an inclusive and pragmatic sample. A request for human subjects determination was filed

with the University of Iowa IRB-01. It was determined by the IRB the project did not meet the definition of human subjects research and, as such, informed consent was waived.

3.5.4 Research Procedures

Quantitative procedures focused on obtaining objective measures to assess the implementation of the collaborative decision-aid tool in a radiation oncology clinic and initial outcomes from its use. The tool was informed from the qualitative strand, customized for both the patient population and the radiation oncology clinic's workflow.

3.5.4.1 Historical Control

Patient participants from the qualitative strand and from a research registry served as the historical control. The control provided historical information regarding emergent treatment (i.e. ER visits, inpatient admissions), cost of emergent treatment, time expended per OTV, patterns of adverse events, concomitant medication prescriptions (including opioids), and the number of add-on oncologist visits. These data were compared descriptively to the data obtained during the first implementation cycle.

3.5.4.2 Visit One

The collaborative decision-aid tool (Shared Decision Making-Communication Questionnaire, SDMCQ) was to be assigned to patient with lung cancer prior to their initial consult. If the patient was to receive long course radiation therapy, the student researcher placed a notation in MOSAIQ® EHR to have the SDMCQ assigned to each OTV and a tablet distributed at that visit's check-in.

3.5.4.3 On-treatment visits

After receiving the day's radiation, but prior to being taken to an exam room, the patient completed the SDMCQ using the tablet. The data were manually mined from Epic[®] EHR and entered into the collaborative decision-aid tool. This tool was printed to the communal workroom, where the treating radiation oncologist picked it up for their OTV with the patient. The radiation oncologist reviewed the printed document with the participant, discussing concerns or new issues that have developed.

3.5.4.4 Endpoints and Analysis

Data mining. Emergent add-on visits within radiation oncology, referrals to other clinics (e.g., medical oncology, emergency room, pulmonology), and inpatient admissions were mined from the EHR (Table 3). Mining was limited to the active radiation treatment timeframe (i.e., consult through last day of RT) but include outside facility records within that timeframe if available. Prescribed concomitant medications were mined and reconciled with the patient's use, if available (i.e., compliance). Time expended for the OTV total (i.e., check in to check out) was mined and, if available, the length of time for the discrete OTV. Use of a physician resident for an OTV, or assignment of a covering radiation oncologist, was also noted for review.

Table 3

Source Data for Quantitative Strand

Data Source	Impact	Implementation
Epic [®] Department Appointment Report	Primary data	Primary data
<i>The Epic[®] EHR provided source data for OTV (e.g., check in time, rooming time, check out time) as well as the time required for SDMCQ completion and time it was completed. The DAR provided the assignment of the SDMCQ and the tablet.</i>		

Data Source	Impact	Implementation
On-treatment Visit Notes (OTV) <i>OTV notes are a source of adverse events, use of the SDMCQ (when assigned), and the time the note was signed (pre- or post-discharge). The OTV are source for errors or ambiguous information that could negatively impact communication.</i>	Primary data	Primary data
Epic [®] EHR, including Care Everywhere [®] <i>Epic[®] provided incidence of unplanned outpatient visits as well as emergency room visits and inpatient admissions. Also served as source for cost analysis, chemotherapy compliance, and prescribed concomitant medications.</i>	Primary data	—
MOSAIQ [®] EHR <i>MOSAIQ[®] provided source for radiation treatment compliance (i.e., the number treatments given, elapsed days, and breaks) and also source for requesting the SDMCQ when assigned.</i>	Primary data	Primary data

Note. Source data will be archived in compliance with HIPAA and retained for a minimum of six years after closure of the IRB application.

Demographics. Self-reported race, ethnicity, gender, and insurer (as a surrogate for socioeconomic status) were collected as demographic variables, as well as also the clinical stage (i.e., T N M), the prognostic stage, pathology, prescribed chemotherapy, and radiation prescription. These data were mined from Epic[®] EHR and MOSAIQ[®] EHR.

Primary objective. The primary objective is to develop the collaborative decision-aid tool and implement it within the radiation oncology clinic. Quantitative measures addressing this objective are time expended per OTV and compliance with SDMCQ completion.

To estimate time expended per OTV, Epic[®] EHR was mined for the following timepoints at each OTV: check-in time, time when patient was roomed, time the patient

was queued as “waiting for MD,” time the resident physician entered the room, time the resident physician exited the room, time the staff physician entered the room, time the staff physician exited the room, time the Epic[®] note was signed, and time the patient was discharged. For patients completing the SDMCQ, the time for completion was also mined from Epic[®]. Times were analyzed using descriptive statistics and presented in tables.

SDMCQ compliance was measured using the number of patients who should have had an SDMCQ assigned, the number who had it assigned, the number of patients who had the tablet distributed to them, and the number of SDMCQ completed prior to physician entry into the examination room. This information was mined from Epic[®] EHR.

Secondary objectives. Shared decision making is explored through surrogate markers of unplanned oncology visits (i.e., same day add-on radiation or medical oncology clinic visit) and concomitant medication prescribing patterns. These are both mined from Epic EHR.

Unplanned outpatient clinic visits were defined as an office visit scheduled during routine working hours outside the routine weekly oncology visits. Additionally, referrals to other outpatient services (e.g., neurology, otolaryngology, ophthalmology) were included if they were made at the request of the oncology service and not performed concurrently with an emergency room visit or an inpatient admission. Nurse only visits were also included, as the nurse clinician was often in contact with the oncologist and providing secondary services. Phone call notes and MyChart[®] messages were not included.

Patients undergoing concurrent chemotherapy and radiation therapy for their lung cancer have medications managed by a multitude of providers. Routine medications such as anti-hypertensives may be managed by the patient’s primary care physician or treating

oncologist. Medications to combat side effects (e.g., nausea, dry mouth, esophagitis) are primarily managed by oncologists but also by emergency room physicians and hospitalists. Most importantly, cancer associated pain and treatment emergent pain are often managed by all divisions (i.e., medical, radiation, surgical, emergency room, hospitalists), which coupled with the current opioid crisis, requires attention to active prescriptions and harmonizing use to the patient's complaints.

Concomitant medications were captured as medications prescribed during the course of the radiation treatment course by any UIHC medical provider as well as those concomitant medications prescribed only by radiation oncologists. Prescribing patterns for concomitant medication were presented in tables with graphical descriptions as appropriate. Medications not included in the review were those prescribed as part of an infusion order set for infusion reactions (i.e., Benadryl, dexamethasone) or administered as part of an emergency room visit or inpatient admission. Lastly, these values represent only what prescriptions were written, not medication use or the number of doses and refills provided.

Medical management was assessed through treatment compliance (radiation and chemotherapy) as well as by review of adverse events. Treatment compliance was evaluated for both radiation therapy and chemotherapy. Radiation therapy was evaluated using three standard metrics for the field:

- $[\text{total dose delivered}]/[\text{total dose prescribed}]$
- number of breaks applied (i.e. times radiation was held)
- number of break days required (i.e., calendar days radiation was held)

It is standard practice for radiation clinics within the United States to follow the U.S. banking holiday schedule; thus, prescribed elapsed days also include any weekends or holidays from radiation treatment 1 to the final radiation treatment. Treatment breaks are measured in calendar days and, if they abut weekends or holidays, these days are also included in the treatment break as it is assumed those days contributed to the resolution of the adverse event requiring the break.

Chemotherapy compliance was evaluated using the Relative Dose Intensity (RDI) ratio (Crawford et al., 2020; Lyman, 2009). Briefly, this value was calculated by determining the standard dose intensity (SDI—the intended dose of chemotherapeutic agents over the original prescribed calendar days) and the actual delivered dose intensity (DDI—the actual dose the patient received from treatment day 1 to the last day of treatment). An RDI of < 85% has been associated with poorer outcomes in patients treated for lung cancer (Crawford et al., 2020).

Adverse events were mined from the radiation oncologists' notes, special complaint notes (i.e., telephone notes, nursing notes, unscheduled radiation oncologist or medical oncologist notes) the emergency room notes, and inpatient admission notes. Adverse event terminology and severity was harmonized to CTCAE version 5 (National Cancer Institute (NCI), 2016a). The sources of information were purposefully selected to evaluate the alignment between the radiation oncologists' notes, unplanned visit notes, and the emergent notes. If the patient was assigned the collaborative decision-aid tool, these answers would also be used to inform the adverse events. Adverse events were presented in summary statistics in tabular format.

Emergent care and associated costs were mined from Epic® but also utilized the UIHC research chargemaster to estimate associated fiscal costs. The number of emergent visits (i.e., ER, inpatient admission) were mined from Epic® EHR as well as from any available secondary sources (i.e., Care Everywhere®, scanned outside medical facility records). Visits were included if they occurred any time between initial consult through the last day of radiation. If the patient was in an active admission during the last radiation treatment, this hospital stay was included until the patient's discharge.

Gross total costs of the emergent visits were estimated based on the UIHC utilized two sources of costs based on the Current Procedural Terminology (CPT®) or Healthcare Common Procedure Coding System (HCPCS) (American Medical Association (AMA), 2021; Centers for Medicare & Medicaid Services, 2020). For emergent visits that occurred at UIHC, the CPT® technical charges and HCPCS charges are summarized in the encounter; these were mined directly. CPT® professional charges required accessing the UIHC professional services fee tool, utilizing the following parameters: 2021, State of Iowa, Facility fee and, if appropriate, the 26 modifier (i.e. physician interpretation only). The resultant value was then multiplied by 1.5 to estimate the professional fee charged to a third-party payor, as outlined in the UIHC professional services fee tool instructions. If the emergent visits occurred at an outside medical facility, the notes were mined for procedures and the appropriate UIHC charges applied.

Generalizability. This clinical implementation project provides information on the first PDSA implementation cycle as well as impact on emergent visits and their associated cost, changes in visit metrics (time spent with patient, overall time from check-in to note provider completion). The implementation mapping should inform

future projects similar in nature to the collaborative decision-aid tool at the UIHC as well as other sites with similar workflows and infrastructure. This work addresses the knowledge gap of implementing a PROM through Epic® EHR through a clinical implementation strategy, utilizing only clinical staff, rather than addressing barriers and facilitators through a human subjects study utilizing an established clinical research infrastructure.

3.5.4.5 Ethical Considerations

Institutional review board (IRB) approval was sought and obtained prior to initiating this study. The University of Iowa IRB-01 served as the IRB of record (IRB00000099, FWA00003007). After initial approval was granted through the University of Iowa, an application was filed with The George Washington University IRB for an IRB Authorization Agreement (IAA). After these steps IAA and GWU IRB were completed, the study moved forward. At the request of the University of Iowa IRB-01, a data usage agreement was also filed between the universities.

Informed consent was obtained from patient participants to participate in the qualitative strand (i.e., describing the collaborative decision-aid tool, the SDMCQ), including these data in the EHR, and the interview, its audio-recording, transcription, and storage. A waiver of documentation of consent was obtained for the radiation oncologists and associated clinical staff. Upon review, the University of Iowa IRB-01 determined the project, designed to implement the SDMCQ as part of the clinical pathway, was not human subjects research and did not require further IRB review. The application for review, and the IRB's determination, is provided in Appendix B.

3.6 Mixed Methods Exploratory Sequential Interpretation

The mixed methods research question *How does the impact of the collaborative decision-aid tool inform recommendations for future designs and implementation?* was addressed utilizing a sequential exploratory design, so that the qualitative strand informs the quantitative strand. However, the qualitative strand and quantitative strand were analyzed in parallel, in which the data sets are independent and analyzed separately (Onwuegbuzie & Leech, 2006; Onwuegbuzie et al., 2007; Teddlie & Tashakkori, 2009) but then a cross-over analysis strategy was applied to identify links or integrate the data to lead to synthesized results (Onwuegbuzie & Combs, 2015; Onwuegbuzie & Leech, 2006). With the quantitative question being descriptive, the cross-over analytic techniques selected were data reduction, data display, data comparison, and integration (Figure 4, Onwuegbuzie & Leech, 2006). The first step for analysis was data reduction (i.e. coding qualitative data, assessing quantitative data through descriptive statistics). The data was then analyzed as listed in Table 4. Sources of data included the qualitative transcripts and resultant codes, the electronic health record (i.e., medications, visits, time expended, notes), commonly used PROM (e.g., PROMIS[®], PRO-CTCAE[™], QLQ-C30), the peer-reviewed literature providing work known to date about implementation and format, FDA guidelines regarding PROM integration in oncology, and recommendations from the implementation committee for the collaborative decision-aid tool. The NIRN framework, the OMRU, and the PDSA implementation cycle informed the mixed analysis (Onwuegbuzie & Leech, 2006).

Table 4*Data Analysis : Mixed Analysis Matrix*

Qualitative Data	Quantitative Data				
	Time	Unscheduled	Medications	Adverse events (AE)	Compliance
Format	—	INTEGRATION T: communication & format codes C: barriers & facilitators	—	COMPARISON T & OTV: AE codes L: Common AEs Q: responses	—
Implementation	DISPLAY T: communication codes C: barriers & facilitators Appt: times L: Frameworks	INTEGRATION T: communication & format codes C: workflow review Q: AEs	—	COMPARISON T: AEs to be listed L: AEs to be captured P: current format	—
Adverse events (AE)	DISPLAY T & OTV: AE codes Q: completion time Appt: times	COMPARISON T & OTV: AE codes EHR: diagnosis EHR: length of stay L: preventable AEs	DISPLAY T & OTV: AE codes Med: number & type prescribed	INTEGRATION T & OTV: AE codes L: Frameworks Q: AEs C: Committee	CORRELATION OTV: AE codes (quantified) EHR: chemotherapy CRT: RDI

T: Transcript; OTV: on-treatment visit notes; L: Literature Q: collaborative decision-aid tool questionnaire

P: PROM tools (PROMIS, PRO-CTCAE, EORTC QLQ-C30) EHR: Electronic health record / Epic® Med: concomitant medications

CRT: chemo-radiation therapy C: Implementation committee

3.7 Human Participant Considerations

The University of Iowa Institutional Review Board (IRB-01, biomedical) served as the IRB of record for this study. The IRB Authorization Agreement ceded oversight to the University of Iowa consistent with The George Washington University IRB's standard operating procedures (The George Washington University Institutional Review Board, 2018). Thus, the human studies were submitted for oversight review to The University of Iowa's Biomedical Institutional Review Board (IRB-01, biomedical), the Protocol Review and Monitoring Committee of the Holden Comprehensive Cancer Center (an NCI-required oversight committee for PI-initiated studies utilizing patients with cancer), and the Data and Safety Monitoring Committee of the HCCC. This human subjects study did not meet the National Institutes of Health definition of a clinical trial and, as such, was not required to be registered on *clinicaltrials.gov*. Research procedures did not begin until IRB approval has been obtained from the University of Iowa and the IRB authorization agreement had been signed and executed by both institutional IRBs. The GWU IRB was required to be notified if there was a change in risk level for the study, there was a subject complaint, there was an unanticipated problem, the research was suspended, there as a change in principal investigator, a change in funding, a change in the GW staff roles or responsibilities or when the study was closed (The George Washington University Institutional Review Board, 2018).

3.7.1 Potential Risks

Breach of confidentiality: Privacy and confidentiality are always at risk when participating in a human subjects study. Additional records were created as a result of the research study and Epic® EHR was reviewed by non-clinical personnel to mine

information from the medical chart. This can put a participant at psychological harm due to breach of confidentiality.

Financial: Participants did not incur additional costs for participating in this research study. However, some insurance companies deny coverage for any patient participating in a clinical research study. This risk was minimized by not linking the medical record to study participants for those consenting to the qualitative study.

3.7.2 Protection Against Risks

Breach of confidentiality: All investigators are required to take classes on human subject research. To minimize risk, only the IRB-approved research team had access to the study's subjects and identifiable data. Once scrubbed of identifiers, data were provided to study team members as described in the Methods section and the approved IRB application.

Privacy. Only the information needed for the study was reviewed. Other medical documentation was ignored. Only those study team members who needed to review the medical data did so.

Confidentiality: The federal code identifies 18 pieces of information deemed to be PHI that result in loss of confidentiality. These patient identifiers were removed from all documentation saved or printed for the purposes of these studies. De-identified data was stored in a research chart in locked offices as described in the IRB application. A password protected tracking log was maintained to link the patient to the research ID. Upon successful completion of the study, the study application will be closed with the IRB of records and documents stored for 5 years. All documents are then to be shredded.

Violations. Research violations, including breach of confidentiality or privacy, are taken very seriously. Upon complaint by a research team member, staff member, participant, or patient, the complaint is forwarded to the Human Subjects Office of the University of Iowa for investigation.

Vulnerable populations: Vulnerable populations, including prisoners, pregnant women, fetuses, and children, were not utilized. Children, due to their unique pediatric status, would be better served by a study designed for their needs. A larger study may opt to include prisoners at a later time.

CHAPTER 4

4 RESULTS

4.1 Introduction

The qualitative strand, with interviews with patients and radiation oncologists, was conducted from March 2019 through June 2020, with a four month shut-down due to the SARS-CoV-2 pandemic. The interim phase for qualitative analysis, tool development, Epic® EHR integration and build, and the *plan* segment of PDSA occurred from June 2020 through June 2021. The collaborative decision-aid tool was implemented starting June 2021 and the end of the first PDSA cycle was completed the first week of August 2021, defining the PDSA cycle as roughly eight weeks. Thirteen patients consented to be interviewed for the qualitative strand; of these, six completed the interviews. Six of the seven radiation oncologists agreed to be interviewed and all completed the interviews as agreed.

This chapter will provide the qualitative strand and quantitative strand results as well as the *Do* and *Study* segments of the first PDSA implementation cycle.

4.2 Qualitative Results

The research question guiding the qualitative strand of this research was *How do the stakeholders, practice considerations, and evidence base inform the ideal design and*

implementation of a collaborative decision-aid tool? This question provided the lens to guide the interviews as well as when exploring participants' responses.

4.2.1 Patient Participants

4.2.1.1 Demographics

Although 13 patients consented to be interviewed at the conclusion of their therapy, only 6 returned for interview. Reasons for withdrawal included death (n=1) as well as SARS-CoV-2 diagnosis (n=1), but the most cited reason was a desire to reduce time at the clinic (n=5). For this reason, the design was modified to allow the interview to occur during the last week of therapy, this reduced participant withdrawal from the study. Demographics of the subjects who participate in the interviews are provided in Table 5.

Table 5

Characteristics of Patients Consented for Qualitative Strand Interview

Characteristic	n=6	Characteristic	n=6
T category		Female	3
T1	2	White	6
T2	0	Non-Hispanic	6
T3	1	Age (years)	
T4	3	50 – 59	3
N category		60 – 69	3
N1	1	KPS [†]	
N2	0	80	2
N3	4	70	3
N4	1	60	1
Prognostic Stage		Insurer	
IIIA	2	Medicaid	1
IIIB	2	Medicare	3
limited stage	2	Private	1
		VAMC	1

Characteristic	n=6	Characteristic	n=6
Histology			
		adenocarcinoma	1
		small cell lung cancer	2
		squamous cell carcinoma	3

†Karnofsky Performance Status is a subjective assessment in units of 10, with 100 having no signs/symptoms of disease, 50 being house-bound, and 0 denoting death.

4.2.1.2 Interviews

Overall, the interviews with patient participants lasted between ten to thirty minutes due to the symptomatic fatigue and dyspnea. Audio recordings were transcribed verbatim and analyzed as previously described. To obtain insight about the information an individualized collaborative decision-aid tool required, the first question asked to the patient participants was, “*Thinking about your radiation treatment, what do you think was important for your radiation doctor to know about how you were feeling?*”

Surprisingly, none of the participants were able to answer this question. Participant 6 stated, “[I]t was really the other way around. Because I didn’t know. I didn’t ... I knew I had lung cancer and that was established before I showed up here... I’m not sure I would of known what to ask at that point;” whereas, subject 34 stated, “It’s...more the other way around and what I needed to hear.” The other interviewed participants noted it was important to let the radiation oncologist know what was occurring during therapy and monitor for side effects described to them. None of the participants prioritized their lifestyles or activity needs when considering therapy. Additional questions then explored the patient’s experience while undergoing radiation therapy, the side effects experienced, and patterns of communication during treatment. Due to the patient participants’ inability

to describe what was important for a radiation oncologist to know regarding their preferences and concerns regarding treatment as well as the SARS-CoV-2 pandemic, the interviews were concluded.

4.2.1.3 Coding, Analysis, and Synthesis

The coding process resulted in six keystones (i.e., conceptual categories); each was then explored with its own analytic map and supportive memos: communication, health literacy, patient reported symptoms, oncologic treatment, format of the SDM tool, and implementation of the SDM tool. Each are described in further detail herein.

Communication. When reviewing the analytic map and relationships between codes, barriers and facilitators are easily evident. Patients identified barriers included the repeated efforts to contact/not knowing who to contact, the emotional responses shared with their radiation oncologist, and the need for a safety net or gatekeeper. *Safety net* was linked to *caregiver* and *new information* but also *isolation*, *COVID-19*, and *fear*. SDM Implementation is linked to Communication through Symptoms but also *safety net* and *choice*. This suggests the shared decision-making tool could address the patient-identified communication barriers of having to repeat information across multiple providers as well as reduce the feeling of isolation while undergoing radiation therapy. An interesting finding was patients often referred to their physicians as *they* when they were unhappy with a decision or a memory; conversely, the physicians were referred to as *we* for a pleasant memory or outcome.

These findings pooled into *Communication*, which upon review, represents the overarching theme, “The shared decision-making tool could address the patient-identified communication barriers of having to repeat information across multiple providers as well

as reduce the feeling of isolation while undergoing radiation therapy.” Quotations highlighting communication between patient and radiation oncologist are:

- “I don’t have an idea of who to call because I don’t recognize the physician on the pill bottle.” [participant 26]
- “That’s a lot of things they asked me. Not in a form like this. They did it verbal. This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don’t. This could have been a reference for all the other doctors this would be helpful. I did a lot of that repeat, repeat. And by the end, I’m tired.” [participant 26]
- “[Y]ou can just hand it to them and they could go over it with you. You could just answer it without going through everything over again.” [participant 27]
- “If there was anything frustrating it didn’t have anything to do with them, you know, it was a matter that no one can be with you and you know, so, you’re sort of responsible to remember all the stuff to take home and to talk about it.” [participant 06]

Analytic maps, links, supporting quotations and code definitions are provided in Appendix G.

Health literacy. The Health Resources & Services Administration, an agency of the Department for Health and Human Services, defines health literacy as “...the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (n.p., Health Resources & Services Administration, 2019). This concept directly impacts Communication, SDM Format, and SDM Implementation but also has a secondary relationship to Treatment and Symptoms through Communication. Thus, the collaborative

decision-aid tool is dependent upon Health Literacy and may impact the tool's implementation and/or usefulness. Health Literacy is associated with codes such as *proactive, patient-to-provider communication, slow reader, choice, medical experience, foreknowledge, and TV commercials*. Two patients stated openly they were slow readers; of which one painstakingly read the sample questions during the interview. During the interview, it took the patient 52 seconds to read a PRO-CTCAE™ question for nausea, an average of 30 seconds for each PROMIS® prompt, and an average of 25 seconds for each QLQ-C30 prompt. The same patient participant commented on the questions, providing key insight that the questions could be interpreted in a way that was not intended. The alternate interpretation was not a reflection on poor health literacy but in the context of the question (e.g., things you *wanted* to do, *normal* activities). The italicized words are those the patient participants found difficult, as under treatment, they no longer had the desire to do anything and they had no normal.

Patient participants were judicious in their source of medical information and its application, restricting themselves to known academic internet sites (e.g., Mayo clinic, National Cancer Institute) or directly asking their providers or allied health care staff for further information. All patients endorsed wanting information provided to them directly, without the need for 'sugar coating,' or hesitancy. The theme represented by Health Literacy is, "The shared decision-making tool is dependent upon health literacy and may impact the tool's implementation and/or usefulness." Representative quotations for this note are:

- "And the doctor would know, but I wouldn't know." [participant 22]

- “You know, I mean, just... you know I’m...I’m never had cancer before.”
[participant 32]
- “I didn’t ask a lot of questions because I didn’t know what to ask.” [participant 06]
- “Well, you know, over the years you always hear when you’re unhealthy that... well the white blood cells that are fighting off infection and stuff and that goes low during chemo and radiation and I figured I would ask.” [participant 34]

Analytic maps, links, supporting quotations and code definitions are provided in Appendix H.

Patient-reported symptoms. Participants were asked to identify and describe symptoms they experienced during treatment. Symptoms could be related to a treatment (e.g., surgery, chemotherapy, radiation), to the underlying malignancy, or to an existing health condition. The most commonly patient-identified symptoms were fatigue, nausea, vomiting, dyspnea, and malaise, all of which are subjective, variable by patient, and negatively impacted activities of daily life and all of which can be more consistently quantified utilizing a collaborative decision-aid tool. Sample quotations include:

- “It’s awful. You’re more tired then...this normal tired you’re supposed to be experiencing. And...you can’t eat, and you know, you don’t want to do anything but lay on the couch or your bed.” [participant 06]
- “Well, I... I wake up most of the time and I’m still tired.” [participant 34]
- “So, when you poke 7 pills one day, 7 the next day. So that was 14 pills dumped down in me and then try to drink enough water to dilute them...and I just couldn’t do it and then I got sick and I couldn’t take my regular pills. I would put ‘em in my mouth. I’d drink water. They would come right back up...I’d just ... I’d give up at a point. “ [participant 27]

- “Since I don’t have any usual or daily activities ...or anything to do... it really doesn’t interfere with anything. All I do is watch TV.” [participant 34]
- “The burn on my back... it didn’t show up until I went home. And the nausea too. Everything was delayed until I was done with it.” [participant 26]

Analytic maps, links, supporting quotations and code definitions are provided in Appendix I.

Oncologic treatment. This is linked to the patient experience, and thus shared decision making, through symptoms and patient reported outcomes. This suggests the impact of shared decision making on treatment is secondary and dependent not only on symptoms but is influenced by the lens of patient reported outcome measures (symptoms, treatment outcomes). This aligns with the research question, which seeks to identify the collaborative decision-aid tool regarding side effects and symptoms (not treatment).

- “So, they immediately jumped on you know, ‘We need the medicine for this and that. You need to do this and that.’ It’s not like they ignore you when you say there’s something wrong. They check it out.” [participant 27]
- They suggested Lubriderm, which is what I put on it. And that took care of ... they’re like, ‘We’re gonna dry your skin out.’” [participant 22]
- “They had me on 3 different pills of medication to help with the nausea so I never noticed it.” [participant 22]
- “They were gonna get me in right away to find out what the infection was. So, they were gonna schedule me for some procedure the next day...Okay, fine. And then they called back: ‘We can’t do that procedure because you have to have a COVID test.’” [participant 06]

Analytic maps, links, supporting quotations and code definitions are provided in Appendix J.

Format of the tool. Patient participants described a useful collaborative decision-aid tool as one that is paper-based, providing detail regarding side-effects and symptoms, with a timeframe that addresses weekends and holidays as well as provides information for providers across multiple clinics. Patient interviews identified a need for the tool to be simple to address slow reading skills, modifiable to address poor health literacy, and provide direct instructions to address concerning symptoms.

- “You don’t want to ask too many questions.” [participant 06]
- “[The PRO-CTCAE] is too general!” [participant 34]
- “I don’t have any usual or daily activities...so... it really doesn’t interfere with anything. All I do is watch TV.” [participant 34]
- “This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don’t. This could have been a reference for all the other doctors this would be helpful. [participant 26]
- “[I]f I’m home, and I had a piece of paper, and all of a sudden I hit that side effect I could say, ‘Oh, this and.... Hmmm, call in!’” [participant 22]
- “[The PRO-CTCAE] are pretty wide open...I mean, [the questions] could go back to prior to you being ill. While you were being sick. So, if you were a patient and you really wouldn’t know what you were answering. I know in the last 7 days... but what about prior, right now I’m not, but back then I did.” [participant 27]

In total, fifty-one codes and categories are linked to SDM Format. There is little interpretation and more directness regarding what should be present, per the patient, to make this functional. Further details are provided in Appendix K.

Implementation of the tool. Patient participants described implementation of a collaborative decision-aid tool as multi-disciplinary, enabling consistent sharing regarding of patient-reported side-effects and symptoms. If effectively implemented, the tool could support the gatekeeper function, serving as a single source of information to the multidisciplinary committee as well as a resource for the patient to know when to escalate situations and who to contact during holidays and weekends.

- “This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don’t. This could have been a reference for all the other doctors this would be helpful.” [participant 26]
- “Then you can just hand it to them and they could go over it with you...without going through everything over again.” [participant 27]
- “Maybe you just want to know from week to week whether it’s getting better. It was REALLY BAD and oh, now it’s not quite so bad, and you know so you can see the trend that it’s getting better and better.” [participant 06]
- “We need somebody that has direct input into the committee who knows what’s going on. Like a gatekeeper. One person I talk to and they direct me.” [participant 26]
- “You’re coming every day for radiation, and that was also sort of a safety net. Because if you didn’t feel good from one day to the next, you knew you were coming back and you could ask somebody the question.” [participant 06]

Analytic maps, links, supporting quotations and code definitions are provided in Appendix L.

4.2.2 Radiation Oncologist Participants

4.2.2.1 Demographics

At the time of the qualitative study, there were seven radiation oncologists on staff at UIHC. Per the IRB of record, written informed consent was not required but an informed consent sheet was to be distributed. All seven radiation oncologists were approached and six scheduled interviews. The seventh did not schedule an interview and this was considered declining to participate. All of the interviewed physicians are board certified in radiation oncology and have practiced in locations other than Iowa.

Demographics are provided in Table 6.

Table 6

Characteristics of Radiation Oncologists Consented for Qualitative Strand Interview

Characteristic	n=6	Characteristic	n=6
Female	2	Academic status	
Race		Assistant professor	2
White	5	Associate professor	3
Asian	1	Professor	1
Non-Hispanic	6	Tenure track	3
Years in practice		Terminal degree	
Average	11	M.D.	2
Minimum	3	M.D., Ph.D.	4
Maximum	28		

4.2.2.2 Interviews

Interviews varied drastically across appointments (average 39 minutes; range 18 to 60 minutes). The longest interviews occurred with radiation oncologists 1, 2, and 5. Despite the shorter length, key insights were provided from radiation oncologists 3, 4,

and 6. For example, physicians 3 and 4 were able to clarify and specify what they would prefer to see in the shared decision making tool (e.g., no scales, granular real-world descriptions of activities of daily life) whereas physicians 1 and 2 had focused on ambiguous terms and how they vary between patients. Similarly, physician 5 described a potential process by which answers change between providers, but physician 6 provided additional detail that answers could change because the event resolved or because the patient was seeking to be admitted and knew the answers that would trigger an inpatient stay. Interviews were often concluded due to clinical or patient interruptions with follow-up clarification as needed.

4.2.2.3 Coding, Analysis, and Synthesis

Due to the focused nature of the interviews with the radiation oncologists, coding and thematic analysis were not performed. Transcripts were reviewed for exemplar points as well as supportive concepts that further informed patient participant interviews and provided triangulation to the analytic maps and memos .

Communication. Radiation oncologists described two themes in communication problems: physician *vs.* patient and the prescribing radiation oncologist *vs.* other physicians. Illustrative quotes highlighting these issues are provided within the following sub-sections.

Communication between radiation oncologist vs. patient. Radiation oncologists described inconsistencies in verbal communication and documentation with patients. This was noted to happen directly to them during their training as well as in a faculty position. The radiation oncologists used the term ‘flip-flopping,’ to describe the shift in patient-reported information from provider to provider. Differences in patient reporting to

physicians was expected based upon the literature review. The physicians had different explanations as to why this might occur, from the initial query by a nurse or resident physician prompting the patient to recall the symptom during reflection to the symptom resolving between provider appointments. It was also discussed that gender bias did occur in the predominantly male field, with female physicians being assumed to be assistants or patients seeking male input even though the men are students. A radiation oncologist believed this could be minimized by a presence of confidence and leadership; the need for confidence and leadership was also mentioned by other radiation oncologists.

Surprisingly, all radiation oncologists' stated the personality of the patient was the key to understanding communication was unexpected and notable. The personality contributed to a shared history between patient and radiation oncologist, which enabled interpretation of actions and non-verbal communication.

- As a resident, patients would flip-flop all the time. They would say one thing and then tell the staff a different thing. And you're standing in the room with the staff and you're like, "Oh great!" Because you're trying to make a good impression in the staff. But now, as staff, I'm expecting the patient to flip-flop. Change their mind. Think about things in between our visits where the resident goes in and five minutes later, I come in. And "Oh, yeah, maybe I do have that symptom!" [MD 5]
- I have not had the experience but [redacted] was on service at VAMC. She had a male resident, a male fellow, and a male student. She goes in to deliver the patient's news. She tells him what the result is. The patient turns to the male student and goes, "What's your opinion about this?" the student is like, "I agree

with Dr. [redacted].” It’s like, yeah, yeah. She’s looking at the student, “Please, please enlighten us about this!” It’s not the student’s fault – clearlySo, I feel that patients probably respond differently to male and female physicians. [MD 6]

- There was one patient...I used to love this lady. Every single time she would come and she would be so unreasonable regarding her spouse’s symptoms to the point that I would have to almost yell at her to stop. I mean, basically I would have to yell at her to stop being so unreasonable and nearly abusive in her frustration. And then she would cry. And then she’d be so happy and apologize and she’d hug me and thank me for explaining what was occurring. And she did this every single visit. And she came in over multiple years...She was a very nice lady [but] she would have to replay this sequence each time. [MD1]

Communication between the treating radiation oncologist vs. other physicians.

Perhaps the most stunning was the revelation from the radiation oncologists that errors in notes were not called out to peers, so they could be corrected. The radiation oncologists described identifying frank errors, omissions, or information inconsistent with known history of the patient. While some would feel comfortable addressing an issue if they were friends with the physicians outside the office, in general the radiation oncologist would resolve the issue by contacting the patient directly or scheduling a follow-up exam. The radiation oncologists could also name specific physicians whose notes could always be trusted and those whose should be discounted. This provides triangulation to the patients’ insights that not all providers were consistent with their notes and also did not share information about the patient consistently.

- [The problems] could have resolved, they could have actually not answered the questions, or asked the questions and had a templated note. It can happen. [MD 6]
- [E]ven if [the notes] are not detailed enough, unless there's an in-between [and] they see other providers, what else can you do? [MD 4]
- Calling a note out with a colleague is not done... Would I talk to the other physician? No. [MD5]
- [O]ften times the inpatient unit notes are way behind and when they are admitted they're supposed to be coordinating care with Heme Onc, but they don't. It's a game of telephone. They are hard to get a hold of. You page them and sometimes they don't respond for 3 or 4 hours. It's just frustrating. [MD5]
- [W]hen they are on the unit they are under the care of the hospitalist or of the inpatient physician So if their inpatient physician says no treatment even if I think they should have treatment, they make the call. When they are outpatient it's more of an egalitarian I'm equal you're equal. [MD5]

Patient reported outcome measures and tools. Radiation oncologists were asked about patient reported outcome measures and their opinion about related surveys.

Perspectives from the radiation oncologist identified two concerns: a patient's poor understanding of the scale of events/outcomes and the relevance of the outcome measures in the oncology clinic.

Severity scales. The National Cancer Institute has employed a tool known as the *Common Terminology Criteria for Adverse Events* (CTCAE). The CTCAE harmonizes adverse event / symptom terms but also provides a severity grading from non-existent (grade 0) to mild (grade 1), moderate (grade 2), severe (grade 3), life-threatening (grade

4), and causing death (grade 5). Patient reported outcome measures, such as the PRO-CTCAE™, use similar terms if not the same exact. Clinical interpretation compared to patient reported measures can cause confusion and frustration.

Oncologists, including radiation oncologists, observe a spectrum of treatment emergent events from none (at initial diagnosis) to acute and serious requiring routine admission or intensive care, to overseeing a rapid response to an antineoplastic therapy. In contrast, the patient's only sphere of reference is their own experience and what knowledge they can glean from third-party sources. This aligned with the patient participants, who stated although they *knew* they would have the side effects of fatigue and esophagitis, they had *no understanding* of what they would truly experience. This also provided foreshadowing for clinical relevance.

- Iowans are stoic. Very different than [State A] or [State B]. In [State A] they let you know. In [State B] they expect you to know based on the labs and everything else. In Iowa, "I'm fine. Everything's great!" but I see they've lost 10 pounds. [MD 5]
- [I]f I, with my years of experience now looking at (side effects) say, "This looks amazing. I've never seen anybody get through it so well," but for the patient this is the worst thing they've ever been through in their whole life. It's still like a level 5 severity or whatever, you know, and it's really hard because the patient doesn't know any better what they could have gone through. [MD 02]
- The whole problem is the written word is very differently interpreted and different written down than the person in front of you when you ask a question....there is something organic in seeing the person's face when they do it. If they have a

score sheet with this ECOG thing and they hand it to me, and they are sitting there, do I know they knew what that meant? Did they internalize that and they justify it? Or are they very stoic? [MD 01]

Clinical applicability. As an NCI-designated Comprehensive Cancer Center, the radiation oncologists are familiar with patient reported outcome measures and the standard instruments utilized by NCI: PROMIS, FACT/FACIT, EORTC, and the newer PRO-CTCAE. Additionally, patient reported outcome measures were often confused by physicians for patient satisfaction scores (e.g., Press-Gainey). This invites concern over the patient's evaluation of subjective outcomes being influenced by the physical appearance of the treatment center or of the physician's bedside manner rather than focusing on the treatment emergent adverse events and outcomes of the treatment.

- PCORI and all these federal agencies wanted to rate health care based on patient reported outcomes. So there were places that had flowers on the desk...they could have completely mistreated you but they were extraordinarily satisfied...there's this lack of recognition from one end of the spectrum to the other end. [MD 1]
- I struggle with the idea of a patient having a piece of paper in their hands with standardized questions, too, because those questions may not actually fit the patient's priorities. Even if you hand me the piece of paper and it has their scores from today if don't have the scores from last week in front of me, I'm not gonna know how this compares. And I'm not necessarily going to be immediately aware of the trend. And I'm not going to take the time to go look up last week's scores. [MD 2]

- The thing I don't like about some of these is when they are simply numerical. And then, as a covering person, you don't necessarily even have a sense of what it means. I mean, to have a useful tool would be one that...you know, very clearly ...almost be like a table with the ranking system but not score 1 2 3 4 5 but like dyspnea, 'none,' 'little,' you know...Something that I can look at say, "Well, that's what's happening." You know? Eating. "hmmm, I really can't eat any solids." "Oh, I can eat something." If I can actually look at it and see what it means and track it over time — that is potentially helpful. But I do agree something that's potentially overly granular or numerical based that isn't intuitively obvious to anybody just walking in the room is not worth anything. [MD 3]

The radiation oncologists identified trends as the critical information in an assessment of a patient reported outcome measure as well as using the patient as their own control. The doctors described three key timepoints in their assessment of a patient undergoing radiation therapy: what were they like before they received *any* radiation, what were they like the last time a radiation oncologist saw them, and what are they like the day of the visit. The radiation oncologists were careful to note the assessment window needed to be since the *last* visit, rather than the typical 7 day window for PROM instruments, because they need to assess the efficacy of a prescribed intervention.

4.2.3 Collaborative Decision-Aid Tool Design

The first consideration for the tool was *what the patients wanted the radiation oncologists to know*. None of the patient participants could voice that. This was the crux of the tool design, as this information would be used to then select questions and prompts from the validated item banks. This was key to tailoring the tool to each individual patient's

needs or concerns. In absence of these data, the decision was made to target the symptoms commonly described by the patient participants as troublesome: dyspnea, nausea, vomiting, esophagitis, and fatigue. The radiation oncologists had also been asked for the symptoms they were most concerned about in the lung cancer patient population. Symptoms outlined by the radiation oncologists also included in-field skin condition (i.e., was the skin breaking down due to the radiation therapy), weight, swallowing, eating, changes in breathing (i.e. concerning for a pulmonary embolism), and chest pain.

The radiation oncologist interviews also informed how the question should be designed, as these physicians were not in favor of numeric or ambiguous scales (Figure 15 & Chapter 1, Figure 3). The numeric format as well as nebulous concepts as “mild,” “somewhat,” and “severe” were considered difficult to interpret due to a patient’s personality, the patient’s interpretation of symptoms, and the patient’s likelihood of seeking intervention. Granular details capturing the activities of daily life were better appreciated by radiation oncologists and patients alike, providing context and examples of how they could be feeling. As such, all participants (including patient participants) ranked the PRO-CTCAE™ lowest (i.e., unfavorably), with comments that it was too general, failing to provide necessary framing. For this reason, PRO-CTCAE™ was no longer considered for the tool.

Review of the PROMIS and EORTC questions regarding nausea and dyspnea by patient participants provided crucial insight for tool design: framing and immediate context was paramount. For example, when reviewing the example PROMIS fatigue prompt ‘*I was frustrated by being too tired to do the things I wanted to do,*’ (Figure 15) participant 34 provided the following feedback:

Since I don't have any usual or daily activities... Can't say I was frustrated doing things that I wanted to do, cause there really wasn't to do. I don't have a gal or anything here with me, so...that would have made a difference!

Participant 34 strictly focused on the 7-day window prompt as the frame of reference, not the activities of daily life he had engaged in prior to therapy (Figure 15). At UIHC, like many U.S. academic medical centers, cancer patients are housed locally in often dormitory-like living arrangements. Thus, there are no normal activities and no

Figure 15

Examples of Items for Dyspnea from PRO-CTCAE™, PROMIS®, and EORTC

PRO-CTCAE™

As individuals go through treatment for their cancer they sometimes experience different symptoms and side effects. For each question, please check or mark an in the one box that best describes your experiences over the past 7 days...

In the last 7 days, what was the SEVERITY of your SHORTNESS OF BREATH at its WORST?				
<input type="radio"/> None	<input type="radio"/> Mild	<input type="radio"/> Moderate	<input type="radio"/> Severe	<input type="radio"/> Very severe
In the last 7 days, how much did your SHORTNESS OF BREATH INTERFERE with your usual or daily activities?				
<input type="radio"/> Not at all	<input type="radio"/> A little bit	<input type="radio"/> Somewhat	<input type="radio"/> Quite a bit	<input type="radio"/> Very much

PROMIS®

Considering your shortness of breath over the past 7 days, rate the amount of difficulty you had when doing the following activities:

	No difficulty	A little difficulty	Some difficulty	Much difficulty	I did not do this in the past 7 days
Dressing yourself without help	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input checked="" type="checkbox"/> X
Walking 50 steps/paces on flat ground at a normal speed without stopping	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> X
Preparing meals	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> X

EORTC

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
Were you short of breath?	1	2	3	4

Note: PROMIS® is ©2006-2017 PROMIS Health Organization; EORTC ©1995 EORTC Quality of Life Group.

household chores. For this reason, Participant 34 marked answered these questions as ‘never’: fatigue *never* interrupted household chores (as there were no household chores) and fatigue *never* interrupted the things he wanted to do (he had none as he was away from family, friends, and work). Thus, the provided answers do not reflect the truth of what the participant was experiencing, as he noted he could not even finish a single television show without falling asleep, yet the responses would indicate a treatment’s minimal impact on the participant’s activities of daily life. Another patient participant noted falling asleep at meals.

The patient reported outcome measure was then designed so the typical EORTC or PROMIS® item ‘lead in / prompt / question’ served as the answer (Figure 15). For example, the radiation oncologists liked ‘taking a short walk (about one block)’ where patient participants described being unable to complete a television show due to fatigue. Item banks were reviewed for prompts capturing this feedback. Once selected, they were reviewed by the thoracic radiation oncologists to determine if they provided enough distinction and captured the symptoms that were concerning. Simple checkboxes for, “I am taking a medication for this,” were also added to provide context and direction if medications needed to be adjusted.

The tool was designed in a MS Word document and consisted of five symptom prompts: nausea/vomiting, cough, chest pain, fatigue, and breathing. The tool was designed pragmatically through the patient’s lens. For example, although the NCI considers nausea and vomiting discrete adverse events, to a patient the end result of nausea is vomiting; thus, vomiting is the most ‘severe’ of the nausea responses (Appendix M). Similarly, chest pain can be caused by esophagitis, coughing, muscle strain, or even a sentinel event such as a

Figure 16*Initial Design for Shared Decision Model/Communication Questionnaire (SDMCQ)*

Radiation Oncology Patient Snapshot		Radiation Oncology Patient Snapshot	
<input type="checkbox"/> I am not up to completing the questionnaire		<input type="checkbox"/> I am not up to completing the questionnaire	
Since the last time you saw a radiation doctor:		Since the last time you saw a radiation doctor:	
Nausea	<input type="checkbox"/> I have vomited (thrown up). <input type="checkbox"/> I have not vomited, but I am nauseated. <input type="checkbox"/> I have not had nausea or vomited but I'm not that hungry <input type="checkbox"/> I can't be around food – the smell or looking at it. <input type="checkbox"/> I have not had nausea or vomited.	Nausea	<input type="checkbox"/> I have not vomited, but I am nauseated. <input checked="" type="checkbox"/> I am taking medication for nausea
Fatigue		Fatigue	<input type="checkbox"/> I can't watch a TV show without falling asleep.
Breathing	Since the last time I saw a radiation doctor: <input type="checkbox"/> I am using oxygen	Breathing	<input type="checkbox"/> I use a wheelchair because I become so short of breath. <input type="checkbox"/> I am using oxygen
Cough	Since the last time I saw a radiation doctor: <input type="checkbox"/> I am taking medication for my cough	Cough	<input type="checkbox"/> I cough when I try to talk or breathe deeply. <input type="checkbox"/> I am taking medication for my cough
Chest pain	Since the last time I saw a radiation doctor: <input type="checkbox"/> I am taking medication for the chest pain	Chest pain	<input type="checkbox"/> My chest hurts, but only when I try to eat. <input type="checkbox"/> I am taking medication for the chest pain
I have a question:		I have a question:	<input type="checkbox"/> Can I use a different medication for I-

Note. Original design for the SDMCQ as implemented through the EHR. Each question was answered using a drop down, with ‘no symptoms,’ as the last option.

pulmonary embolism. The prompt for chest pain provides the context (e.g., it feels like burning, it feels tight) and enables the provider to further assess the symptom to assist in the diagnosis. The tool was shared with Epic[®] EHR programmers who created a simple questionnaire that could be assigned to patients on demand (Figure 16). Prior to release, the tool was required to undergo regulatory and legal review.

Once cleared for use, the digital tool was installed within Epic[®] EHR and could be pushed out through MyChart[®] (Epic[®] EHR Systems Corporation, Verona, WI) as well as through the UIHC tablet, a digital pad with touch sensitivity. The UIHC tablet is wirelessly connected to the EHR for direct patient information capture. MyChart[®] is an application available *via* the internet as well as through applications for Android and Apple smart

devices. MyChart[®] connects seamlessly with Epic[®] EHR and enables real-time access to the electronic health record for patients.

The questionnaire responses then needed to be provided in an easy-to-interpret print layout. After discussion with the radiation oncologists, a table format was selected (Appendix M). This would be printed, provided to the radiation oncologist for the on-treatment visit, to serve as a collaborative decision-aid tool. The hybrid tool (electronic questionnaire, printed tool) was implemented as the SDMCQ. The questions and answers from the patient's visit can be reviewed by the physician within Epic[®] EHR and by the patient through MyChart[®] access.

4.2.4 Implementation: the PDSA's DO Segment

The first SDMCQ was assigned the first week of June 2021. The first subject to successfully completed the assigned SDMCQ on 02 August 2021. In addition to the data sources cited in Table 2, emergent source data for the implementation included field notes from the researchers as well as communication artifacts (i.e., emails, text pages) between the researcher, clinical staff, and stakeholders. These data sources supported multiple observations during the first PDSA cycle. The two significant problem areas identified during initial implementation were (1) assigning the SDMCQ and (2) providing the tablet to the patient:

1. **The department opted out, remember?** The key stakeholder representing the front desk (a supervisor) believed assigning a questionnaire and releasing a tablet to be common foundational knowledge. The supervisor is also a senior administrator within the hospital with significant experience in clinic management as well as the scheduling front desk. However, when the workflow initiated, the front desk staff did

not know either of these procedures (i.e., assigning a questionnaire, releasing a tablet) because the department had opted out of questionnaire assignments. This resulted in a crash course during a hectic Monday morning opening schedule to assign the first SDMCQ. After the crisis was over, it was realized through reflection that because the supervisor cross trains and serves on many committees (including the Epic® EHR committee), the knowledge base differed from the staff's.

2. **Wait, there are TWO schedules?** Epic® EHR enables clinical staff to leave messages regarding a patient's appointment in a *comments* field. For clinical staff, this is readily apparent in Epic's SCHEDULE, which is a conveniently located tab labelled 'schedule'. After three missed tablet distributions, the student researcher learned the front desk staff uses only the Department Appointment Report (DAR). This is significant because the DAR does not show the *comments* field — only the *notes* field, so this is the field the front desk staff relied on. In contrast, clinical staff only have access to modify the *comments* field through patient schedule, although it shows both the *comments* field and the *notes* field. The front desk staff were unaware of the comments made to them in the *comment* field (such as, 'tablet needed'). Humorously, as it was discussed amongst staff, the research nurses reflected that it explained a few things – as they had noticed a problem getting front desk to act on comments placed for research subjects over the past few years.
3. **That doesn't mean what you think it means.** At the start of the PDSA cycle, an adaptation was made to have the front desk both assign the SDMCQ as well as place the prompt text for handing out a tablet at that OTV within the *notes* field. By assigning an SDMCQ, a unique code is then assigned for the front desk staff to

unlock the tablet and have it load all documents unique to that patient. It was misunderstood by front desk staff that this code was equivalent to the SDMCQ being assigned, not realizing that other departments could apply forms to the radiation oncology clinical appointment as well. The supervisor re-educated the staff regarding what the code meant.

4. **Patients wanted a paper decision aid.** Despite providing the samples to the programmers and discussing the objective for the SDMCQ, the final product could not be printed to represent the three timepoints requested by the radiation oncologist: before treatment, visit before, current visit. The programmers were not certain how this could be performed and, in the interim, the decision was made to manually create the printout by monitoring patient completion of the SDMCQ.
5. **You haven't even *had* radiation yet.** For both the *fatigue* and *dyspnea* prompts, a response of, 'I feel the same as before I started radiation therapy' had been provided as an option. A brief interim review suggested this was perhaps too easy – most notably when patients answered that they felt the same as 'before starting radiation therapy' at their initial consult appointment – which was, indeed, before radiation therapy. By providing this answer, a true baseline and assessment of function prior to radiation therapy is not available. The student researcher contacted the Epic[®] programmer and substitute fields were implemented, so the pre-therapy baseline SDMCQ truly reflected the symptoms the patients were experiencing.

4.2.5 Implementation: the PDSA's STUDY Segment

Over the eight week cycle, the SDMCQ was requested 42 times for a total of 15 patients. Six of these patients were short-course radiation and did not continue with

completing the SDMCQ. Of the remaining nine, five were currently receiving therapy, three completed radiation, and one passed away from an unknown cause during the course of therapy. The overall completion rate was 78% (32 completed of 41 assigned); the majority of omitted SDMCQ were assigned to the short course radiation (2 completed / 6 assigned). For the long course subjects, two patients had SDMCQ omissions: one patient due to an SDMCQ assignment error resulting in 4 missed questionnaires and the second patient due to a scheduling failure from planning to the front desk resulting in a single missed questionnaire. Thus, 30 out of 35 SDMCQ scheduled for long-course radiation treatment were completed.

An end-of-cycle-1 meeting was held with the key stakeholders one week after the completion of the first subject who completed baseline and the entire course of radiation. After reviewing the Plan-Do-Study-Act cycle and its iterative nature, seven observations were discussed utilizing a program theory logic chain model (i.e. *if...then...*). The outcomes model was selected from the Kellogg Foundation's development guide. It utilizes a basic strategy employing a simple rationale: *if* this were to occur *then* the outcome(s) would occur. As designed, the model is stepwise over time and identifies resources, activities, outputs, outcomes, and/or impacts (W. K. Kellogg Foundation, 2004). The discussion and model yielded four critical outcomes to be implemented in the next PDSA cycle (Table 7). The radiation oncologists expressed concerns that completion of the SDMCQ by the patients was lengthening the OTVs. Time expended to complete the SDMCQ was requested for cases to date.

Table 7*Observations Made During SDMCQ PDSA Cycle 1*

If...(observation)	Then...(logic outcome)
a lung cancer consult is placed	the SDMCQ/tablet needs assigned
1.§ SDMCQ/tablet needs assigned	clarify the appropriate lung cancer patients
clarification is needed	all patients with treatment consult are assigned
SDMCQ is needed at OTV	the physician marks it on the imaging form
2.§ the imaging form is marked	CT tech copies text into MOSAIQ EHR
the text is in MOSAIQ EHR	therapist marks SDMCQ on scheduling sheet
SDMCQ is on scheduling sheet	front desk schedules SDMCQ/tablet at OTVs
3. the tablet is not distributed	the SDMCQ will not be collected
4.§ a patient has a special complaint	the SDMCQ will not be assigned/collected
5.§ a patient leaves before review	the SDMCQ is not reviewed
6. SDMCQ and physical exam (OTV) notes don't align	the physician will ensure the notes address the discrepancy for clarity and resolution.
7. a 30 day follow-up is scheduled	SDMCQ will not be assigned/collected
§ denotes critical outcome impacting the next cycle.	

4.2.6 Implementation: the PDSA's ACT Segment

The decision was made to adapt the implementation strategy and initiate a second PDSA cycle. Both radiation oncologists believed the information to be valuable, with one stating their routine questions have changed as a result of the SDMCQ and the second explaining the excitement as research is demonstrating the underlying value for patients, emphasizing that if it is at no cost to the department, the benefit to the patient should be underscored. The stakeholders decided to maintain a structured implementation and mapping strategy to enable future adoption of the decision/communication aid into other

clinics, with the breast cancer clinic, head and neck cancer clinic, and brain cancer clinic identified as potential targets. There were four action items from the first PDSA cycle:

1. **Scheduling the SDMCQ at a consult.** For the first PDSA cycle, the potential cases were identified by the student researcher and the front desk was notified to assign the SDMCQ/tablet. With the first cycle complete, it was decided to adapt the implementation to address the treatment consult visits. Front desk staff cannot identify patients with lung cancer who may be considered for long course radiation therapy, as this is determined by physicians after consult. The radiation oncologists agreed regardless of prescribed radiation, the SDMCQ had meaningful information for all patients with lung cancer and, as such, should be scheduled for any lung cancer treatment consult.
2. **Scheduling workflow outlined.** During the first PDSA cycle, if a patient was prescribed long course radiation therapy, the radiation oncologist or student researcher noted in radiation oncology's MOSAIQ EHR the patient required SDMCQ assigned at OTV. The radiation therapists would then notify the front desk at the time of OTV scheduling. This was considered a weak point and consistency was required. Points of discussion included a pre-filled prompt as well as text for the CT-techs to copy from a form into the MOSAIQ EHR notes. The final workflow to implement was for the radiation oncologist to 'uncheck' a box in the imaging request form if a patient with lung cancer was to receive only short course radiation therapy. If the box was checked, the CT-techs could copy text from the imaging request form and paste it into MOSAIQ EHR. This then would notify the therapists to have the SDMCQ/Tablet scheduled at OTV. This was a significant change to workflow for the clinic.

3. **Omitting the SDMCQ for special complaints.** Patients undergoing radiation often have special complaints, which necessitate a review by a radiation oncologist. It was discussed if these complaints should have SDMCQ assigned. Administration pointed out there is not a code to the Epic[®] EHR visit to identify that level of encounter. The radiation oncologists stated that many special complaints are without acute medical need, such as requests for medication refills or parking placards. After discussion, the determination was made not to assign the SDMCQ to special complaints.
4. **What to do if the patient leaves early.** Planning for the first PDSA cycle focused heavily on recent oversight determinations that physicians were required to review patient reported outcome measures and attest to that review. This hampered some SDMCQ assignments, as a licensed provider is required to attest to review. To provide attestation, the radiation oncologists must physically see the patient (or defer that physical visit to another provider). If patients do not have an SDMCQ scheduled for consult, or if it was omitted in error, the radiation verification (i.e., dry run) visit was ideal to obtain a baseline SDMCQ. The problem was a physician visit for attestation is not required that day. During the study review, the radiation oncologists stated they were comfortable if a patient was inadvertently discharged without their oncologist seeing the SDMCQ answers. Feedback from oversight was technically the OTV and was not considered an independent outpatient clinic visit and was thus not subject to attestation requirements. Despite this feedback, both radiation oncologists in the meeting believed it to be a best practice to review in contemporaneously, using a paper printout, as the decision aid was designed to be used.

4.3 Quantitative Results of the Implementation

The Shared Decision Making/Communication Questionnaire (SDMCQ) went live in Epic® EHR the first week of June 2021. It was assigned to any patient that was receiving, or suspected to receive, long course radiation for the treatment of their lung cancer. The first patient received a baseline SDMCQ during the third week of June 2021. The SDMCQ was applied on the patient's first day of treatment. Data were collected through the calendar week the patient completed the course of radiation – approximately eight weeks and captured 4 patients.

4.3.1 Case Demographics

During the first implementation cycle, SDMCQ was requested for 15 patients who were being consulted for radiation treatment for lung cancer. Demographics are provided for the nine patients prescribed long course radiation therapy and for all 15 patients assigned an SDMCQ (in parentheses) (Table 8). In addition to age, gender, race, ethnicity, and insurance status, histology of the lung malignancy is provided as is staging. The TNM staging provides information on the size and extent of the tumor (T), the number and distance of regional lymph nodes (N), and if distant metastasis is present (M). Prognostic staging utilizes the TNM staging with the context of the tumor type and histology.

Table 8*Characteristics of Patients Assigned at Least One SDMCQ*

Characteristic	n =9 (15)	Characteristic	n =9 (15)
Tumor category		Female	3 (6)
Tx	1 (1)	White	9 (15)
T1c	0 (3)	Non-Hispanic	9 (15)
T1	4 (5)	Age (years)	
T2	1 (2)	50 – 59	0 (1)
T3	1 (2)	60 – 69	0 (1)
T4	2 (2)	70 – 79	7 (8)
Node category		80 – 89	2 (5)
N0	1 (6)	KPS [†]	
N1	1 (1)	80	2 (5)
N2	6 (7)	70	7 (8)
N3	1 (1)	60	0 (1)
Metastasis		50	0 (1)
M0	9 (15)	Prognostic Stage	
Insurer		IA	0 (1)
Medicaid	3 (3)	IB	0 (2)
Medicare	4 (9)	IIIA	2 (2)
Private	0 (0)	IIIB	3 (4)
VAMC	2 (3)	IV	0 (2)
		limited stage	4 (4)
Histology			
adenocarcinoma			2 (5)
poorly differentiated non-small cell carcinoma			0 (0)
small cell lung cancer			4 (4)
squamous cell carcinoma			3 (5)
unknown			0 (1)

[†]Karnofsky Performance Status is a subjective assessment in units of 10, with 100 having no signs/symptoms of disease, 50 being house-bound, and 0 denoting death.

4.3.2 Control Demographics

For comparison, data were mined from 20 patients who had undergone long-course radiation therapy: patient participants from the qualitative strand and an available registry for chart-review research. Sample size was larger due to the anticipated sample size of the SDMCQ cohort. Demographics are provided (Table 9).

Table 9

Characteristics of Patients within the Control Cohort

Characteristic	Characteristic	Characteristic			
Tumor category	20	Node category	20	Prognostic Stage	20
T1a	2	N0	4	IA3	1
T1b	1	N1	0	IIB	1
T1c	3	N2	8	IIIA	5
T2a	1	N3	8	IIIB	3
T2	2	M category	20	IIIC	3
T3	3	M0	18	IVA	2
T4	8	M1	2	Limited stage	5
KPS [†]		Female	12	Age (years)	
60	1	White	18	50 – 59	4
70	2	African	2	60 – 69	11
80	12	American		70 – 79	4
90	5	Non-Hispanic	20	80 – 89	1
Insurer		Histology			
Medicaid	2	adenocarcinoma			6
Medicare	13	poorly differentiated carcinoma			1
Private	4	poorly differentiated non-small cell carcinoma			2
VAMC	1	small cell lung cancer			6
		squamous cell carcinoma			5

[†]Karnofsky Performance Status is a subjective assessment in units of 10, with 100 having no signs/symptoms of disease, 50 being house-bound, and 0 denoting death.

4.3.3 Expended Visit Times

The primary objective is to create the collaborative decision-aid tool and to also implement it within the radiation oncology clinic. To assess potential disruption or delays, expended time for OTVs was calculated. Epic[®] EHR provides a patient's check-in time, the rooming time (i.e., time the patient is taken to the examination room), waiting for physician (i.e., the time the medical assistant/nurse is completed and out of the room), the times the resident enters and exits the exam room (if a resident is assigned), the times the radiation oncologist enters and exits the exam room, and the time the patient is discharged from clinic. Unfortunately, these times are manually obtained based on reporting, such as the medical assistant marking the resident's entry into the room or the radiation oncologist marking their exit from the exam room. The two values consistently collected are check-in and discharge.

The radiation oncologists expressed the most interest in the time from check-in to when they entered the exam room, as this would indicate the SDMCQ was delaying the clinical workflow. This was calculated by subtracting the check-in time from the physician-out time or, if this was unavailable, the discharge time (Table 10).

A second measure of OTV time is the time spent by the radiation oncologist in the exam room. This was calculated based on available values using the *waiting for physician time* subtracted from *physician out* time. Values were calculated for controls as well as for patients assigned the SDMCQ. The number of visits is provided that were used for the calculations (Table 11).

The final measure was the time expended to complete the SDMCQ. This is provided and is a unique value to only the clinical implementation project.

Table 10*Average Time Expended for a Radiation Oncology On-Treatment Visit*

	SDMCQ (n)†	Control (n) †
Clinic check-in to physician out	31 (35)	29 (119)
Clinic check-in to physician out <i>or</i> discharge time	31 (43)	30 (134)
Waiting for physician to physician out	17 (25)	17 (87)
SDMCQ completion time	5'55"* (36)	—

† Value is measured in average minutes per OTV; n represents the number of OTV with the specified criteria used to calculate the average

* Calculated at 5 minutes 55 seconds for average completion time.

Of the 32 SDMCQ assigned during OTV, 27 had a referenced patient rooming time.

Comparing the SDMCQ completion time to the patient rooming time, two-thirds were completed before the patient was taken back to an exam room (18 / 27). Of the remaining nine, three were not completed prior to the physician completing the visit (3 / 27). Two of these visits with SDMCQ delays were patients participating in a clinical trial (and were with clinical trial staff) and the third was an inpatient who required complicated care.

4.3.4 Emergent Visits

Three types of emergent visits were captured: unplanned visits to an outpatient clinic (i.e., physician visit during routine office hours), an emergency room visit, and inpatient admission (Table 10). Of those subjects included in analysis, only four had completed their radiation course. Reasons for emergency room visits included bleeding, nausea, and chest pain. Reasons for admissions included chest pain, sepsis/sepsis-like syndrome, chest pain, and hypoglycemia.

Per the Centers for Medicare and Medicaid, emergency room visits for nausea, pain, and febrile neutropenia are considered to be services that could be addressed in an

outpatient setting, not requiring emergency room visits. Emergency room ‘only’ visits for the control cohort were due to pain (n=3), dyspnea (n=1), rectal bleeding (n=2), nausea (n=1), and a central venous access device clot (n=1). Using the CMS criteria, four of these visits (57%) could have been avoided. Of the four patients who had the SDMCQ applied, one had an emergency visit for pain control; this also would meet the CMS criteria as a potentially avoidable visit. The average cost for emergency room visit per patient was \$1,976 for the patients who had completed SDMCQ and \$1,363 for the control cohort. Although this likely reflects the small sample size rather than a difference between the cohorts, it emphasizes the fiscal cost of events deemed by CMS to be preventable.

Table 11

Characteristics of Patients Assigned at Least One SDMCQ

	SDMCQ (n=4)	Control (n=20)
Visits, unplanned outpatient clinics [†]	1	11
Visits, Emergency Room	2	13
Estimated costs	\$ 7, 903	\$ 24, 525
Average cost / patient	\$ 1, 976	\$ 1, 363
Admissions from ER	1	6
Inpatient admissions	2	14
Total days	7	55
Days / admission	3.5	3.9
Estimated costs	\$ 41, 210	\$ 322, 411
Average cost / patient	\$ 10, 303	\$ 17, 912

[†]Non-routine medical oncology, radiation oncology, or surgical oncology visits or referrals to other outpatient clinics as per the oncology service. Services/clinics as part of an emergency room visit or inpatient admission were not included.

4.3.5 Concomitant Medications

For the control population, 199 prescriptions were written during the course of radiation. This averages to slightly over 1 ½ prescriptions per week per patient when assuming the standard 6 week course of radiation for lung cancer (Table 12). Of these, radiation oncologists wrote 45 prescriptions, roughly 1 prescription every 3 weeks for a patient. Comparatively, patients assigned the SMDQ had 1.29 prescription per patient per week with radiation oncologists averaging 1 prescription every other week per patient.

Weekly clinical visits are scheduled with both the medical oncologist to determine tolerance to chemotherapy and radiation oncologist to determine tolerance to radiation. However, prior to each radiation treatment, the radiation therapist will ask if the patient is experiencing pain or if there are any other problems or concerns that need to be addressed. If an issue is raised, the radiation therapist notifies the treating radiation oncologist's clinical nurse or the radiation oncologist. Given the visit ratio (six in radiation oncology, one in medical oncology), it would be expected medications would be prescribed principally in radiation oncology. However, the data do not support this supposition as radiation oncologists were responsible for only 22% of the prescriptions written for the control cohort.

For the control population, opioids were the most common prescription by the radiation oncologists during the course of therapy, accounting for 35% of the opioid prescriptions, ranging from tramadol (0.1 morphine equivalent dose) to Fentanyl (2.4 morphine equivalent dose) (Table 12). Although limited by the small sample size, patients assigned the SDMCQ had only one opioid prescription written and it was not by a radiation oncologist. Interestingly, all of the bolus sodium chloride 0.9% intravenous infusions were

administered by radiation oncologists, even though medical oncology typically maintains infusion therapy. Despite their use as a treatment for esophagitis, radiation oncologists did not prescribe proton pump inhibitors (e.g., omeprazole, pantoprazole, lansoprazole) for the control population but did for patients completing the SDMCQ. Although twenty-one antimicrobial/antifungal prescriptions were written during the radiation therapy courses for the control population; only one was written by a radiation oncologist (nystatin for candidiasis) and none were written for the SDMCQ patients.

Table 12*Concomitant Medications Prescribed During Radiation Course*

	SDMCQ (4)		Control (20)	
	RAD	ALL	RAD	ALL
Prescriptions–All				
Total	12	31	45	199
Per patient	3	7.75	2.25	9.95
Per week	2	5.17	7.5	33.17
Per patient per week	0.5	1.29	0.38	1.66
Opioids	0	1	11	30
Vicodin [®]	0	1	4	8
oxycodone	0	0	1	7
fentanyl	0	0	3	3
MS Contin [®]	0	0	0	3
tramadol	0	0	2	3
promethazine-codeine	0	0	1	2
Dilaudid [®]	0	0	0	1
morphine	0	0	0	1
Percocet [®]	0	0	0	1
Carafate	2	3	7	8
NaCl 0.9% 500 mL bolus	4	4	7	7
lidocaine viscous solution	2	2	5	10

	SDMCQ (4)		Control (20)	
	RAD	ALL	RAD	ALL
lidocaine-prilocaine cream	2	1	4	6
pantoprazole	1	1	0	5
Tylenol [®]	0	0	2	2
albuterol	0	0	1	3
alteplase	0	0	1	1
benzonatate	0	1	1	1
magic mouthwash	0	0	1	1
meloxicam	0	0	1	1
nystatin	0	0	1	3
ondansetron	0	3	1	17
Silvadene [®]	0	0	1	1

4.3.6 Adverse Events

The radiation oncology on-treatment visit notes as well as nursing notes were coded for adverse events using the CTCAE v4.03. The OTV notes captured 292 adverse events for the control cohort (n=20) and 26 for the four patients who had the SDMCQ applied through the first PDSA cycle (Table 13). The most common adverse events identified in the control cohort were fatigue (12%), odynophagia (11.6%), dysphagia (6.5%) and esophagitis (5.8%). The control group had an average of approximately 14.6 adverse events documented per patient. For the limited SDMCQ sample size, the most common adverse event was esophagitis (11.5%) followed by odynophagia (7.7%) and throat pain (7.7%). Patients with the SDMCQ applied had an average of 6.5 adverse events documented in the OTV.

The most common symptoms and treatment emergent adverse events described by patients in the qualitative strand were fatigue, dyspnea, nausea & vomiting, dysphagia,

pain, dermatitis radiation, and esophagitis. These symptoms contributed to the design of the tool; however, this is not consistent with the OTV documentation. Although fatigue is the most commonly coded for the control cohort, it is not present in the SDMCQ cohort – despite the four patients coding for fatigue nine times in the SDMCQ. Nausea & vomiting was documented approximately 4% of the time in the control cohort and not at all in the SDMCQ. However, antiemetics / antinausea medication use was marked six times by the SDMCQ patients and a lack of appetite to nausea four times. It is reasonable to consider the radiation oncologist did not further capture the nausea or fatigue, as the SDMCQ answers are imported directly into the OTV note by the radiation oncologist. However, a lack of independent assessment or comment from the radiation oncologist within the OTV note suggests an agreement or validation by the radiation oncologist of the symptoms and their severity.

On-treatment visit notes for both the control cohort and the patients who had completed the SDMCQ were reviewed (SDMCQ = 22; control = 131). Of the 153 notes reviewed and coded, the most common physical assessment performed by the radiation oncologists was for skin (n=148), general appearance (e.g. ‘looks ok,’ ‘in no apparent distress’; n=87), and breathing (e.g., ‘breathing comfortably on room air’; n=41). Surprisingly given the patient population’s disease under treatment, a respiratory examination was completed in only 11.1% of the OTVs.

4.3.7 Shared Decision Making Questionnaire (SDMCQ) Responses

The SDMCQ was applied beginning the first week of June 2021, targeting patients prescribed long-course radiation therapy for treatment of their lung cancer. All patients had the SDMCQ applied, regardless of how far along they were in their radiation treatment.

During the first implementation cycle, 20 questionnaires were completed across four patients; responses are provided in Appendix N. A brief summary is provided in Table 13.

Fatigue (n=9) and cough (n = 14) were the most common endorsed symptoms (Table 13), although use of a cough medicine was only acknowledged three times. Interestingly, these were the symptoms most frequently not captured within the OTV. The least common symptom was dyspnea, which was acknowledged only 3 times by a patient and documented once within an OTV. When there was agreement between the SDMCQ responses and the OTV documentation, it was primarily due to an absence of symptoms rather than an alignment between the patient and provider.

Table 13

SDMCQ Answers Compared to OTV Documented Adverse Events (AEs)

Symptom / Adverse Event	Documentation Source	
	SDMCQ	OTV notes
Patient 50		
Nausea	1	0
Cough	2	0
Pain	2	0
Fatigue	3	0
Breathing	0	0
Patient-51		
Nausea	2	0
Cough	4	1
Pain	3	2
Fatigue	4	0
Breathing	3	1

Symptom / Adverse Event	Documentation Source	
	SDMCQ	OTV notes
Patient-52		
Nausea	0	0
Cough	1	1
Pain	1	1
Fatigue	1	0
Breathing	0	0
Patient-53		
Nausea	0	0
Cough	6	0
Pain	0	0
Fatigue	1	0
Breathing	0	0

Reviewing OTVs for the four patient participants, documentation addresses some of these discrepancies. For example, patient 53 marked on the SDMCQ that “I may cough but it doesn't bother me.” The radiation oncologist further documented in the OTV note of the same date, “...reports an occasional cough...did have a small amount of hemoptysis yesterday.” The hemoptysis was not reported in the SDMCQ despite a prompt for, “I am coughing stuff up (snot, sputum, blood).” Similarly, patient 52 answered on the SDMCQ that they were not experiencing chest pain (which also queues for pain with eating or swallowing), but upon evaluation by the radiation oncologist, the following is noted, “Has some gastric reflux over the weekend (esophagitis grade 2) that occurred with the water; improved with sulcrafate [*sic*] and pantoprazole.” Esophagitis/gastric reflux should have triggered the SDMCQ response, “My chest hurts, but only when I try to eat.” This highlights misalignment that is captured in the SDMCQ response *versus* the OTV note. It is unknown if this was reconciled in a collaborative

discussion between the radiation oncologist and the patient, if the patient was educated about chest pain and symptoms, or if the discrepancy was simply allowed to exist. None of the OTV reviewed had explicit documentation that differences between the physical exam and SDMCQ were discussed or a determination of which assessment was considered final or ‘true’.

4.3.8 Radiation Therapy Compliance

The MOSAIQ® EHR is a ‘verify and treat’ system for radiation oncology, capturing the dose administered from each radiation beam, the end time of that beam, and if there are any errors or overrides that have occurred during delivery. Recorded within the system directly from the linear accelerator, doses, times, and dates are not subject to human errors, such as transcriptions or omissions. All patients received their prescribed total dose of radiation and the fractionation strategy (i.e., dose per radiation fraction, number of fractions per day) remained unchanged (Table 14). Breaks are marked as “B” in MOSAIQ® whereas a no-show/cancellation (e.g., weather, patient preference) are

Table 14

Radiation Oncology Treatment Compliance

	SDMCQ (4)	Control (20)
Prescribed dose completed per patient (average %)	100	100
Treatment breaks per patient (average)	0.75	0.4
Range	0 – 3	0 – 3
Total break days per patient (average in days)	0.375	0.65
Range (days)	0 - 1.5	0 - 5

marked as an “X” by the attending radiation therapists. This enables number of treatment breaks to be distinguished from a patient’s failure to show for treatment. Unfortunately,

reasons for radiation breaks are not routinely documented by medical staff in Epic® EHR or MOSAIQ®. Documented reasons for breaks included infection, anemia requiring blood transfusion, general malaise, chest pain requiring emergent evaluation, and treatment emergent altered mental status.

4.3.9 Chemotherapy Compliance

Chemotherapy is also a function of dose over elapsed days. In addition to tumor histology and stage, considerations for prescription include age, body mass, body surface area, renal function, and bone marrow function. National guidelines for lung cancer include multiple therapeutic regimens, including weekly regimens, an every 21-day regimen, and an every 28-day regimen. To evaluate efficacy across these varied regimens, a relative dose intensity (RDI) calculation is employed (Chapter 3). This calculation evaluates how much of a prescribed drug was administered against the ideal and the number of elapsed days for the treatment against the ideal. Literature indicates the RDI must be ≥ 85 for efficacious chemotherapeutic treatment. Chemotherapeutic regimens prescribed as well as the calculated RDI are provided for both the control and patients assigned the SDMCQ (Table 15). The details provided do not account for provider-determined modifications to the regimen, such as adjusting for actual creatinine or using ideal vs. actual body weight.

In total, the 20 control patients experienced 14 breaks in totally 26 weeks. The most common reason for holds was inadequate blood cell counts (n=10), including decreased neutrophils, platelets, or generalized pancytopenia. Esophagitis (n=2), febrile neutropenia (n=1), sepsis (n=1) and anaphylaxis (n=1) also contributed to holds as did the patient declining further chemotherapy (n=3). Two control patients had their

chemotherapy regimen changed: one patient was switched from cisplatin / etoposide to carboplatin / etoposide due to acute kidney injury and another switched from carboplatin / paclitaxel to carboplatin / Abraxane[®] due to paclitaxel-associated anaphylaxis.

Table 15*Chemotherapy Details and Treatment Compliance*

	SDMCQ (4)	Control (20)
Initial prescribed cytotoxic regimen (count)		
cisplatin / etoposide [†]	1	2
carboplatin / vinorelbine	0	1
carboplatin / paclitaxel [*]	3	12
carboplatin / etoposide	0	4
cisplatin / pemetrexed	0	1
Cycle length		
7 calendar days (weekly)	3	13
21 calendar days	1	7
Relative Dose Intensity		
Average	91.9	80.8
Range	70.5 – 100	41.1 - 100
Number < 85	1	10
Holds (i.e., chemotherapy omitted for 7 days)		
Average holds / patient	0.5	0.7
Average weeks / patient	0.5	1.3
Average weeks / hold	1	1.9

Although sample size is small, patients who had the SDMCQ applied had a higher level of chemotherapy compliance, with only one of the four having a calculated relative dose intensity of less than 85. The reason for the hold contributing to the low RDI was a localized infection requiring multiple courses of antibiotics. Incidentally, this same

infection triggered an emergency room visit; presumably, this could have been addressed by an outpatient visit.

4.3.10 Summary and Key Points

Initial findings suggest the collaborative decision aid tool does not add time to the on-treatment visit, with the average completion time of the SDMCQ averaging just over six minutes and the OTV averaging 30 minutes for visits utilizing SDMCQ whereas control visits average 29 minutes. The initial implementation of the SDMCQ and the collaborative decision aid tool, as well as review of the on-treatment notes highlights that these documents do not align well with the adverse events recalled by patients and radiation oncologists. The on-treatment visit physical exam principally notes skin and OTV notes document fatigue, odynophagia, dysphagia, esophagitis, cough, and dermatitis radiation as the treatment emergent events most frequently documented. Odynophagia, dysphagia, and esophagitis are the common sources of pain for patients undergoing radiation therapy for lung cancer and are well-established sequelae. However, roughly 50% of the patients presented to the ER for potentially preventable events as determined by CMS. Lastly, 50% of the control patients did not achieve the relative dose intensity literature has associated with improved treatment outcomes, with some of the holds due to esophagitis and patient declining further treatment. This provides an area of improvement for shared decision making and collaborative communication to help reduce the side effects of treatment and increase treatment compliance.

4.4 Mixed Methods Results

This exploratory sequential study sought to answer the question:

How does the impact of the collaborative decision-aid tool inform recommendations for future designs and implementation ?

by designing a collaborative decision aid tool for patients undergoing radiation for lung cancer, implementing it within an academic radiation oncology center, assessing its impact, and then integrating these results. Considerations and integrations are provided (Table 16) with emphasis on barriers, facilitators, practice considerations, stakeholders, and insights from the literature.

4.4.1 Adverse Event Comparisons

The three most common adverse events as identified through the semi-structured interviews with patient participants, the literature, the on-treatment visit notes, and the SDMCQ were compared (Table 16). This mixed analysis explores adverse events that were recalled during the patient interviews *versus* adverse events that were contemporaneously reported (transcript *vs.* SDMCQ), the adverse events physicians document compared to their concerns or the patient's SDMCQ responses, and the patient educational materials citing the top side effects of combined chemotherapy and radiation for lung cancer. All adverse events listed in the transcripts and on-treatment notes are on the SDMCQ except dysphagia; however, odynophagia, heartburn, and esophagitis are grouped with chest pain. It is unclear if patients are identifying 'chest pain' with the esophageal pain. Further use of the SDMCQ is necessary before considering an adjustment to align with CMS' potentially avoidable adverse events that could trigger emergency room visits.

Table 16

Top Three Adverse Events as Identified From Interview Transcripts, On-Treatment Visit Notes, Patient-Education Material, and Centers for Medicare & Medicaid Services.

Source	Adverse Event		
	1	2	3
Patient transcripts	Fatigue	N / V*	Dyspnea
Radiation oncologist transcripts	Weight	Breathing	Esophagitis
OTV notes – controls	Fatigue	Odynophagia	Dysphagia
OTV notes – cases	Esophagitis	Heartburn	Odynophagia
SDMCQ responses	Fatigue	Cough	Chest pain
Patient education material [†]	Odynophagia	Fatigue	Erythema
CMS potentially avoidable	N / V*	Fatigue	Pain

[†]Patient education material provided by The American Society for Radiation Oncology (ASTRO) (2020)

*N / V: nausea & vomiting

4.4.2 Time Expended During On-Treatment Visit and Adverse Events

Literature identifies time expended for patient reported outcome measure implementation as well as shared decision making to be a significant barrier. A contributing factor to shared decision making is the complex nature of patients with multiple comorbidities. The mixed analysis explored if time expended for an on-treatment visit was impacted by the number of adverse events as recorded by the on-treatment visit notes (Table 17). The SDMCQ is not included in the analysis, only adverse events recorded by the radiation oncologist in their on-treatment visit note.

Table 17

On-Treatment Visit Time and SDMCQ Completion Time Compared to Number of Adverse Events

	On-Treatment Visit		
	Adverse Events		Time [†] (mean ± s.d.)
	count	mean ± s.d.	
Control cohort, overall n=20	301	15 ± 7	30 ± 15
SDMCQ cohort, overall n=4	31	8 ± 4.3	30 ± 16
Control cohort			
≤ 10 AEs	48	8 ± 2	24 ± 10
10 < AEs ≤ 20	151	15.1 ± 3.1	32 ± 15
> 20 AEs	102	25.5 ± 5.4	36 ± 17
≤ 30 minutes / OTV	121	12 ± 6.2	25 ± 10
> 30 minutes / OTV	180	19 ± 7	36 ± 16
SDMCQ cohort			
≤ 10 AEs	17	5.7 ± 1.2	24 ± 10
10 < AEs ≤ 20	14	N/A	47 ± 18
≤ 30 minutes / OTV	17	5.7 ± 1.2	24 ± 10
> 30 minutes / OTV	14	N/A	47 ± 18

[†] Measured in minutes

4.4.3 Unscheduled Visits and Adverse Events Comparison

The Centers for Medicare and Medicaid identified seven causes for emergency room visits as potentially avoidable: nausea, vomiting, diarrhea, dehydration, anemia, febrile neutropenia, and pain. Thus, emergency room visits and diagnoses were compared against the number of recorded adverse events in OTV notes as well as in the interview transcriptions (Table 18). The table reveals that the CMS adverse events have been captured in OTV notes and also in the diagnosis for the emergency room visit

(i.e., nausea, pain, anemia). These adverse events are manageable by radiation oncologists and, as such, should be reviewed against the likelihood of a need for urgent care.

Table 18

Frequency of CMS' Potentially Preventable Adverse Events as Captured Through Transcriptions, On-treatment Visit Notes, and Emergency Room Visits

Potentially preventable Adverse Event	Interviews	Data Source [†]			
		OTV		ER [‡]	
		C	S	C	S
Nausea	14	7	0	1	0
Vomiting	8	4	0	0	0
Diarrhea	3	5	1	0	0
Dehydration	2	1	0	0	0
Anemia	0	3	0	2	0
Febrile neutropenia	0	2	1	0	1
Pain	14*	69 [§]	9	4	1

[†] Interviews: those completed during qualitative strand; OTV: On-Treatment Visit; ER: Emergency Room; C: control cohort; S: SDMCQ cohort

[‡] Includes ER-to-admission visits

* Includes esophagitis, odynophagia, throat pain, and unspecified pain

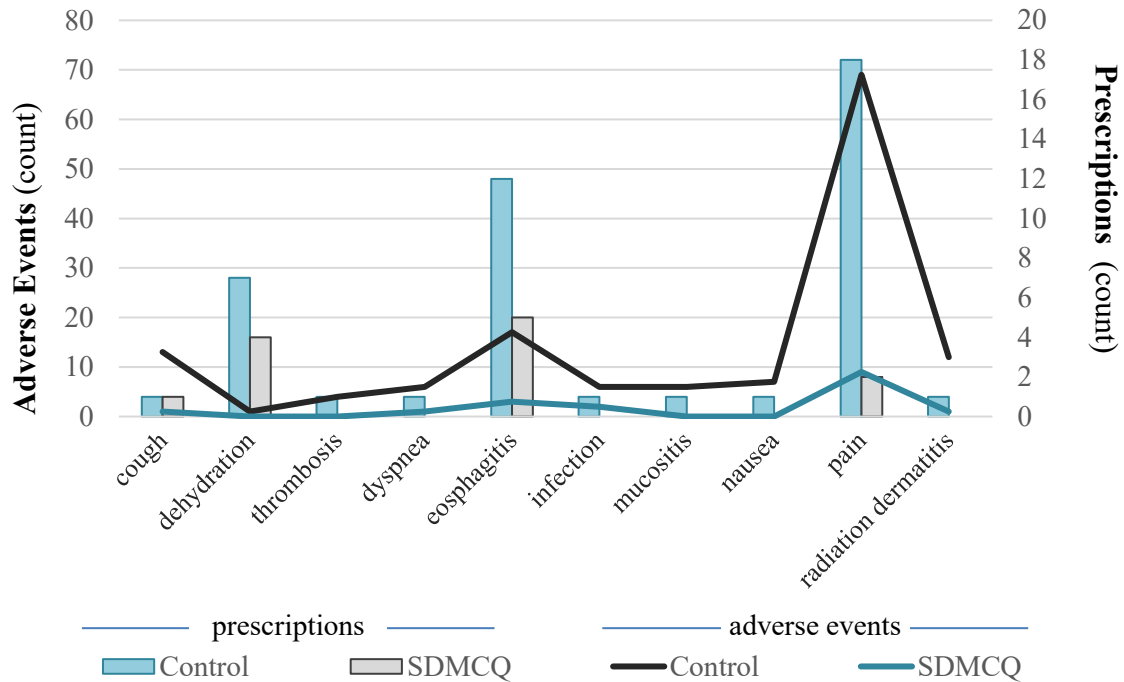
[§] Includes abdominal pain, chest pain, back pain, hip pain, esophagitis, odynophagia, and throat pain.

4.4.4 Adverse Events and Concomitant Medications

Adverse events identified by radiation oncologists can drive prescriptions for concomitant medications, including opioid prescriptions as well as antimicrobials and antifungals. The collaborative decision-aid tool could heighten awareness to adverse events, initiate earlier medical interventions, reduce emergency room visits and possibly reduce admissions. Adverse events and the associated concomitant medications

Figure 17

Incidence of Adverse Events Contrasted to Prescriptions Written by Radiation Oncologists During Long Course Radiation Therapy for Lung Cancer



Note. Prescriptions are those written by radiation oncologist during the long-course radiation therapy treatment.

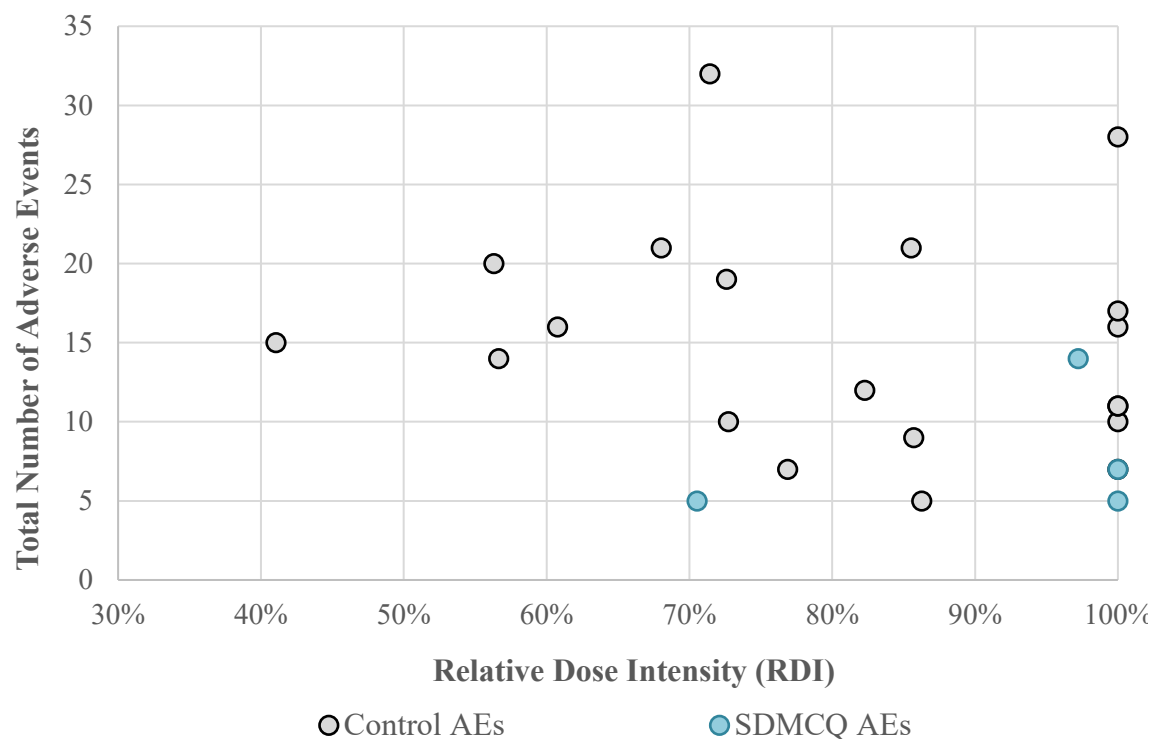
prescribed in an outpatient basis were explored against the control cohort and patients who had the SDMCQ applied (SDMCQ cohort) (Figure 17). Due to the limited sample size of the SDMCQ, correlations and inferences cannot be drawn. The graph does not reflect drug compliance or the number of refills provided for each prescription.

4.4.5 Compliance and Adverse Events

Adverse events can create delays or dose reductions in chemotherapy and radiation therapy, reduce the overall efficacy of therapy and resulting in decreased survival. Adverse events were abstracted from on-treatment visit notes, quantified, and plotted against the relative dose intensity administered during the chemo-radiation therapy (Figure 18).

Figure 18

Relative Dose Intensity for Chemotherapy compared to the Total of Adverse Events



Note. Adverse events reported as total documented in on-treatment notes. Each data point represents a single patient.

4.4.6 Format of the Collaborative Decision-Aid and Adverse Events

The collaborative decision-aid tool was formatted to review the most common or problematic adverse events, whether they are related to treatment, symptoms of the cancer, or other underlying comorbidities. Three sources of information were utilized when considering format and adverse event inclusion: interview transcriptions (patients and radiation oncologists), literature regarding format, and the three selected sample patient reported outcome measure surveys (PROMIS[®], PRO-CTCAE[™], QLQ-C30) (Table 19). The recall period was a concern for patients and context/granularity was

positive, as was a written record and paper tool. The format needed to adapt for patients who were slow readers.

Table 19

Format Consideration using Adverse Event Prompts for the Collaborative Decision-Aid Tool as Identified by Interviews, Literature, and Current Patient Reported Outcome Measure Tools

Formatting for Time	
QUAL	The seven-day recollection window confused patients when reviewing sample PROM questions. The radiation oncologists did not find a strict window meaningful – instead wanting to know what had happened since the last radiation oncologist visit. Codes: timeframe – negative, question timeframe, timeframe-interruption, timeframe – important, and SDM: usefulness.
QUANT	90.9% of the commonly used instruments in oncology utilize a seven day recall period. The Symptom Distress Scale does not have a defined recall period.
MIXED	Because radiation is not delivered on holidays or weekends, and the number of outpatient physicians’ visits the patients, a strict window does not meet needs pragmatically. Patients are concerned they must omit problems that were of significance to them whereas radiation oncologists expressed wanting to know current concerns rather than resolved events from a week prior. The format of the questionnaire was adapted to reflect the milestone of “last radiation oncology doctor visit.”

Table 19 (cont'd)

Format Consideration using Adverse Event Prompts for the Collaborative Decision-Aid Tool as Identified by Interviews, Literature, and Current Patient Reported Outcome Measure Tools

Formatting for Severity	
QUAL	<p>Patients described adverse events as being more severe than they had a frame of reference for, particularly heartburn and fatigue. The severity of the events was such that patients no longer had routine daily activities. Codes: no normal, new normal, granularity, and no frustration. Quantizing the on-treatment visit notes revealed the most commonly documented adverse events to be fatigue (49%), odynophagia (43%), cough (26%), esophagitis (24%), and dysphagia (24%).</p>
QUANT	<p>The current instruments queue for severity without context: PRO-CTCAE™ has ‘very severe,’ for the maximum score (i.e. four points), where PROMIS® has ‘much difficulty,’ for the maximum (3 points), and QLQ-C30 has ‘very much’ (four points).</p> <p>Without context for severity, a patient may prematurely provide the maximum quantitative score when they have not yet reached the most difficult part of their cancer treatment. This was echoed by radiation oncologists, who were aware a patient’s only sphere of reference is their personal experience, compared to the medical training of the physician.</p>
MIXED	<p>For this reason, numeric scales were not considered helpful by physicians, as there is no true gold standard for the severity scales. Providing a contextual answer (rather than a numeric one) serves two purposes: providing commonly understood benchmarks as well as preparing patients for the severity of the side effects they will experience.</p>

Table 19 (cont'd)

Format Consideration using Adverse Event Prompts for the Collaborative Decision-Aid Tool as Identified by Interviews, Literature, and Current Patient Reported Outcome Measure Tools

Formatting for Function

QUAL	<p>Interviews revealed patients valued their physicians' medical knowledge as well as preferred academic knowledge compared to publicly available information. Identified barriers included feeling as being the only one to receive the information, a need for a gatekeeper, and taking the time to read during the hecticness of a clinic visit. Codes: slow reader, reading, academic information, written record, intelligence, and health literacy. A participant who identified as a slow reader took 52 seconds to read a PRO-CTCAE™ question for fatigue, one minute and 37 seconds</p>
QUANT	<p>answering three PROMIS questions for fatigue, and one minute and 41 seconds to answer four QLQ-C30 questions regarding fatigue. This extrapolates to just over 12 and a half minutes for this participant to complete the QLQ-C30.</p>
MIXED	<p>Literature recommends a questionnaire be no more than 20 minutes time investment at baseline and then 10 to 15 minutes for subsequent assessments. As suggested by observation during the qualitative interviews, a self-described slow readers who are medically literate can take up to 32 seconds per question prompt, restricting the number of questions to as few as 28 questions. With caregiver constraints due to the pandemic, as well as tight staffing requirements within the clinic, at this time the more reasonable solution is to create a short, pragmatic, and focused collaborative decision-aid tool that will addresses clinical needs rather than focusing on maintaining validation.</p> <hr/>

4.4.7 Format and Unscheduled Visits

The format of the instrument encompasses the format of the questionnaire (i.e. SDMCQ) on the MyChart[®] application or tablet and also its printout which is considered the collaborative decision-aid tool). Paper was requested by patients to minimize on repeated communication due to their dyspnea and also to provide the same discrete information across providers (codes usefulness, paper: positive, paper: graphics, repeated communication, and trend over time). As stated by patient participant 26, “[Paper] would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don’t. This could have been a reference for all the other doctors this would be helpful.”

However, a paper printout is a significant barrier to using the tool for an unscheduled visit: someone having to log in to Epic[®], print off the collaborative decision aid tool, provide it to the radiation oncologist, and all without slowing down a very active clinic for a patient who does not have a scheduled appointment. Additional considerations from the implementation committee were *who* would identify the patient needed a questionnaire, *when* would it be completed (waiting room or exam room), and *how* would the radiation oncologist be notified. Typical on-treatment visits are scheduled in 15 minute slots with providers only allowed two to three exam rooms to run their clinic. This does not seem to be an issue until reviewing the expended time per OTV: an average of 30 minutes per visit with a standard deviation of 15 minutes. If a radiation oncologist has only two exam rooms and is expected to see four patients, the time within the exam room cannot be more than 30 minutes. An addition of a unscheduled visit or a

‘special complaint,’ staffed by the attending nurse clinician or resident can have significant ramifications that impact the day’s entire clinical workflow.

Paper format for the tool was considered a priority for routine on-treatment visits but was not deemed key for an unscheduled medical visit. Hybrid models, such as the SDMCQ only or having a smart-text for the physicians to use to query directly, can be reviewed as uptake increases.

4.4.8 Adverse Events and Implementation of the Collaborative Decision-Aid Tool

The collaborative decision-aid tool was formatted in Microsoft Word to fit on a single sheet of paper focusing on five symptoms identified as troublesome or medically important (i.e. nausea/vomiting, fatigue, dyspnea, cough, chest pain). Weight was also included from the day’s vital signs. Additionally, a mockup of the desired printed output was created. This was provided to the Epic[®] software group to implement the questionnaire’s build and required four months for implementation. This was due to regulatory and compliance confirmation in addition to the foundational programming. Additional formatting conditions became apparently: swipe from page to page or scroll, check-boxes or press-buttons, choose only one vs. choose all that apply, and selecting the order of the responses. There was not a test environment for the SDMCQ so it was unable to be seen by the researchers.

Once initiated, the SDMCQ responses were reviewed weekly for issues, and one became readily apparent. Radiation oncologists had requested a way to know if a patient felt the same as prior to receiving radiation. To address this, both the fatigue and dyspneal prompts included, “I feel the same as before I started radiation therapy.” The thought was patients would understand this should be selected only after beginning

radiation therapy – however, for the first four patients to have the baseline assessed (i.e., 0 fractions or fraction 1), the prompt for dyspnea was answered *I feel the same as before I started radiation therapy* despite it being a baseline assessment. For this reason, this answer was removed and contextual detail provided.

Patient participants had positive responses with MyChart[®] and were computer literate (codes: proactive, single-line access, new information, MyChart: yes, safety net, and gatekeeper). This is significant because the SDMCQ can also be accessed through MyChart[®] up to one week prior to the completion date; the specific window for completion (i.e., 1 day prior, 2 days prior) is set when the SDMCQ is assigned. Ideally, the SDMCQ should be completed when an outpatient visit is scheduled due to a welfare concern for the patient if they complete a question indicating a need for immediate medical intervention. The minimum completion window possible in Epic[®] is one day; thus, it is possible a patient couple complete the questionnaire the night before. That has not yet happened.

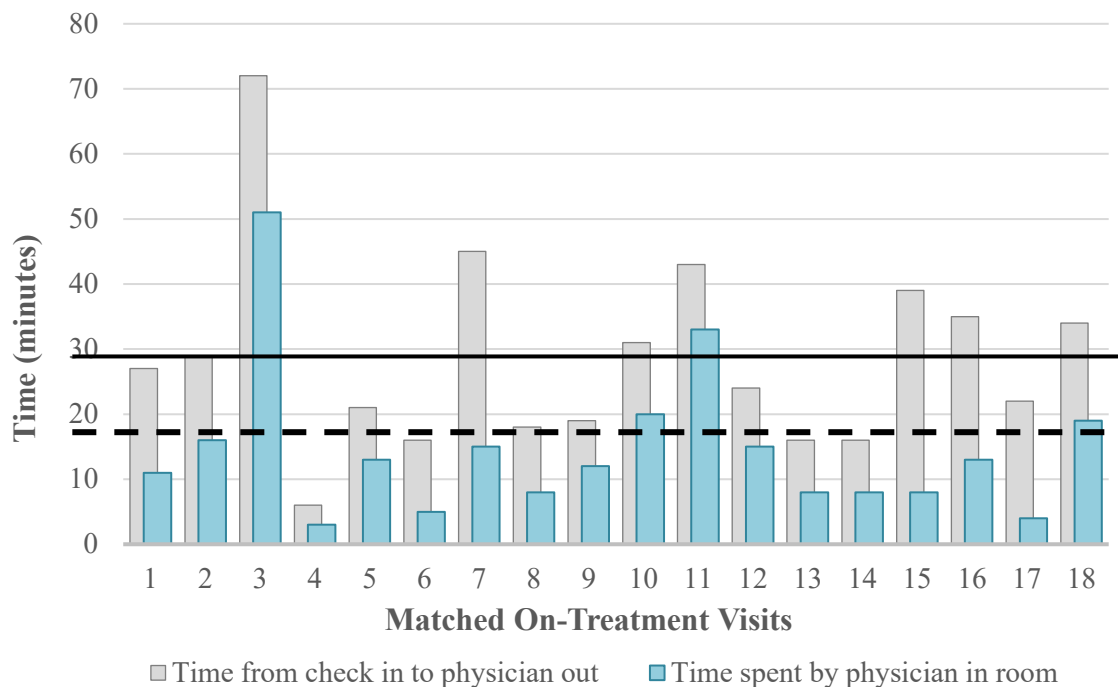
When reviewing the adverse events noted by the radiation oncologists and comparing them to the on-treatment notes, there was a discrepancy. Focusing on the adverse events of interest to the Centers for Medicare and Medicaid Services, nausea was reported by three times but not mentioned by the physician and pain was captured only 50% of the time (Table 14). Fatigue was not captured by the physicians but was reported by patients nine times, including the most severe metric *I have not been able to watch a TV show without falling asleep*. This aligns with the literature which indicates installation of the instrument is only part of the process and that active implementation of subjective, assessment, and plan must be primed and maintained to increase shared decision making and having the patient's voice heard.

4.4.9 Implementation and Expended Time

A concern expressed both in the literature and throughout the work was the impact on the clinic as a function of expended time. The average on-treatment visit times are provided in Table 10. Taking this a step further, the time spent by the physician with the patient was compared to how long the patient was present in the clinic (Figure 19). Times are estimates from workflow times logged into Epic[®]. Time spent with patient by physician was calculated by subtracting the “physician out,” time from “waiting for

Figure 19

Estimated Time Spent by Radiation Oncologist with Patient During On-Treatment Visit



Note. Represented on-treatment visits are those when the collaborative decision-aid tool was utilized. Data represent 18 on-treatment visits that had both the time spent with physician as well as time spent from check in to when the physician left the exam room. Dashed line represents average time for time spent by physician in room for the control cohort (17 minutes). Solid line represents control cohort average time from check-in (29 minutes). Average times for SDMCQ visits are 14.5 minutes with the physician and 28.5 minutes from check-in to physician exit.

physician.” Time spent until physician exit was calculated by subtracting “waiting for physician,” from “check in time.” Using the SDMCQ cohort, data were pulled for visits where both the ‘time spent by the physician,’ and ‘time from check in to physician exit,’ were available. This display explores the impact of the SDMCQ on time spent with physician and time spent in clinic, as best can be estimated from Epic[®]. Due to limited sample sizes, an inference cannot be made but a trend is not observed.

4.4.10 Implementation and Unscheduled Visits

Implementation of the collaborative decision-aid tool should help reduce the number of after-hours urgent care visits or emergency room visits if uptake is maintained. Two problems with unscheduled visits could be addressed with the SDMCQ and the resultant decision-aid tool and are analyzed briefly using a mixed strategy (Table 20, next page).

Table 20*Implementing Unplanned Outpatient Visits into the Collaborative Decision-Aid Workflow***Continuing the Continuity of Care**

QUAL	<p>Patients liked feeling as part of the team but expressed frustrations and doubt when providers failed to communicate between each other or provided them conflicting information. Radiation oncologists note the key to providing quality care for a patient is as much about the patient's personality as it is about the practice of medicine. The collaborative decision-aid tool was considered key to provide consistent information across multiple providers, including on-call and emergency room staff (codes: barriers to communication, repeated efforts to contact, medicine by committee, information traffic, and familiarity with provider). Codes: team, familiarity with provider, provider-to-patient communication, and characteristics and context.</p>
QUANT	<p>Radiation oncology is one of three oncology outpatient services caring for patients with lung cancer. A review of the baseline cohort suggests that on average, patients with lung cancer have 44 notes written during the radiation treatment; of these, only 36% are from radiation oncology (~ 15.5 notes / patient).</p>
MIXED	<p>In addition to these notes directly in Epic[®], UIHC participates in CareEverywhere[®] and scans in any outside medical records into the 'Media' tab as a PDF. This, coupled with the UIHC policy not mandating notes to be finalizing for 10 business days, leads to a delay in information and a loss of signal regarding key events. Patients sought to resolve this issue by having a paper communication-aid tool. Radiation oncologists would like to see the patient reported outcome measures as a centralized screen or report that they can review, similar to the Epic[®] snapshot screen. Patient reported outcome measures as a trend over time will assist in decreasing a knowledge gap to medical staff unfamiliar with the patient. A centralized location would be best for these metrics.</p>

Table 20 (cont'd)*Implementing Unplanned Outpatient Visits into the Collaborative Decision-Aid Workflow***Toxicities Over Time and Iowa Stoicism**

QUAL	<p>Patients acknowledged they were not as honest as they should have been, contributing to emergency room visits and unplanned outpatient visits. Radiation oncologists – particularly those who had practiced outside of Iowa – termed this the Iowa Stoicism, possibly associated with the agrarian culture with over 90% of the state’s land dedicated to farming. Patients described this as “toughing it out,” and interestingly families also did not take action. Codes: treatment, self-reliance, self-care, choice, symptoms, and trust in provider</p>
QUANT	<p>Toxicity over Time (ToxT) is an adverse event evaluation method that is unique to treatments where the patient is evaluated daily or is willing to self-report in a daily log. The concept is the number of days a patient experiences not only the adverse event but also the severity level for those days. Thus, ToxT provides insight not only into the maximum severity of an event experienced, but also how long the patient can expect to experience the adverse event and if is expected to get worse and – if so – when. Converting the text answers to severity grades (i.e. quantizing the data) provides a bridge to radiation oncologists, who are trained in the NCI’s severity scoring system.</p>
MIXED	<p>Failing to promptly report adverse events not only jeopardizes a patient’s health, it also negatively impacts future patients as they will not know what to expect regarding treatment and its side effects. With the ever-increasing focus on the patient’s voice, it is not simply a function of listening, but a function of encouraging patients to speak. Consistent with the literature, ‘toughing it out’ and stoicism remind us patients may not want to be labelled as difficult and may seek to please providers rather than be open about their problems and concerns.</p>

CHAPTER 5

5 DISCUSSION

5.1 Introduction

This primary objective of this research was to explore the creation and initial implementation of a collaborative decision-aid tool by addressing the following questions:

1. How do the stakeholders, practice considerations, and evidence base inform the ideal design and implementation of a collaborative decision-aid tool?
2. What is the impact of the collaborative decision-aid on the medical management of patients actively undergoing radiation treatment for lung cancer?
3. How does the impact of the collaborative decision-aid tool inform recommendations for future designs and implementation ?

These questions will be addressed through synthesis of qualitative, quantitative, and mixed results as well as from the literature base. The contribution to the knowledge base is implementation of a hybrid collaborative decision-aid utilizing a pragmatic quality improve process. Literature searches suggest a clinical implementation process is novel for a collaborative decision-aid utilizing patient reported outcome measures; the current literature base has evaluated applying and evaluating decision aids through the traditional clinical trial methodology, assigning dedicated research staff and research

procedures to a clinical process. Regimented research interventions provide internal validity but may be negatively impacting generalizability and fidelity. Implementing the collaborative decision-aid tool as a clinical initiative enables real world findings—not only for outcomes of interest but also for future implementation strategies.

5.2 Major Findings of the Dissertation

5.2.1 Ideal Design and Implementation

Shared decision making as well as the use of patient reported outcomes within oncology lags behind other medical disciplines. Initial work in oncology research utilized instruments focused on symptoms and their impact on quality-of-life, such as the EORTC QLQ-C30 (Aaronson et al., 1993). Although validated, there was a knowledge gap between interpretation of the results and clinical applicability; these scores were also not used to support drug research by the U.S. FDA (Boyce & Browne, 2013; Snyder et al., 2017). In 2008, initial research was funded by the National Cancer Institute to symptoms during chemotherapy using patient self-reporting (National Institutes of Health, 2021). This was the seed of development for NCI's current PRO-CTCAE™ instrument, which is considered the patient version of the Common Terminology Criteria for Adverse Events (CTCAE), which provides matrices for physicians to harmonize adverse event terms as well as their severity (Cancer Therapy Evaluation Program (CTEP), 2017). The PRO-CTCAE™, which is freely available for download, has been validated for use in multiple languages and has been used to explore the patient's assessment of events compared to healthcare providers (Atkinson, Hay, et al., 2018; Atkinson, Reeve, et al., 2018; Badalucco & Reed, 2011; Basch et al., 2012; Basch et al., 2015; Basch, Pugh, et al., 2017; Basch et al., 2014; Bennett, Dueck, et al., 2016; Bennett, Reeve, et al., 2016;

Bruner et al., 2011; Dueck et al., 2015; Falchook et al., 2016; Gilbert et al., 2015; Hay et al., 2014; Kim et al., 2018; Kluetz et al., 2016; Kluetz, Kanapuru, et al., 2018; Mendoza et al., 2017; National cancer Institute (NCI), 2016d; Wood et al., 2015). It is enticing to consider a tool that has a patient component and a provider component, yielding insight into the assessments of treatment emergent adverse events.

5.2.1.1 Initial Design

Disappointingly, sample questions from the PRO-CTCAE™ were ranked lowest by patient participants when considering questions for the collaborative decision-aid tool. Patients like context and details, neither of which was provided by PRO-CTCAE™. In reflection, this highlighted a gap between the PRO-CTCAE™ and the physician's version CTCAE. The CTCAE has qualifying descriptors, such as moderate fatigue being a fatigue not relieved by rest or that interferes with instrumental activities of daily life. However, the PRO-CTCAE™ does not provide this clarification (Chapter 1, Figure 3), as it prompts only for *mild, moderate, severe, or very severe* without any guiding context. Although two radiation oncologists preferred the simplicity and directness of the PRO-CTCAE™, the remaining four did not like it. The prompts, open to interpretation by each patient, requires the physician to “know” the patient or be familiar with their personality, causing problems for new consults or secondary providers (e.g., covering physicians, emergency room physicians, hospitalists). Radiation oncologists also disliked numeric rating scales for the same reason. The importance of the need to know a patient's personality was heightened with the emergence of the pandemic, which ended the UIHC's long standing tradition of allowing all caregivers and family to attend each visit. Patients were now alone and radiation oncologists quickly realized the extent that they

relied on other individuals as secondary sources of information. The new normal requires radiation oncologists to hone their interpersonal communication skills and has created a desire to utilize additional information sources available to them to offset the absence of secondary informants. To address these concerns, the tool utilized standard quality-of-life prompts as the responses to questions (Chapter 4, section 4.2.3).

With the design of the tool sketched, the question turned to what symptoms were of concern to the patient or radiation oncologist. The initial goal was to create decision-aid instruments that would be individualized for each patient, addressing their unique concerns or complaints. However, during interviews patients were not able to voice concerns they had during initial diagnosis and treatment – other than survival. The average age of the interviewees was 67, members of a generation who are doctor-trusting and tend to be less autonomous (Kahana et al., 2018; Wrede-Sach et al., 2013). Without individual guidance, the decision was made to use the symptoms commonly mentioned during patient-participant interviews and noted as concerning to radiation oncologists. In future years, this may need to be revisited as the younger generations mature and experience lung cancer. These younger, technically-savvy generations may continue to be self-advocates and autonomous (Kilbride & Joffe, 2018). If so, these future generations may be able to describe their concerns and the symptoms they wish to monitor.

Lastly, despite the population being older, the patient participants all endorsed use of technology and had favorable opinions of its use in healthcare. This was somewhat surprising given the average age and the deference to the radiation oncologists as a key source of information. The patients requested a paper printout as the collaborative

decision-aid as a source of harmonized information between providers as well as to take home as a reference document for caregivers and themselves.

5.2.1.2 Implementation

The paper print-out request served as a focus for implementation within the department and was the first step in shared decision-making between the radiation oncologist and the patients. The radiation oncologists' clinics were hectic, typically overscheduled, and the physicians were concerned about slowing the clinic down. This is consistent with the literature, which lists time per clinic visit as a common barrier to SDM (Martin et al., 2019; Paladino et al., 2019). Use of a paper printout that could only be printed after the patient's arrival for that day's clinical visit would unavoidably alter clinical flow. The first challenge of the radiation oncologists' commitment to their patients occurred when planning the tool's implementation began at the first committee meeting.

The departmental administrator expressed confusion as to why a patient would want paper when they themselves had just completed the questionnaire. One of the radiation oncologists was confused as to why *anyone* would want paper when electronic is easier. Yet both of these concerns were resolved with the "give them a pickle," customer service philosophy taught within the department, wherein it is better to provide a pickle at no cost than to lose the customer's business (Farrell, n.d.). This customer focused training was required within the department and is honed in monthly meetings. Similarly, changes in workflow management are not new to the department – for example, in 2005, the department became the first truly paperless radiation oncology clinic in the nation. These two examples highlight the culture of the department, which significantly impacted the collaborative decision-aid tool's implementation by reinforcing

a “can-do,” attitude as well as the need to put patients first. Rather than the discomfort adapting to a new shift in workflow would cause, the implementation committee focused on the potential benefit to patients’ outcomes.

As a result of this culture, and despite a delay in an Epic® generated printed report, the radiation oncologists stated they were willing to print out the tool themselves, if required, to meet the patients’ request. With this decision, the printed report was prioritized and a manual report and workflow created. This example illustrates the significant impact of culture and practice considerations on implementation. The healthcare culture, described as a culture of “do, do, do,” by Reed and colleagues (2016) is a barrier to thoughtful implementation. Healthcare’s pervasive pressures of resolving issues quickly and not engaging in review or reflection, can lead to the initiative not being performed as originally intended or designed (Reed & Card, 2016).

In addition to the department’s culture serving as a strong implementation facilitator, the academic setting also served as a facilitator. In the academic culture of publish or perish, the radiation oncologists were keenly aware future publications would require patient reported outcome measures. The radiation oncologists identified routine collection of PROM as an investiture for stronger chart review research and better academic success. Additionally, as physician researchers translating bench to bedside, they were also aware of FDA’s requirement that clinical trials (including investigator-initiated clinical trials) include patient reported outcome measures in the trial design (U.S. Food and Drug Administration (FDA), 2020a, 2020d). As professors serve as the superiors in the American academic paradigm, if a new resource is identified by faculty as necessary for continued academic prowess, support staff accommodate the request.

Key Points. Patients and radiation oncologists wanted an easily understandable decision-aid that provided contextual details. Strong facilitators were (1) the department's culture (2) the department actively engages when faced with a paradigm shift, and (3) PROM data were deemed significant by both FDA and NIH. As an academic medical center, PROM data are an important currency for publications to support tenure as well as research funding research funding. The most significant barrier is found throughout the literature and was repeated by radiation oncologists: *do not slow down clinic*. This did not prevent implementation but did expended clinical visit time as a critical metric to maintain uptake. Identified local barriers included the downtime for designing a software build as well as approval through hospital regulatory / legal and not being able to test the software before it was put into production. A mild barrier was encountered with faculty and staff confusing patient satisfaction scores and PROM; however, this did not negatively impact implementation planning.

Despite planning, there were difficulties during implementation (Chapter 4). The initial implementation design focused on three pivot points: assigning the questionnaire (i.e., SDMCQ), distributing the tablet, and printing the decision-aid tool. Assigning the questionnaire was a three-step process requiring the radiation oncologist to notify the imaging specialist who then notified the front desk/scheduling. The radiation therapist on the committee volunteered to train all of the radiation therapists about this new process and workflow and completed it the next day at their team meeting. The front desk was informed about the new process via an email workflow distribution; due to the gap between the email and initiation, this was forgotten and resulted in poor start-up and frustration (Chapter 4). Unlike radiation therapists, who have a group lunch break for an

hour, the front desk must be staffed at all times, removing any chance for a harmonized group training. A refresher email should have been distributed when the decision-aid tool was initiated. The third process – printing the tool – was managed by the student researcher as a bridge until the Epic[®] build is completed. This requires monitoring check in times, questionnaire answers, and then paging the radiation oncologist to notify of the printed tool. Similarly, this is supported by the department with the end-goal of improved patient outcomes and benefit to the clinic (e.g., reduced add-on visits, reduced resource usage). This departmental culture and investment are seen as a significant facilitator to implementation which is most likely not realized at other academic institutions

5.2.2 Impact on Medical Management

The goal of the collaborative decision-aid is to have a positive impact on the patient, hopefully both in quality-of-life as well as in medical outcomes. From an operational standpoint, attention turns to resource use and costs for services. Management in an outpatient clinic is preferable to an emergency room visit not only for cost considerations but for an immunocompromised patient's exposure to hospital acquired pathogens. Of interest, CMS has identified treatment emergent adverse events considered to be potentially avoidable; this list includes nausea, vomiting, diarrhea, dehydration, and pain (Centers for Medicare & Medicaid Services, 2021). Of these, nausea/vomiting and pain were identified by patients, radiation oncologists, on-treatment documentation, and patient educational materials as common side effects of therapy for lung cancer. These symptoms are manageable in an outpatient radiation oncology clinic and provide a target metric that can be compared to state and federal claims data through CMS claims.

Although this work is too premature to begin to draw conclusions (Chapter 4), CMS claims data provides a metric for future review as well as information specific to the region.

Of interest to the radiation oncologists was time expended per on-treatment visit to determine what impact the decision aid tool had on their time in clinic and patient throughput. Despite the small sample size, this was easier to assess because of the number of clinic visits completed by each patient. When reviewing these data, it takes less than 6 minutes for a patient to complete the questionnaire and the clinic visit time (from check-in to physician exit) are comparable. A trend is apparent of having the patient starting the questionnaire but then taken back to have vital signs assessed and taken to the clinic exam room while the questionnaire is incomplete. This could contribute to an artificial elevation of questionnaire completion times.

Although the radiation oncologists were focused on questionnaire completion times delaying clinic, a review of the data indicated it was the workflow of the questionnaire causing delays. Factors contributing to delays included failing to distribute the tablet timely, patients taken to the exam room while the questionnaire was incomplete, and staff declining to participate in the tablet distribution. This underscores the need to increase buy-in and planning for implementation but also stresses the need to refrain from conclusions regarding the cause of a concern. When the completion times and patterns of time (i.e., check in time, completion time, rooming time) were shared with the radiation oncologists, their attention turned from the tool delaying their clinic to staff needing further training and alignment.

An incidental yet significant finding was identifying that physicians will not request corrections or revisions to a colleague's note. This possibility was not revealed in

the literature review and was unanticipated. If a radiation oncologist is covering for a treating radiation oncologist's absence and a mistake is made in the physical exam, the assessment, or the plan, physicians would prefer to call the patient directly to discuss or request a return visit as evidenced by this interchange:

Query: If you had concerns about the notes at all would you have addressed them at all?

Physician: No...calling a note out with a colleague is not done.

Query: Is it fair to say that a faculty member may be willing to allow a gap in a documented clinical note rather than...

Physician: ...cause conflict? Yes.

Query: So there could be gaps in documentation that could lead to patient frustration...because this is not addressed.

Physician: Yes.

This discussion aligned with patient participant 26 who had stated, "Some doctors take good notes and other doctors don't. This could have been a reference for all the other doctors this would be helpful." Three other physicians concurred with the statement of not asking for note revisions or corrections, describing that it was akin to a breach of etiquette that could result in hard feelings, difficult clinics, and perhaps even impacting livelihood if it results in fewer referrals. Physicians providing coverage for absences rely on notes to be complete and accurate; when covering for an unfamiliar patient, these notes can serve as lifelines. In absence of robust notes, radiation oncologists would seek out resident physicians or the nurse clinician to provide background on the patient.

This finding provided a previously unconsidered opportunity for the collaborative decision-aid tool to further impact medical management: an ability to provide accurate information directly from the patient (i.e., SDMCQ) and for the treating radiation oncologist to provide direct medical information to the patient on the collaborative decision aid tool. As a paper tool, the patient can then retain it to review for direction on what to watch for, instructions on what to do for an adverse event, and who to contact, including names and clinics. Unfortunately, because errors in notes are not routinely identified and, most likely, resultant harm is not catalogued it is difficult to compare the impact of the collaborative decision aid on adverse events stemming from outpatient visit *errata*. It is hoped that by reducing frustration the quality-of-life for patients would be improved and the continuity of care between providers would also be better served.

5.2.3 Recommendations for Future Tool Designs and Further Implementation

In contrast to the literature presented in Chapter 2, which provided insight into the patients' descriptions of intolerable side effects and the risk-to-benefit ratios of treatment (Rocque et al., 2019), this work also explored the perspectives of the radiation oncologists. Both patients and physicians identified lack of detail as a significant concern; context would provide a translation between provider and patient regarding the adverse event's severity and if it is impact on their daily life. This translation serves as the first step to shared decision making because when physicians assume their goals are the same as the patient's, shared decision making fails (Beers et al., 2017; Herrmann et al., 2018). Thus, translating the severity of a treatment emergent event and its impact on the patient's activities, becomes critical when considering future tool design.

As tested, the tool is a hybrid, employing an electronic strategy to collect the data (i.e., questionnaire, SDMCQ); whereas, a printed paper serves as the ‘true’ collaborative decision-aid tool. The format of the collaborative decision-aid tool is basic and mirrors the questionnaire (Appendix M) but also reports the baseline and prior visit responses. Work by Bennett et al. (2016) suggests the majority of patients prefer tablet completion over paper (59% vs. 23%). The work of Basch and others explored the use of a tablet-only system and did not describe utilizing the patient reported outcome measures as a function of shared decision making, even though they were shared with clinicians as medical information (Basch, Deal, et al., 2016; Basch, Pugh, et al., 2017). It is reasonable that the current hybrid format could become outdated for future patient generations. To address this proactively, a future tool design could query patient’s preference for information distribution (i.e. paper vs. electronic through MyChart[®] or similar).

Recall disparities are endemic in healthcare and radiation oncology is no exception (Chen et al., 2021; Gabrijel et al., 2008; Lee et al., 2018; Linford et al., 2020; Temel et al., 2011). A proposed solution in the literature is to have caregivers/family present for discussions; however, the current pandemic has removed that capability for most healthcare clinics (Linford et al., 2020; Smith et al., 2017). Additionally, the solution assumes the family member or caregiver can be present for visits regarding a chronic healthcare condition, such as cancer. The collaborative decision-aid tool not only provides an opportunity for patients to share direct information with their family and caregivers but also treatment, side effects, and outcomes to be reinforced through iterative review. Findings from the patient interviews are consistent with Smith et al. (2017), who found patients were ill-prepared for the severity of the side effects they

experienced while undergoing radiation therapy. Additionally, the adverse events documented in the OTV notes, the SDMCQ responses, and adverse event codes from the patient participant interviews do not align (Chapter 4). This suggests adverse event trends change over time and, as a result, the tool may need adjustment. This could be done based on review of prior SDMCQ responses or an adaptive design could be created. This would enable a patient to independently report an adverse event that is unexpectedly serious or distressing.

The collaborative decision aid tool can also minimize both patient and provider distress by providing an opportunity for clear documentation. Both patients and radiation oncologists commented on problems with documentation, contributing to stress and continuity problems during treatment. This is consistent with literature which has identified errors in radiation oncology documentation which has contributed to treatment errors (Blakaj et al., 2017; Schechter et al., 2020). Currently, the questionnaire results are imported into the radiation oncologist's note using an Epic[®] smart text strategy. Inadvertently, this is contributing to documentation confusion, as the patient's reported outcome measures may be markedly different than on exam. A best practice would be for the provider to clarify in the notes, at minimum, what the ground truth is. When discussed with providers, this was seen as additional time expenditure. Thus, a future tool design would be to enable a mechanism to provide comments to the questionnaire answers by the provider with minimal intervention.

Additional considerations include:

- **Look for outliers.** Time per question is available by report and questions presenting as outliers – either by time or the number of reviews – should be

considered for redesign. Redesign could be a visual layout, an order layout, or a response needing to be changed. This requires time for reflection and review, which is not typical in healthcare (Reed & Card, 2016)

- **Mix it up.** The collaborative decision-aid tool can be adapted by replacing the responses with prompts capturing the appropriate context from established patient reported outcome instruments . The tool is not intended to be validated at this time – a site could also use a verbatim description if it aligns with a population’s culture.
- **Different cultures, different problems.** Research demonstrates problems occur at varying frequencies and severity based on race, ethnicity, and culture. Versions of the tool could be designed using a community participatory approach to identify unique situations and culturally sensitive context.
- **It works better when shared.** Currently, the SDMCQ is tied to the on-treatment visit to which it is assigned and requires access to the specific encounter to view the responses. Although the radiation oncologist imports the results into their on-treatment visit note, this also requires other physicians to be aware the tool exists and where to find it. The PROM is not beneficial only to radiation oncologists but to any physician treating the patient. For this reason, a key modification would be to centralize the tool and the responses within Epic® EHR for tool awareness and ease of access.

5.2.3.1 Recommendations for Implementation

Considerations for tool design should be done in concert with a renewed implementation cycle . Detailed implementation procedures have been discussed previously (Chapter 4). The Plan-Do-Study-Act (PDSA) model worked well for the tool’s

implementation with its iterative nature enabling a focus on initial priorities, evaluation, adjustment, and then initiation of another implementation cycle to amend the workflow or to expand the implementation (The W. Edwards Deming Institute, 2021). The detractor to the PDSA is well described in an article by Reed and colleagues (2017), who caution the simplicity of the PDSA leads to poor implementation outcomes if it is not combined with other models and frameworks. For this work, the PDSA was combined with the Ottawa Model of Research Use, which was selected in part due to its grounding in research (due to the clinic being an academic research clinic) as well as the cues it provides for planning, studying, and acting (Graham & Logan, 2004). However, there are multiple models and frameworks that could be used to augment PDSA dependent upon the implementation needs (Chapter 2, section 2.4). For example, implementing patient reported outcome measures for improved communication could use the framework by Golden et al. (20187) whereas focusing on improved patient management could utilize Santana and Feeney (2014). End-users focusing on a clinical trial to align with FDA's objectives should utilize the framework of van der Wees et al. (2019), which emphasizes the FDA's priorities of defining the objective, select the appropriate patient reported outcome and its measure, and identify the metric to be used as an indicator of quality. As a project matures and the PDSA cycle goes under additional cycles, additional frameworks or models should be considered for the next cycle.

Despite the use of the guiding framework and models, there were oversights for implementation that should be considered for future projects and similar tools:

- **Stakeholder = the worker.** Stakeholders in the meeting were the supervisors of the individuals who would the work rather than the staff themselves. This

decision was guided by the logic that the supervisors had the authority to change workflows and authorize training. At implementation, it was identified that supervisors had a broader knowledge base, contributing to the failure to identify a knowledge gap (i.e., tablet assignment, SDMCQ assignment). Future implementation should include representatives of the workers engaged in the workflow as well as their supervisor.

- **Upgrades affect us all.** Epic® EHR underwent an upgrade concurrently with the SDMCQ initiation. Training provided on accessing the SDMCQ answers and how to print them was negated as the upgrade version removed those pathways. This was a reminder that, in the scheme of electronic health records, an end-user designed questionnaire is not on the list of checks and balances when upgrades are performed. If possible, implementation cycles should have access to a test version of the upgrade with the SDMCQ/questionnaire installed. If this is not possible, resources should be dedicated the following business day to evaluate the workflows and identify potential solutions to new functional challenges. This issue should be addressed proactively by the committee to clarify this contemporaneous solution as unique compared to those problems that arise as a function of the implementation.
- **What! It was finished...when?** There is not a mechanism in Epic® EHR to automatically notify the physicians when the SDMCQ is completed. The completion is the milestone to trigger review by the radiation oncologist, collect the printed document, and enter the exam room for the outpatient visit. The solution employed by the site was a manual intervention and monitoring

completion. This is an implementation barrier that must be thoughtfully reviewed and addressed prior to the first implementation cycle.

- **Perfection will not be achieved.** The simplicity of the PDSA cycle is its iterative use to slowly ramp up implementation. This translates to the initial implementation cycle not addressing all issues identified at start-up as well as those identified during the DO and STUDY segments. A project manager should be identified for the STUDY segment to memorialize problems, one-offs, and questions for the end-of-cycle ACT segment meeting. Attempting to solve the problems during the STUDY segment leads to a failure of an interdisciplinary committee to address the issue as a team and ultimately weakens the implementation. A recommended strategy to avoid the instinct to fix in the moment is for the committee and the implementation project manager to accept problems are not only expected but needed to fully assess implementation and customize it to the site.
- **SDMCQ on demand, please.** Currently, patients can contact the care team through MyChart® but responses to MyChart® messages can be delayed and should not be used for time critical concerns. Radiation therapy provides a unique opportunity as a patient undergoing radiation therapy is seen daily. Prior to the day's radiation therapy, if a patient is feeling marginally unwell or has a medical concern, the patient could request a tablet with an SDMCQ to provide the healthcare provider a review of the complaint through the patient's lens and also document an emergent issue.

- **Share the rationale.** Buy-in and investiture is critical for tool success. Much of the literature emphasizes physician buy-in, but the critical step in implementation was the front desk staff assigning the SDMCQ and distributing the tablet. This added work to an already hectic clinic day and, due to the ‘new’ nature, led to errors during the first cycle. Rather than adopting a punitive response, all involved should be educated as to why the PROMs are so important for patients and what literature demonstrates to date. When the rationale is provided (i.e., for patient benefit), staff understood the necessity for the workflow change and that they were – in their part – contributing to better care for the patient.
- **Are we there yet?** Human tendency is to have success and a sense of completion. Implementation and uptake require maintenance and review, removing a formal sense of completion for the project. To maintain investiture and buy-in, small milestones should be identified for celebration as well as a feedback loop to the committee and stakeholders of findings to date. Although this will use data from the STUDY and ACT segments of the implementation cycle, the focus should be on team building and celebrating achievements, a respite from the work.

5.3 Study Limitations

This work as conducted does have limitations. The predominant factors contributing to study limitation are it is not intended to be a source for objective measures, the sample/population homogeneity, the SARS-CoV-2 pandemic, and the midwestern culture. Minor limitations include the unique culture of the study site, study-site clinical workflow, the use of Epic® EHR, and the predominantly Medicare/Medicaid insurer status.

5.3.1 Measurement in Patient Reported Outcome Measures

The collaborative decision-aid tool was designed as an impetus to communication regarding adverse events between the radiation oncologist and their patient. The goal was to obtain information about the experienced events, allow the radiation oncologist to review, and then for a purposeful communication to occur about managing the events and what to expect next. For this reason, the description of the toxicity had to easily correlate to the experienced adverse event. By transitioning away from a severity concern and to a pragmatic description, there is no longer an ordinal ranking established. Some descriptors may be the same in severity (i.e., the intervention required) but require different interventions or education. For this reason, the decision-aid tool has multiple “equitable” options and does not make an attempt to rank them based on severity. In summary, the tool is not used to quantitatively measure a patient’s reported outcome but to inform their radiation oncologist how the patient is assessing the adverse event at that point in time.

5.3.2 Sample and Population Homogeneity

This work took place at University of Iowa Hospitals and Clinics within Iowa City, Iowa, a city of just over 75,000 individuals. Per census data, the population is 78% white and 75% white, non-Hispanic or Latino. (United States Census, 2019). Approximately 8% of Iowa City’s residents identify as black or African American, 7% Asian, and 5.8% Hispanic or Latino. The same data indicate over 90% of the state’s population identify as white, 85% do not identify as Hispanic, 4% identify as black or African American, and 2.7% identify as Asian – the remaining races are represented at less than 1% (United States Census, 2019). Approximately eight percent of the state’s population speaks a language other than English at home (United States Census, 2019). The predominant religion is

Christianity (77% of adults) with Protestants being the dominant denomination (58%) (Pew Research Center, 2021). Non-Christian faiths comprise 1% of the population with Muslim being the dominant non-Christian faith (Pew Research Center, 2021). The UIHC's coverage map includes the state of Iowa in its entirety as well as border counties in the neighboring states, primarily Illinois and Missouri.

This homogeneity limits generalizability of the tool . Application to other races, ethnicities and religious cultures should be considered during implementation. Impact of sample and population homogeneity is minimized on measures of impact if an implementing site uses its own historical data as its control.

5.3.3 SARS-CoV-2 Pandemic

The impact of the pandemic in oncologic care and its research is indeterminate but certain to be significant. The primary pandemic control measures contributed to a foundational communication change: prohibiting caregivers at appointments, telemedicine *in lieu* of physical follow-up visits, social distancing, use of a mask and face-shield, and minimizing paper transfer. This resulted in immediate changes in communication strategy, from being unable to see a person smile in solidarity or provide a comforting touch on the shoulder to having to rely on a single source for information about a patient's treatment tolerance, health, and welfare. Additional context was the emotional burden of additional pandemic precautions, the stress of a life-threatening virus which did not have a prevention or cure during the study, and having to quarantine from family to protect them from spread. All of this contributes to an atypical communication pattern that may be reflected in the results of the work.

Implementation is not impacted by the pandemic in so far as the PDSA model enables adaptation to the continually shifting landscape of the pandemic. When reviewing measures of impact, such as time spent per OTV and cost of unplanned ER visits, pandemic conditions should be considered, especially if attempting any correlational assessments.

5.3.4 Midwest & Iowa Nice

The term *Iowa Nice* became prevalent during the 2012 presidential caucuses as a result of video produced in response to the commercial media's coverage of the state (Iowa Filmmakers, 2012). The video, which quickly went viral, highlighted aspects of Iowa that seem often contradictory. The term *Iowa Nice* is used to describe the stoicism of the average Iowan, who tends to care for their family and themselves but will not impose upon others. This self-reliant attitude may stem from the isolationist lifestyle of farming; however, it extends beyond livelihood as well as across religion, race, and locale. It is a unifying characteristic within the state and a 'tell' to identify someone who is not an Iowa native.

This Iowa Nice culture created one of the tool's communication needs: breaking down a wall of self-reliance, decreasing the stoicism, and giving patients permission to complain. This creates a limitation when generalizing to other communities or cultures without this inherent trait (e.g., stoicism, isolationism, self-reliance). The communication goal will need to be reviewed prior to implementing this collaborative decision-aid tool outside of Iowa (i.e., increasing communication, clarifying communication, harmonizing information provided).

Similarly, the metrics of decreasing emergency room visit were based on information from the qualitative strand that patients would unknowingly allow adverse events to increase in severity by attempting to ‘tough it out,’ ultimately resulting in an after-hours ER visit. For areas where the ER visits are triggered due to knowledge gaps or resource availability, ER visit as a measure of medical impact may not be appropriate. Lastly, many larger metropolitan areas have after-hours clinics tailored to the needs to oncology patients; this is unavailable in Iowa. The presence of such a clinic would also shift measurement of medical impact. Thus, this should be evaluated at the PLAN stage of implementation.

5.3.5 Other Limitations

Additional limitations the unique culture of the radiation oncology clinic where the work was performed (e.g., pickle philosophy), the clinic’s routine workflow, the use of Epic® as the electronic health record system, and the predominant Medicare population (which can also be used as an estimate of socioeconomic resources). These are not considered prohibitive but should be carefully considered when tailoring the tool to another radiation oncology clinic. Lastly, the tool was not reviewed by patients for their thoughts and feedback prior to implementation.

5.4 Recommendations and Directions for Translational Research

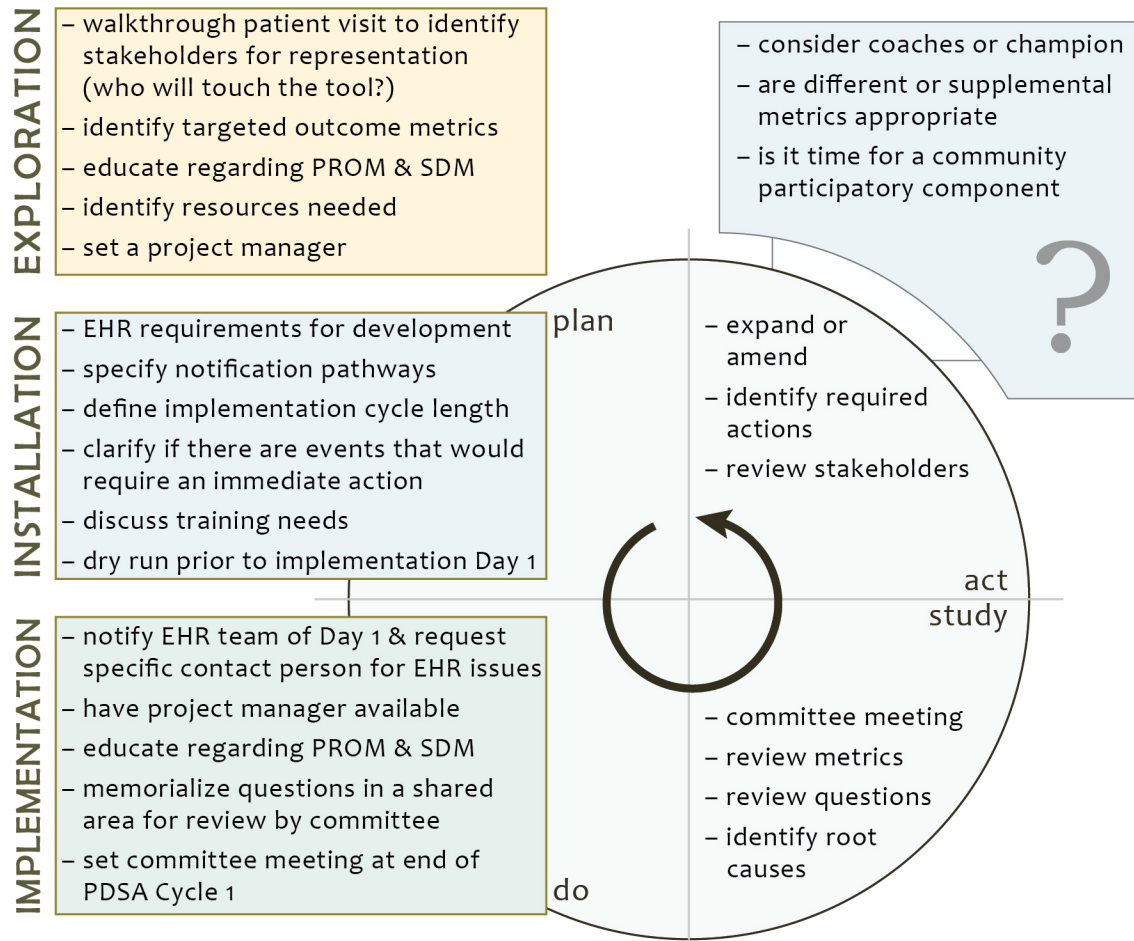
Shared decision making has been identified as beneficial to patients since 1972 with work from Veatch. Despite the known benefits of improved quality-of-life, treatment adherence, and reduced psychological distress, SDM has not routinely been adopted within oncology. To add to this, with the 21st Century Cures Act PROMs have not only been thrust into the arena of clinical research but were also deemed a valid

measure of outcome by the United States regulatory establishment – a measure just as important to oncology as objective disease measurements or hematologic counts (U.S. Food and Drug Administration (FDA), 2020a). This is a stark change from prior expectations and, as a result, the oncologic world is ill-prepared. The logic is straightforward: if a drug or device is FDA approved to improve quality-of-life, how does an oncologist discuss this in a cogent manner with their patient? This highlights a disconnect between the existing literature and what is occurring in practice. Thus, this work targeted the T3 chasm as defined by Drolet and Lorenzi in 2011 to move patient reported outcome measures and shared decision making beyond a controlled research paradigm and to a routine clinic.

This novel work addresses the first step in crossing the chasm: how to implement patient reported outcome measures in a radiation oncology clinic. It provides an implementation map for a collaborative decision aid tool into a radiation clinic through a clinical implementation strategy, rather than employing a clinical research pipeline paradigm. This implementation map (Figure 20) thus provides real-world strategies to install a collaborative decision-aid tool. Based upon the literature review (Chapter 2), this is unique information that can further standard use of patient reported outcome measures and collaborative decision-aid tools into routine clinics, rather than targeting the research enterprise.

5.4.1 Translating the Collaborative Decision-Aid Tool

The resultant collaborative decision-aid instrument has unique characteristics: compared to validated tools currently in use, such as QLQ-C30, the PRO-CTCAE™, FACT-L, and PROMIS (Basch et al., 2005; Haraldstad et al., 2019; Minasian et al., 2007)

Figure 20*Proposed Implementation Map for Collaborative Decision-Aid Tool*

Note. Adapted from the NIRN framework (Bertram et al., 2015), the OMRU model (Graham & Logan, 2004), and the PDSA cycle (Langley et al., 2009).

the tool does not use a numeric scale for quantitative assessment nor is there is not a defined recall window. The tool is adaptable based on the symptoms of interest and the desired context for severity. By removing the numeric scales, the ability to quantify subjective responses was severed, anchoring the tool to the clinic and emphasizing its designed to stimulate communication between provider and patient.

In creating the tool, it was decided not to focus or pursue validity (i.e., the instrument measures what is intended to be measured), reliability (i.e., consistency of

measurement across a population) or acceptability (i.e., the ease of use) (Jerosch-Herold, 2005; Streiner, 2003; Streiner et al., 2015). It is recognized that these measures are important for the simple reason that if used to assess a patient's health or recovery there should be confidence in knowing the measures reflect a true change in health. However, for the purposes of this study, the tool was intended to simply initiate conversation about concerning adverse events to increase shared decision making.

By reducing emphasis on validation and focusing on the patient and clinic, the tool gained real-world applicability. Rather than being a static instrument, the tool serves as a functional scaffold, for clinicians to substitute the symptoms of interest and to incorporate the context from any of the existing PRO instruments. The layout of the collaborative decision-aid tool would remain unchanged, providing trends over time for the monitored symptoms. This provides an extremely adaptable tool to meet the needs of multiple clinics, increasing the likelihood of its use across the T3 chasm.

5.4.2 Implementation of the Collaborative Decision-Aid Tool

This work used the NIRN framework, the OMRU model, and the PDSA model to guide implementation (Figure 2). Despite the proactive plan, there were missteps during the cycle 1 of the implementation (Chapter 4). Based on this experience, and the resulting logic chain, an implementation map based on the PDSA cycle and OMRU is provided for implementation of PROM measures in a radiation oncology clinic (Figure 20). The map identifies specific considerations that were required when implementing the decision-aid tool. Priorities for implementation should be identification of how the questionnaire will be added to the electronic health record and the workflow for that installation, who will touch or interact with the questionnaire and the resulting decision-aid tool, and who will

be the project manager or owner of the implementation. The implementation map, as designed, is generalizable to any clinic utilizing an EHR. A clinic seeking to utilize the map will have investments for implementation:

- **Walk through.** The clinic considering implementation should walk through the process, stepwise and slowly, using a logic chain model. This can be done as a meeting or as an actual walk through the clinic. The logic chain (*if/then*) should be edited contemporaneously with feedback from attendees. The work path should identify stakeholders at the basic foundational level to not only provide key information but also serve as champions at implementation.
- **Project management.** A project manager / coach should be assigned. In addition to funneling information to the appropriate staff, this person should memorialize issues and obtain metrics for review.
- **Consider patient representation.** Depending upon the metric selected, patient representation or community participation may be beneficial. Patients experiencing the disease under study and treatment should contribute to identifying outcome measures of significance. This should be strongly considered when tailoring a tool to specific populations within the community.
- **EHR requirements.** Dependent upon the organizational structure, the clinic may be required to support the EHR build financially. If this is not feasible, the implementation team should consider shifting from an EHR-focused tablet to a paper form and how that would affect the workflow.
- **Team environment.** The project manager and implementation champion (the person who is requesting the tool be adopted) should provide a team environment

that is a psychological safe space. Additionally, the end goal should be clearly identified as well as team roles and expectations.

- **Day 1 contact.** If using an EHR, the clinic will need to identify a contact person when the first implementation cycle begins, to address any emergent EHR or programming issues.
- **Staffing.** A clinic considering implementation will need to provide adequate staffing with protected time for the staff. The amount of hours and staff is dependent upon the stakeholders and path identified in the clinic. Staffing will be required to memorialize issues and questions as well as to educate regarding the importance of the tool and its outcomes.

Adopting this implementation map should aid in crossing the T3 chasm, resulting in a greater chance at clinical adoption. To share the information map, information will first be distributed to radiation oncology clinics as well as community oncology clinics within Iowa. Information dissemination will occur through two primary means: the statewide radiation oncology annual meeting (ISTRO) and through a newsletter distributed to former students, staff, and faculty of the UIHC Department of Radiation Oncology. This first roll-out will focus on similar geographical and cultural locales. The second distribution will be through traditional academic pathways but will include the nursing journals in addition to academic publications. The third distribution will occur contemporaneously with the second and will focus on information distribution through the Oncology Nursing Society. It is hoped by targeting patient champions, such as oncology certified nurses, implementation and adoption will snowball within the state and – hopefully – beyond.

This research crosses the T3 chasm to partially address the knowledge gap in current literature that shared decision making and patient reported outcome measures are not being routinely used in radiation oncology clinics. Knowledge gained from this research should increase shared decision making and improve the patient experience through the implementation of a collaborative decision-aid tool. Lastly, this tool has been created and implemented such that it should be usable by other clinics within the Midwest and, with adaptation through a robust PLAN segment of PDSA cycle utilizing the NIRN framework and OMRU model, it is hoped the decision-aid tool can be used outside the midwestern locale.

5.5 Next Steps in Research

Research of PROM and SDM within oncology crosses decades without realized implementation in the clinic or community. To gain forward momentum, research must continue *pragmatically*, either through quality improvement designs or consent-waived comparative effectiveness research. Both PROM and SDM are research areas that benefit from community participatory research, both at the *community* level but also at the more focused *disease* level. Next steps in this vein of research must include:

- **Identify the downstream impact.** Outcomes of interest include inpatient admissions, emergency room visits, scheduled outpatient visits, emergent outpatient visits, concomitant medication and opioid prescribing patterns, treatment compliance, and healthcare costs. It is unknown how these outcomes will shift: for example, increasing emergent outpatient visits may appear to be negative but not if the trade-off is decreased emergency room visits. Thus, a next

step is to not only estimate impact but also assess if it is potentially positive, negative, or neutral.

- **Remix.** The initial PDSA did not include patient advocates or representatives. Similarly, patient participants did not review the instrument designed from their input. A subsequent mixed methods study to (1) obtain direct feedback from the representative patient population as well as clinical staff through focus groups, (2) complete semi-structured interviews from patient participants who completed the instrument during therapy, (3) invite patients to have their on-treatment visits recorded to assess shared decision making, and (4) compare the outcomes of interest with historical data.
- **Tool quantization.** As designed, the tool focuses on increasing communication through patient reported outcomes. To employ the tool for an investigator-initiated clinical trial, an investigator may wish to quantize the data similar to the Common Terminology Criteria for Adverse Events (CTCAE), which quantizes subjective assessments to ordinal categories. This enables statistical evaluation (e.g., Wilcoxon Signed Ranks Test, Spearman Correlation, Mann-Whitney U test). This is likely to increase adoption due to the familiarity of oncology with the CTCAE as well as quantitative clinical trial data.
- **Psychometric analysis.** This study could also be broadened to include psychometric analysis (i.e. validity, reliability, responsiveness) to further examine its role in assessing and reporting adverse events. Validity demonstrates the tool is measuring what it is designed to be measure. Reliability demonstrates the tool provides consistent responses within groups being examined. Responsiveness is

the tool's sensitivity to change. These should be examined within groups (e.g., same location, same patient base) and across groups (e.g., different tumor sites, different practice types, different locations). Determining the tool's validity, reliability and responsiveness will support generalizability and increase uptake.

- **Clinician adoption.** The tool was implemented pragmatically but within one patient base focused on one treatment. The tool should be expanded for use for adoption across patients within a clinician's practice. Within the practice, for the purpose of increasing communication and shared decision making, psychometric analysis is not a top priority and the tool can be tailored to the clinician's practice.
- **Facility adoption.** The tool can be expanded so patient results are incorporated into sister oncology clinics (e.g., medical, surgical, radiation) as well as emergent and inpatient care for their use. This expands the tool's purpose from increasing communication and shared decision making to also use PROM as a key healthcare measure. With this framing, at minimum the facility should consider the shift in targeted use but, ideally, should consider psychometric analysis. In addition to utilizing the implementation map, this would require assessing readiness for change, harmonized goals across the clinics, and identifying the primary clinic that would champion the tool.
- **Interfacility adoption.** A reasonable use of the tool would be to increase communication and shared decision making between cancer centers and then determining the impact the tool has on downstream measures. Similar to individual clinician adoption, this may not require validity, reliability, and responsiveness assessments as the goal is to increase *discussion* and not determine

measures reliable across sites. However, if the tool is also to be expanded to utilize PROM as a healthcare measure, psychometric assessments are essential to the tool's use. Variables to explore include tumor type, oncologic practice (e.g., medical oncology, surgical oncology, gynecologic oncology, radiation oncology), treatment location (i.e., physiologic area of the body to be treated), and cultural considerations of the different locations. When assessing for use between centers, further exploration could be undertaken to reduce the size of the individual query response, identify barriers to response understanding, and the need to individualize responses by culture, treatment center, and/or tumor type. This will increase generalizability of the tool.

- **Provide the translational feedback.** Due to the failure of both PROM and SDM to be implemented in routine clinical care, both bench science and drug/device development have been starved of the patient perspective. The instrument will not provide quantitative data; instead, it will provides more meaningful, rich detail about how the patients experience experimental treatments. This informs current and future research about the tolerability of treatments and real-world impact on patients' side effects, activities of daily living and quality of life. To move forward with introducing the instrument into clinical research, an initial psychometric analysis would be required for the tool.

5.6 Final Reflections and Conclusion

Radiation oncologists have a critical role for a patient undergoing combined therapy for treatment of lung cancer. Radiation oncologists have a tremendous amount of knowledge to share with their patients so the treatments are tailored to their needs and to

prevent emergency room visits or inpatient admissions. Although literature reports radiation oncologists are not participating in shared decision making OTVs (Fromme et al., 2016; Golden et al., 2016; Golden et al., 2017), this work suggests patients are not sharing their symptoms and side effects with their radiation oncologists. Interviewing patients with lung cancer identified the patients' tendency to not want to burden others by reporting side effects. This stoicism masks problems and contributes to emergent healthcare needs and expenditures as well as exposing the patient to additional risk through community acquired infections. Thus, this work created a collaborative decision-aid tool informed by both patients with lung cancer and radiation oncologists at a midwestern cancer center. The resultant tool is a hybrid that is both electronic (the questionnaire, SDMCQ) and paper (the collaborative tool). Digitally, the patient's responses can be easily imported into a clinic note; other providers, such as emergency room providers, can review the radiation oncologist's note to read the patient's responses directly. In paper format, the instrument serves as a springboard, providing the radiation oncologist information to discuss with the patient and a medium to write down additional notes or instructions. The patient can take home the information to their caregivers or family but also provide it to other caregivers to minimize verbal communication (due to dyspnea) and provide continuity in documentation. This becomes more significant as an incidental finding during the interviews was that errors in notes remain unchallenged between physicians, resulting in the medical record having poor and/or inconsistent documentation regarding a patient's care.

After developing the collaborative decision-aid tool, the decision was made to implement it pragmatically through a clinical initiative, rather than utilizing the tool in a

controlled clinical research method. This provided insights into barriers and facilitators but also broke down the steps necessary to begin the implementation process. The resultant implementation map provides a pathway for community clinics to install the tool without dedicated research personnel. Both the collaborative decision-aid tool and the implementation map should serve as a keystone in increasing SDM and PROM utilization in clinical radiation oncology practice, making their use routine and increasing the known potential benefits to the patient community.

This work is considered novel because neither decision aid tools or patient reported outcome instruments have been described in the peer reviewed literature as being implemented directly in the clinic, rather than a research trial. This work creates a foundation to (1) tailor a collaborative decision-aid tool to the unique needs of a community or culture, (2) eliminate ambiguity of an adverse event's impact on a patient and their daily lives, (3) improve shared decision making through discussion about adverse events during weekly on-treatment visits, (4) provide a secondary information source for providers when caregivers and/or family cannot be present, and (5) implement this adaptable tool into a community radiation oncology clinic. The next step in furthering this work is to continue the tool's implementation within the target clinic and determine effect size for emergency room visits and expenditures. Through its pragmatic installation, as well as its focus on the patient and provider needs, this instrument has the potential to truly place the patient in patient-focused drug development and patient-centered medicine.

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APPENDIX A: SARS-COV-2 IMPACT

This work was designed to be completed in two parts: the qualitative strand and the quantitative strand. Both strands were significantly impacted by the ongoing SARS-CoV-2 pandemic, which mandated changes to both human subjects research procedures as well as clinical modifications to minimize risk to staff and patients (The University of Iowa Human Subjects Office, 2020; The University of Iowa Office for the Vice President for Research, 2020).

The qualitative strand and the control for the quantitative strand were opened for accrual 03 May 2019 with the first consent obtained in July of 2019. Beginning in March 2020, human subjects research at University of Iowa and University of Iowa Health Care, was restricted to only essential, life-sparing research which was justified – and approved – by the University of Iowa Human Subjects Office (HSO, 2020; OVPR, 2020).

During this time, University of Iowa Health Care was faced with an impossible reality: protective equipment shortages, a lack of effective testing methods, and the absence of an effective treatment for a potentially lethal disease. For this reason, the difficult decision was made that no one could patients to their appointments in an attempt to stop community spread and minimize risk to all (e.g., family, friends, caregivers). Patients could be dropped off at only two approved hospital entrances and the driver could wait in a nearby parking lot. Similarly, volunteers, students, and hospital escorts were also prohibited entry into University of Iowa Health Care, stranding infirm patients who were dropped off at one of two the approved entrances but needed to get to their oncology clinic three buildings away. Without escorts and volunteers, physicians and allied healthcare staff returned to treating the *patient* and not the *disease*. For example,

attending physicians wheeled patients to their waiting car, nurses sat with patients in the cafeteria so they could eat, and providers *talked* to their patients, acknowledging that the doctor's appointment may be the only interaction the patient had. To add to the strain, staff were assigned overtime hours to screen incoming patients, faculty, and staff for COVID-19 symptoms at the designated entry points.

With so little prevention or treatment possible, potential sources of contamination (e.g., exam table paper, pamphlets, paper towels, pens) were obsessively stripped from exam rooms. Staff were no longer allowed to walk down the hall side-by-side. Only two individuals were allowed in an elevator at once. The use of communal clinical workrooms was minimized. Residents no longer gave report to their attending physicians in person but over the phone using screen share technology to review key information and imaging. Routine cancers treatments (e.g., pulmonology, chemotherapy, standard radiation) were referred to local clinics away from UIHC, which was considered similar to ground zero for the pandemic.

On 16 June 2020, the University of Iowa Human Subjects Office and the Office for the Vice President of Research agreed to allow research to resume provided there were no 'research only' visits and the departmental chair approved the restart. On 18 June 2020, after discussion with the site's nurse manager, administrator, and attending physicians, the departmental chair deemed it appropriate to continue with interviews as long as they were on an established on-treatment clinic visit, as follow-up visits were now performed through telemedicine. Additionally, the clinic's workroom as well as workflow was irrevocably altered: communication occurred *via* phone, rooms were

evaluated for maximum occupancy using social distancing, and staff were assigned non-traditional work roles.

In November 2020, Iowa saw a secondary peak of SARS-CoV-2; as a result, human subjects research was again immediately placed on hold. This was to accommodate the foreseen burden: to accommodate the burden, outpatient floors were modified to house additional critical care and required the appropriate healthcare staff to maintain them. Faculty and staff were reassigned to these floors; licensed research staff were then reassigned to address these vacancies (HSO, 2020). As of December 2020, human subjects studies were restarted but the workflows and healthcare processes at UIHC remained altered due to the pandemic. The long-term impact of SARS-CoV-2 on healthcare, its workflow, and clinical research remain unknown but are likely to be widespread and long-lasting.

APPENDIX B: HUMAN SUBJECTS DETERMINATION FOR INSTRUMENT
IMPLEMENTATION



**Human Subjects Office/
Institutional Review Board (IRB)**

105 Hardin Library for the Health Sciences
600 Newton Road
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319-335-6564 Fax 319-335-7310
irb@uiowa.edu
<http://research.uiowa.edu/hso>

March 16, 2021

TO: Kellie Bodeker
Cmed-Radiation Oncology

FROM: J. Andrew Bertolatus, MD, BA
IRB Chair or Chair Designee

RE: Not Human Subjects Research Determination

I have reviewed the information submitted with your project titled 202103430 Implementation of a shared decision making / communication tool in the radiation lung cancer clinic: a quality improvement project. I have determined that the project described in the application *does not* meet the regulatory definition of human subjects research and does not require review by the IRB, because this is a quality improvement project focused on a specific group of patients in a specific clinical service.

We appreciate your care in submitting this application to the IRB for review. If the parameters outlined within this Human Subjects Research application request change, re review and/or subsequent IRB review may be required.

Please don't hesitate to contact me if you have any questions. The Human Subjects Office can be reached via phone (319)-335-6564 or email irb@uiowa.edu.

APPENDIX C:

SAMPLE PATIENT PARTICIPANT INTERVIEW QUESTIONS

Lead in: Before we begin, I want to remind you that your participation is voluntary. You can stop participating in this study without any impact in your healthcare. If you choose to continue, you can choose to skip any question you would like or even choose to answer none at all. (pause). Is it okay to continue?

- **if no**, thank the participant for their time and ask if they would like to end study participation.

- **if yes**, “Thank you, I am going to begin the recording.”

- A1. Thinking about your radiation treatment, what do you think was important for your radiation doctor to know about how you were feeling?
- A2. I’m interested in how patients being treated with radiation describe their symptoms to their radiation oncology doctor. Please describe a time when you had difficulty describing a symptom to your radiation doctor?
- A3. Thinking about that time, what do you think could have made it easier to help your radiation doctor understand?
- A4. Think about your radiation treatments and your visits with your radiation doctor during that time. Think about how you felt, how much time the visits took, and what you were worried about or what you were experiencing. If you could create a paper or report to share what you were worried about, what would that look like?
- A5. During your radiation treatment for your lung cancer, how would you prefer to communicate your symptoms and concerns to your radiation doctor?

APPENDIX D:

SAMPLE RADIATION ONCOLOGIST INTERVIEW QUESTIONS

[TREATING RADONC, LUNG CANCER FOCUS]

- B1. What are the common medical concerns for patients undergoing definitive chemotherapy and radiation therapy for lung cancer?
- B2. What information do you need to know to manage the on-treatment visits?
- B3. What information do you find difficult to obtain from patients or information that varies from provider to provider?
- B4. What format do you prefer information conveyed (graphics, tables, etc.)
- B5. A decision-aid tool is often a report, paper, or other prompt that helps patients understand the decision that needs to be made, to help empower the patient. If RADONC were to design a decision-aid tool to help patients describe their adverse events, how do you envision that tool?
- B6. If patients were to complete patient-reported outcome questions, and this information was available for review in Epic[®] EHR, where would you like to see it? Where do you believe it is most accessible?
- B7. What process or workflow do you have after your patient has been seen by a covering RADONC?
- B8. What is the most common cause for add-on visits or special complaints in the lung cancer patient base?

APPENDIX E:

SAMPLE RADIATION ONCOLOGIST INTERVIEW QUESTIONS [COVERING]

Note: Small group interview structure

- D1. You have been identified as radiation oncologists who cover for a treating radiation oncologist for a lung cancer patient. What is your average workflow to prepare for that on-treatment visit?
- D2. A decision-aid tool is often a report, paper, or other prompt that helps patients understand the decision that needs to be made, to help empower the patient. If RADONC were to design a decision-aid tool to help patients describe their adverse events, how do you envision that tool?
- D3. If patients were to complete patient-reported outcome questions, and this information was available for review in Epic[®] EHR, where would you like to see it? Where do you believe it is most accessible?
- D4. What do you consider to be the most concerning or difficult AEs for lung cancer patients?

APPENDIX F:

SAMPLE RADIATION ONCOLOGIST INTERVIEW QUESTIONS

(TREATING RADONC, NON-LUNG CANCER FOCUS)

- C1. You specialize in primary tumors other than lung, but you treated (name of patient) for lung cancer. How does the lung cancer patient base compare to the patients you normally treat?
- C2. What type of communication problems do you have with lung cancer patients compared to your routine patients?
- C3. What do you consider to be the most concerning lung cancer symptoms, or treatment AEs, that can lead to problems?
- C4. What do you find the most difficult about managing or treating lung cancer patients?
- C5. A decision-aid tool is often a report, paper, or other prompt that helps patients understand the decision that needs to be made, to help empower the patient. If RADONC were to design a decision-aid tool to help patients describe their adverse events, how do you envision that tool?
- C6. If patients were to complete patient-reported outcome questions, and this information was available for review in Epic[®] EHR, where would you like to see it? Where do you believe it is most accessible?
- C7. What process or workflow do you have after your patient has been seen by a covering RADONC?
- C8. What is the most common cause for add-on visits or special complaints in the lung cancer patient base?

The shared decision-making tool could address the patient-identified communication barriers of having to repeat information across multiple providers as well as reduce the feeling of isolation while undergoing radiation therapy.

- I don't have an idea of who to call because I don't recognize the physician on the pill bottle.
- That's a lot of things they asked me. Not in a form like this. They did it verbal. This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don't. This could have been a reference for all the other doctors this would be helpful. I did a lot of that repeat, repeat. And by the end, I'm tired.
- [Y]ou can just hand it to them and they could go over it with you. You could just answer it without going through everything over again.
- If there was anything frustrating it didn't have anything to do with them, you know, it was a matter that no one can be with you and you know, so, you're sort of responsible to remember all the stuff to take home and to talk about it.

Analytic Memos

There are a total of 12 direct links to communication; of these, 4 are codes, 5 are categories, and 3 are upper level categories (i.e. conceptual categories, ATLAS.ti 'nodes').

Codes

Approval is directly associated with communication with a generalized symmetric relationship – approval for communication was coded in comments from participants such as, “He did really well with that,” as well as, “All I can say is... he pretty much nailed on the head what was gonna happen to me.”

Choice is identified as part of communication, from communication method (e.g. reading vs. verbal) but also regarding type of chemotherapy as well as clinical trial participation.

Isolation is secondary to the current COVID-19 pandemic and negatively impacts communication. In the abstract, isolation could also extend directly to the code *single-source of information* and inversely to *gatekeeper* and *team*. This is based on participant comment such as, “[B]y the time I walked from the truck ... to where I needed to be... I thought my leg was gonna fall off. It was so swollen,” and “I was wondering on potassium cause the doctor said one day the potassium was low so I asked him.”

Information root. This code represents an abstract concept arising from participants' responses when queried what they believed was important for their radiation oncologist to know. The question was geared to explore lifestyle goals and/or maintain abilities. Instead, participants responded that it was what they needed to hear and not that they had information to share with the radiation oncologist. This extends beyond a lack of foundational knowledge, mixing with paternalism and perhaps a low prioritization of normal in the face of a life-threatening disease.

Categories

Barriers to communication is a category that negatively impacts communication. Participants describe barriers such as failure to respond (*I called up here one time, on a Friday morning, and they didn't get back to me til Tuesday.*) as well as failure to prioritize communication with the patient (*Cause I kept calling back to Minnesota... “Well your doctor isn't here today.” “Oh...your doctor – she went on vacation.”*). Barriers identified were person-to-person barriers; participants did not note a problem with technology. Interestingly, participants were aware of MyChart, approved of MyChart, would muse that they should have used MyChart, and then

would become irritated with other patients who did not use MyChart and complained (wherein MyChart would have presumably solved the issue). There was never a negative mention of MyChart per se; just a failure to use it when they knew they should have.

Factors affecting communication. The code information root as well as health literacy are two factors that affect communication; however, three other unique codes were also identified as factors: “didn’t know,” “medicine by committee,” and “team.” Depending on the presence in statements made by the participant, communication was team-oriented and patient-centered (“we,” “our,”) or was isolative, with the participant receiving treatment from a committee (“medicine by committee,” “they”). Participants would switch between “they,” and “we,” in interviews; this was not investigated for further significance. It’s an interesting flip/flop that may mean nothing.

Emotional reactions. This category aggregates verbal responses that extend beyond the words and into the tone or emotion behind the statement and thus influences communication. Examples include the code comradery (*So then when he lifted my pant leg and said, “SWOLLEN!?”*), feeling lucky (*So, knock on wood I guess I’m one of the weirdos that didn’t get anything*), and not concerned (*It wasn’t something I was freaking out about*). Emotional reactions provide insight into the participant’s lived experience through their treatment, a glimmer into the humanity of their responses to healthcare communications and their mindset.

Characteristics & context. If emotional reactions category provides a framing to the psychological or social reactions, characteristics and context category provides framing to the setting and context of the communication. This category also influences communication depending upon the situation. Characteristics such as verbal communication, active listening, and direct information were appreciated by participants as was accuracy of information provided. Two quotations that capture this with relationship to communication are *“It was down to earth, he made me understand. He’s very good at that, I think.”* and *“So they fed me the information. I... I’m not sure I would of known what to ask at that point.”* Both quotes have a nurturing context (down to earth, fed me) in an educational context (...made me understand). None of the participants declined to know their prognosis and all stated they were interested in longevity despite side effects. Prognosis & diagnosis were not considered difficult conversations, other than being described as a bit overwhelming.

Information traffic. This category centers on the patient/provider dyad and is the combination of the codes provider to patient communication, patient to provider communication, and information sharing. Patient to provider is unilateral, with discussion points ranging from discussion of diagnosis (*I would do the research and write down a question, like my particular diagnosis...*) to seeking reassurance (*“If it was something that spooked me or something, I could call and talk to someone on the team.”*). Provider to patient is also unilateral, but as retold by the participant; primary areas were diagnosis, treatment, and control of adverse events. Information exchange is the mutual sharing of information between patient and provider; perhaps the strongest quote for this code is *“I’m used to what they tell me and how they act and how I act back to them. The exchange of information.”* Although the literature suggests some patients still prefer paternalism and – as such – in pursuit of true patient autonomy, participants’ expressing paternalism also expressed that it was their responsibility to share information with their provider (*“[K]eep her in touch with how I was feeling and what was going with my body and stuff...stay in touch, basically be honest with, you know, what’s going on with how I’m feeling and all that stuff. I think that’s pretty important.”*) This provides insight that paternalism and shared decision making may not be oppositional as some of the peer-reviewed

literature suggests and that a simplistic SDM tool can still be used for patients who prefer a paternalistic relationship with their provider(s).

Upper Level Categories / Conceptual Categories

HEALTH LITERACY. This upper level category captures not only medical literacy but also individual concepts/factors that impact an individual's use of medical information. For example, commitment, proactive, comparison, printed education documents, and reading. Health literacy as a concept is best captured in two oppositional quotes:

- “Then I was like, ‘Okay, after 5 days, it’s time to give.’ ...So, I called. And the nurse was, she was really sympathetic about it but then at the end, she’s like ‘You are either up here today or you are in Fairfield, one or the other. You have no options.’ And she goes, ‘You should have called me the first day, not now.’ I said, ‘I realize this.’”
- “I was having a hard time breathing so I went in to see the doctors so I figured it was probably COPD. Took a chest x-ray... and said it was, uh, a mass...and that was in December. FINALLY (emphasis) got it sent out to Nevada... in February – beginning of March. It took ‘em a while to get stuff sent out there. By the time they found out what it was and that it was cancer and stuff, and since it was one that grows fast, it probably went from stage two to *four* because the doctors were just so *slow*.”

SYMPTOMS. An adverse event is defined by FDA as an untoward medical event that occurs during the contact of a clinical trial; this is then extended to an event that occurs during routine clinical care. There is a subtle nuance for this study that patient-reported symptoms are those that the patient reported but have not been confirmed by physical exam. Additionally, anticipated events are those side effects a provider noted were possible but may not have been realized. Concerning symptoms are those that necessitated urgent intervention, emergency care, or intensive care. Symptoms can also be present at baseline, consistent with the underlying disease or another comorbidity. SYMPTOMS serves as a critical category for the research question, as it is partnered to COMMUNICATION to create the shared decision making tool. Special interest was taken in the symptoms that were most commonly commented on by participants (fatigue, dyspnea, nausea, vomiting) as well as those that appeared to significantly interrupt their daily life (fatigue, edema, cognitive impairment). It is interesting to note that participants consistently noted prompting about symptoms across providers. This provides an opportunity for the SDM tool to capture this information consistently.

SDM IMPLEMENTATION. This upper level category focuses on the science and strategy behind implementation of the shared decision making tool. How the SDM tool will interact with all the categories is unclear, but the goal is that the SDM will positively impact communication through information sharing. How SDM implementation interacts with communication (if at all) will further be explored in the quantitative strand of this study.

Representative Codebook

Arranged alphabetically, definitions are provided for the codes shown in the COMMUNICATION depiction above. Categories are listed in **bold** with upper level categories in UPPERCASE. In general, a code is the most basic concept or construct present in an interview transcript. A category reflects a grouping or pool of constructs with a common idea. An upper-level category reflects the largest amalgamation of information, a pool or sea comprised of rivers of thought. Categories can serve as codes as well, dependent upon the concept/construct.

Code	Comment
accuracy	Information provided to the patient aligned with the lived experience. Information is provided by a healthcare provider and not by an alternate source (i.e., website).
active listener	Physician engages in active listening: eye contact, acknowledging what is said, or acting on information provided.
all-at-once	Information strategy; direct transfer of information at a single timepoint. Not piecemeal.
approval	to speak or think favorably of; pronounce or consider agreeable or good; judge favorably
Barriers to communication	Category encompassing events, situations, or factors that impede communication between patient and provider.
blame chemo	Reaction, explanation, or coping mechanism that blames chemotherapy for the event, reaction, or symptom
caregiver	A person who provides support to the patient during treatment.
Characteristics & context	Category encompassing characteristics & situational context of communication.
choice	Ability to choose or option to choose. May be patient, caregiver, or provider.
COMMUNICATION	Upper level category representing the totality of medical experience, foreknowledge, academic information as well as commercial information sources.
communication expectation	Expectations regarding communication whether it is patient, caregiver, or provider.
comradery	Attribute of communication and/or interaction; playful, friendly, and warm.
COVID-19	Disease caused by SARS-CoV-2; this can refer to the frank disease or pandemic precautions due to COVID-19
didn't know	Lack of background knowledge (medical, health), context, or electing to deprioritize in the face of other decisions or information requirements. Often associated with 'information root,' which is the nebulous concept around the goals of treatment and defining the patient's desired new normal.
direct	Direct communication strategy and/or methods; using direct language
disbelief	mental rejection of something as untrue
doubt	Calls into question if it is real or true
Emotional reaction	Category encompassing a response elicited to a prompt, situation, or stimulus that conveys more than the spoken words.
Factors affecting communication	Category encompassing things that impact communication negatively or positively. Not to be confused with characteristics & context, which are properties and/or traits.
failing to communicate	Failure of a patient, caregiver, or provider to actively communicate regarding an adverse event or concern.
failure to provide necessary tools	Failure to provide the patient or caregiver the tools needed for self-care, concomitant care, and/or supportive management.

Code	Comment
failure to respond	Failure by the patient, caregiver, or provider to respond to communication requests (e.g., email, phone, on-call).
failure to use available tools	failure to use available tools to reduce burden (e.g., MyChart).
familiarity with provider	Knowing the name and/or clinic of the provider.
fear	unpleasant emotion associated with anxiety, sense of foreboding or danger.
feeling lucky	Patient reaction / emotion that they are fortunate with their outcomes and that this outcome is mostly likely related to chance.
fun	Enjoyment, happy experience or sensation
HEALTH LITERACY	Upper level category; defined by Institute of Medicine as <i>the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.</i>
honesty	Truthfulness, being open regarding treatment, outcome, side effects.
information root	The recognition that the information is not available to the patient or provider and they cannot act due to the lack of information. The information root is missing.
information sharing	Information sharing (back and forth) between at least two parties: provider, patient, caregiver.
Information traffic	Category encompassing verbal signals or messages for communication
isolation	Frank or subjective separation from caregiver, family, or other providers.
medicine by committee	Negative connotation regarding the use of multiple providers in providing a single treatment.
new information	New medical information regarding treatment or side effect.
not concerned	Patient and/or caregiver was not concerned regarding treatment or side effects.
open ended	Communication format enabling descriptive or qualitative responses.
overwhelmed	inundated with information and / or the intensity of the situation.
patient repeated communication	Patient or caregiver must repeat the same comment, information, or symptoms to a provider or provider(s) within a reasonable timeframe (same clinic day, same visit, same phone triage).
patient to provider communication	Communication initiated by the patient to the provider, as per the patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider 'information sharing.'
physical contact	Physical contact between provider and patient that is occurring outside a physical exam or medical assessment.
pragmatic	Real-world and free of jargon.
prioritizing	Prioritization of symptoms or adverse events in communication.
prognosis	Expected trajectory and outcome of therapy.
provider cares	Verbal communication, physical interaction, or other indication that the provider cares personally for the patient as a person, beyond medical obligation.

Code	Comment
provider personality	The personality of the provider and its impact in communication
provider prompting	Provider's prompting for further information and/or communication
provider support	Providers providing support on a personal level, beyond the stereotypical patient/provider relationship.
provider to patient communication	Communication centered around, or from, the provider to the patient - as per patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider 'information sharing.'
provider to provider communication	Communication between the providers, as per patient.
reaction	The reaction to news, a circumstance, or event. Non-verbal or contextual communication.
repeated efforts to contact	Repeated efforts are made by the patient, caregiver, or provider to reach the other.
safety net	Something, or someone, that is reassuring to the patient.
SDM IMPLEMENTATION	Upper level category representing pool of information regarding implementation of a shared decision-making tool for patients diagnosed with lung cancer undergoing radiation therapy at a Midwestern academic hospital.
stress	Bodily or mental tension
surprise	Unexpected news or situation.
sympathy	An affinity, association, or relationship between persons or things wherein whatever affects one similarly affects the other
SYMPTOMS	Upper level category representing pooled information regarding symptoms, side effects, and adverse events.
team	Positive connotation regarding the multiple providers involved in the treatment and care of patient. This is the opposite of medicine by committee code. One of the facets of TEAM is if the subject describes decisions as "we," rather than "they," and/or describes a seamless interchangeability with the providers.
understanding	Caring and/or compassionate
verbal communication	Verbal communication
winning	Completion of goal to a satisfactory outcome

Health Literacy directly impacts Communication, SDM format, and SDM implementation but also has a secondary relationship to Treatment and Symptoms through Communication. Thus, the shared decision-making tool is dependent upon Health Literacy and may impact the tool's implementation and/or usefulness.

- And the doctor would know, but I wouldn't know.
- You know, I mean, just... you know I'm...I'm never had cancer before.
- I didn't ask a lot of questions because I didn't know what to ask.
- Well, you know, over the years you always hear when you're unhealthy that... well the white blood cells that are fighting off infection and stuff and that goes low during chemo and radiation and I figured I would ask.

Analytic Memos

In total, only thirty-three codes and categories are linked to health literacy; this is the smallest set of links for any of the upper level categories. However, of these there are 17 direct links to health literacy, which is more than Symptoms or Communications (which Health Literacy feeds to). Of the 17 links, 8 are source links (i.e. originating from Health Literacy) and 9 are target links (i.e. moving to Health Literacy). Of these links, of these, 26 are categories with 13 being upper level categories (i.e. conceptual categories, ATLAS.ti 'nodes'). These 17 are described below.

Codes

Academic information has a direct and positive impact on health literacy. Academic information is medical information obtained by participants outside of clinical visits, from verified academic secondary sources ("...there is the Mayo Clinic site and the University of Iowa site you can research. So, there are good sites out there, just stay away from WebMD."). Information obtained / provided between patient & providers in the clinical setting is not tagged as Academic Information because this is captured through routine communications. Of the two quotations tagged with academic information, the second reflects academic information intention / SDM when discussing the SDM tool: "*You mean for [the doctor] to just ... while s/he is looking over my stuff... to take some notes and then give me those notes?*" This is a weak code, having only two quotations, and can easily be confused with the robust academic medical information provided/shared in weekly on-treatment visits with radiation oncologists. However, the lack of associated quotations could be informative. Two participants noted using the internet for information (with only one specifically stating to look for academic sites) and preferred not to use computers. This is – ultimately – beyond the scope of the study.

Choice is identified as part of communication as well as part of SDM implementation. It is directly impacted by Health Literacy. Logic suggests a direct relationship, as health literacy increases, choice should then begin to align with the patient's goal (which may be different than the physicians' and/or caregivers). A common thread through *choice* is provider held information such that choice is limited:

- They really ... they say this is what you need to do. And that was about it, so. I could'a refused it except...I had two options there, I think, you know.
- He explained then more than the immunotherapy at that time about whether to have it or not have it in general. It wasn't a matter of a menu of many choices – it was more like, 'This is what it is about.'

– So, we got the 50 or the 60 percent... ((pause)) I don't know. But all these side effect things? I didn't care. I didn't care, really.

As with informed consent in research participation, a patient's lack of knowledge regarding options and side effects negatively impacts autonomy. The impact of poor health literacy, coupled with the power dynamic between provider and patient, could impair consent to treatment as well as the patient's active participation in treatment and treatment decision. Prior literature indicates there are patients may prefer a paternalistic relationship with their provider(s); this should be an active choice rather than an assumption or fall into a standard operating procedure. Although the shared decision making tool would be utilized during active radiation therapy, initiation of the shared decision making tool would occur at treatment planning. The discussion regarding concerning side effects related to chemotherapy/radiation therapy that should be tracked on the shared decision making tool may spark awareness by the provider regarding health literacy level. This may, in turn, remedy some literacy deficits.

Commitment in the context of health literacy demonstrates the participant's efforts to increase their health literacy. This is evident in participant's actions that occur beyond standard patient/provider interaction. For example, reading & re-reading a packet of information after treatment, or even struggling to read as the participant prefers verbal information. All participants described a commitment to improving their health literacy, whether reading, communicating with the team, researching information at home, and organizing information provided to them to disseminate to their caregivers. Logically, commitment is most likely driven by diagnosis and prognosis – however, this association was not explicitly made by the participants during the interviews. Participants endorsed using an SDM tool to further guide their research regarding their side effects and treatment. For this reason, commitment is considered to have a positive influence on health literacy.

Comparison. Three participants compared their adverse events to symptoms/illnesses they were familiar with (e.g., gastroesophageal reflux disease, dyspnea, fatigue, chemotherapy effects). Only one participant compared their treatment experience to the connotatively common side effects of cancer treatment. Except for that comparison, the participant descriptions regarding *expectation* of how the side effects would feel compared to what the participant *experienced* (“*[I had reflux] sometimes but not like that. It was pretty nasty.*”) suggests patient reported outcome measures should be framed by patients undergoing antineoplastic treatment to capture the nuanced differences and/or severity experienced.

Expectancy is an outlier code which represents the anticipated, yet unknown, results of treatment. There is only one quotation linked to the code (“*They actually said a survival rate of 50%. And ... and... 60... maybe 60... I thought I didn't like those numbers. I thought I had a bigger number.*”) Although the same numbers occur in other transcripts, the reflection back to self is absent. Like academic information, expectancy may require being merged into another code. The quotation provides insight that *expectancy* provides a bridging concept between prognosis and health literacy. Health literacy influences (positive or negative) expectancy whereas and prognosis is influenced by expectancy (positive or negative). Although an argument could be made that prognosis spurs interest in medical literacy resulting in an impact in health literacy and ultimately the shared decision making tool – this was not voiced by participants (and is thus not captured on the nodal map) and seems a convoluted logical path.

Goal is a code that conceptualizes the desired end result. Goal has a nuanced difference from expectancy, whereas expectancy captures the ‘given,’ or ‘expected,’ end results the concept of goal reflects the end result the patient must work for, earn, or achieve. This is reflected not

only in treatment outcomes (*"I know my goal ... I know my goal was that I wasn't give up and I was gonna fight through whatever I had to go through, so, you know – whatever it be this and I get sick from it or whatever I'm gonna deal with it."*) but also as a rationale for the disease (*"The way I looked at it. God put me on here. He gave me this challenge. I have to climb this mountain."*). Health literacy influences goal(s) (*"...we wanted to treat it aggressively and this was the way to do it. So, I guess I wasn't really interested in learning any other treatments."*) but a direct connection from goal to health literacy was not voiced during the interviews.

Information root. This code represents an abstract concept arising from participants' responses when queried what they believed was important for their radiation oncologist to know. The question was geared to explore lifestyle goals and/or maintain abilities. Instead, participants responded that it was what they needed to hear and not that they had information to share with the radiation oncologist. This extends beyond a lack of foundational knowledge, mixing with paternalism and perhaps a low prioritization of normal in the face of a life-threatening disease. It is presumed information root and health literacy likely have an inverse relationship; poor health literacy increases the information root as an abstract concept (e.g., not knowing what to know, not knowing what to ask). It is unclear if a stronger health literacy foundation decreases the information root and, if so, would it have a positive impact on identifying goals for patient reported outcome measurements on the shared decision-making tool?

Medical literacy provides insight into a participant's ability to apply layperson's medical knowledge to general events (*"I can't eat hamburger. I will throw it up... I think it is because it is so fatty."*), their current cancer therapy (*"I have other issues with my liver tumors on my liver that can be treated. Autoim...autoimmune therapy."*) as well as familiarity with the medical regime (*"I broke my leg, on crutches for 5 years, 20 some procedures. So, I know about the student teaching hospital part of it. And they would come in 4 or 5 physicians and residents and stuff and they would talk to you in third person. Because it was a learning opportunity."*) Medical literacy represents a relationship between medical experience, foreknowledge, and shared information sources (e.g., internet, TV commercials). Medical literacy directly influences health literacy in a relationship that is influenced by the patient's evaluation of the medical information source as well as their experience.

Patient to provider communication is directly influenced, positively and negatively, by health literacy. Using the IOM definition, health literacy includes the (in)ability of a patient to communicate effectively with their provider. Barriers to communication can include not knowing who to contact (*"I'm not sure I have [a primary medical oncologist], it changes. Whoever's on call... whoever's working that day..."*) as well as simple issues in trust (*"I took some medicine and I had a horrendous diarrhea and it wasn't supposed to affect it the opposite way. I think he didn't believe me ... and it was really bad."*) In reviewing patient-to-provider communication, it becomes apparent the communication patterns between patient, provider, and health literacy are unidirectional, representing a triad and not contributing to a bilateral information sharing. Health literacy directly influences patient-to-provider communication in a unilateral flow.

Provider to patient communication directly influences health literacy. The healthcare providers (e.g., physicians, nurses, radiation therapists, respiratory therapists) provide medical information directly to the patient and, if available, the caregivers. The goal of provider to patient communication is to transfer knowledge to the patient and increase their health literacy (*"It was down to earth, he made me understand. He's very good at that, I think. He lets*

you know what's going on.") as well as instruct so that it is clear when further services are needed (*"But there were many times where uh ... one of those nurses would say to me, 'If you have any problems with this, that or this, vomiting or whatever, and you think it is unusual, do not hesitate to call these numbers.'"*). Again, this is a unilateral flow of information from the provider(s) to the patient and not a mutual information exchange.

Printed education materials are provided to patients through routine nursing practice at UIHC. Participants described reading them, including the participant who described himself as a slow reader (*"In fact, I have my sister do most of it."*). This provides insight into the patients' willingness to read information for self-education.

Proactive is codified for one participant regarding her engagement in the healthcare process; consider merging with "self-reliance."

Reading introduces the only barrier to the health literacy nodal map: slow reader. Reading directly influences health literacy, SDM implementation, and format of the SDM tool. The barrier reminds to keep the SDM tool with the appropriate readability but also short to reduce burden for a patient with slow reading skills. Logically, illiteracy also becomes a barrier to reading, although not identified during interviews. During implementation, workflow will need to be considered for slow readers as well as illiterate patients.

Categories

Factors affecting communication. The code information root as well as health literacy are two factors that affect communication; however, three other unique codes were also identified as factors: "didn't know," "medicine by committee," and "team." Depending on the presence in statements made by the participant, communication was team-oriented and patient-centered ("we," "our,") or was isolative, with the participant receiving treatment from a committee ("medicine by committee," "they"). Participants would switch between "they," and "we," in interviews; this was not investigated for further significance. It's an interesting flip/flop that may mean nothing.

Upper Level Categories / Conceptual Categories

COMMUNICATION. This upper level category and health literacy mutually influence each other. Communication & Health literacy are captured in two oppositional quotes:

- "Then I was like, 'Okay, after 5 days, it's time to give.' ...So, I called. And the nurse was, she was really sympathetic about it but then at the end, she's like 'You are either up here today or you are in Fairfield, one or the other. You have no options.' And she goes, 'You should have called me the first day, not now.' I said, 'I realize this.'"
- "I was having a hard time breathing so I went in to see the doctors so I figured it was probably COPD. Took a chest x-ray... and said it was, uh, a mass...and that was in December. FINALLY (emphasis) got it sent out to Nevada... in February – beginning of March. It took 'em a while to get stuff sent out there. By the time they found out what it was and that it was cancer and stuff, and since it was one that grows fast, it probably went from stage two to *four* because the doctors were just so *slow*."

SDM FORMAT. This upper level category focuses on the format and presentation of the shared decision making tool. In addition to being linked to SDM Implementation, both reading and health literacy also influence SDM format unilaterally (from Health Literacy / reading to FORMAT).

SDM IMPLEMENTATION. This upper level category focuses on the science and strategy behind implementation of the shared decision making tool. How the SDM tool will interact with all the upper level categories is unclear. It is unlikely that SDM implementation will impact or influence health literacy. There are no plans to measure health literacy during SDM implementation.

Representative Codebook

Arranged alphabetically, definitions are provided for the codes shown in the HEALTH LITERACY depiction above. Categories are listed in **bold** with upper level categories in UPPERCASE. In general, a code is the most basic concept or construct present in an interview transcript. A category reflects a grouping or pool of constructs with a common idea. An upper-level category reflects the largest amalgamation of information, a pool or sea comprised of rivers of thought. Categories can serve as codes as well, dependent upon the concept/construct.

Code	Comment
academic information	Medical information obtained from an accredited academic institution (e.g. Mayo, UIOWA, MSKCC).
accomplishment	Synonymous with completion or achievement.
choice	Ability to choose or option to choose. May be patient, caregiver, or provider.
commitment	Resolved to do something; expended energy or effort to complete.
COMMUNICATION	Upper level category representing the totality of medical experience, foreknowledge, academic information as well as commercial information sources.
comparison	Patient-specific attribution.
coping	Synonymous with "cope with." Deal with and attempt to overcome problems and difficulties. Primarily patient construct; could be used with caregiver as appropriate. ^[P] _[SEP]
doing better	Subjective assessment that frank symptoms of disease or treatment emergent adverse events are improving or have improved. This assessment can be made by patient, caregiver, or provider.
expectancy	Anticipation of results or outcome
Factors affecting communication	Category encompassing things that impact communication negatively or positively. Not to be confused with characteristics & context, which are properties and/or traits.
foreknowledge	A patient's or caregiver's familiarity with cancer, the healthcare system, or medicine in general.
Format of SDM tool / SDM FORMAT	Upper level category representing pool of information regarding the format, design, and graphical layout of the shared decision making tool
goal	Synonymous with aim; the desired end-result treatment.
HEALTH LITERACY	Upper level category; defined by Institute of Medicine as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.
hope	To want something to happen or be true

Code	Comment
information root	The recognition that the information is not available to the patient or provider and they cannot act due to the lack of information. The information root is missing.
inspiration	An influence or action that is used to keep momentum, positivity, or faith.
Internet search	Using the internet as a source of information about the cancer, treatment, or side effects.
medical experience	Patient's medical experience prior to receiving radiation therapy.
medical literacy	Ability to obtain, read, understand, and use healthcare information in order to make appropriate health decisions and follow instructions for treatment.
new normal	A lifestyle, activity level, or physical issue (taste, cough) that is not consistent with life prior to the disease or treatment.
patient abilities	The physical, emotional, or social abilities of a patient. These are typically queried in quality of life assessments as well physical examinations. Should not be confused for Activities of Daily Life which are those specific activities that are assessed for adverse event severity and criteria.
Patient reported outcome	Category and code. An outcome (disease outcome, treatment outcome) as reported frankly by the patient. This may include an adverse event if the event aligns with a final outcome (e.g. weight gain, hair loss) rather than a treatment emergent event. Often, this is in summary or retrospect and in the framing of a response to therapy; can also include a lack of response to therapy.
Patient to provider communication	Category and code. Communication initiated by the patient to the provider, as per the patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider 'information sharing.'
printed education documents	Education materials in printed format provided to the patient and/or their caregiver.
proactive	Self-actuation or care; patient putting self-first to ensure best treatment, best outcomes.
prognosis	Expected trajectory and outcome of therapy.
provider to patient communication	Communication centered around, or from, the provider to the patient - as per patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider 'information sharing.'
reading	Information that was conveyed by reading and/or the preference to read.
SDM IMPLEMENTATION	Upper level category representing pool of information regarding implementation of a shared decision-making tool for patients diagnosed with lung cancer undergoing radiation therapy at a Midwestern academic hospital.
self-reliance	Patient relying on self through treatment and post-treatment
slow reader	Having a slow reading speed, limiting reading functionality
TV commercials	Information about cancer treatments obtained from television commercials

The most commonly patient-identified symptoms are fatigue, nausea, vomiting, dyspnea and malaise, all of which are subjective, variable by patient, and negatively impact activities of daily life and all of which can be more consistently quantified utilizing a shared-decision making tool.

- It’s awful. You’re more tired than... this normal tired you’re supposed to be experiencing. And...you can’t eat, and you know, you don’t want to do anything but lay on the couch or your bed.
- Well, I.... I wake up most of the time and I’m still tired.
- So, when you poke 7 pills one day, 7 the next day. So that was 14 pills dumped down in me and then try to drink enough water to dilute them...and I just couldn’t do it and then I got sick and I couldn’t take my regular pills. I would put ‘em in my mouth. I’d drink water. They would come right back up...I’d just ... I’d give up at a point.
- Since I don’t have any usual or daily activities ...or anything to do... it really doesn’t interfere with anything. All I do is watch TV.
- The burn on my back... it didn’t show up until I went home. And the nausea too. Everything was delayed until I was done with it.

Analytic Memos

In total, seventy-three codes and categories are linked to symptoms. However, there are only 16 direct links to symptoms of which 5 are source links (i.e. originating from symptoms) and 11 are target links (i.e. moving to symptoms). Of these links, of these, 7 are codes, 5 are categories, and 4 are upper level categories (i.e. conceptual categories, ATLAS.ti ‘nodes’). These 16 are described below.

Codes

Burden is a direct result of symptoms represented by a unilateral relationship. Burden was identified explicitly only once (“...(caregiver) ... asking if it is okay if they come and pick it up now and those types of things.”) but is also implied in quotes such as *“In fact, I have my sister do most of it,”* as well as, *“Some of the side effects kinda scare me from what they say. But my husband’s like, ‘and it is if. IF IF IF.’”* Burden encompasses not simply physical support from family, friends, and caregivers, but also pthe psychological and social support. Burden remains intangible but continually present, most likely impacted by COVID-19 (perhaps heightened), and reminds of the possibility of an unreliable patient narrator, as the patient may attempt to minimize symptoms in order to reduce burden.

Patient abilities are the participant’s insights into their functions: “Can I actually do this? Am I able to?” as well as “Cause they would take me longer. Um, to do that type of stuff. Where you do one thing, and you have to sit and rest.” Patient abilities also refers to the participant’s abilities to complete the sample questions provided (“I can answer any of these. I would think.”).

Provider-to-patient question is a code capturing provider prompts to further assess adverse events as well as encourage discussion between provider and patient. Four of the six participants commented on provider questions, from *“What can I do to make your day better?”* to *“Are you having any pain?”* as well as *“Anything else you want to talk to me about?”*. Prompts are identified through participant recall. Provider prompts were described as similar to quality of life questions provided as samples to participants (*“That’s a lot of things they asked me. Not in a form like this. They did it verbal.”*)

Recall. This code is the action of a participant remembering details regarding diagnosis, treatment, and decision making. Recall, as a whole, was inconsistent, with deficits in memory regarding key points in the cancer journey (i.e., treatment options, decisions). Lapse or inconsistent recall could be a function of stress or chemotherapy.

Self-care is a code that reflects the participant's care for self (i.e., physical, social, psychological spiritual, emotional). Self-care was described by five of the participants, with supportive quotes including the physical (*"I talked to them about getting the flu shot since I wasn't sure."*), social (*"[my brother and sister-in-law] just wanna take me out for dinner with them. I forget the place she said."*) and psychological (*"But I already told them I need a break. You gotta give me some time off."*). However, quotations supporting explicit emotional self-care or spiritual self-care were not identified. Although emotional could be seen as part of the psychological health system, spiritualism in the context of self-care was not identified in any transcript. This could be due to the medical setting of the interview as well as the limited scope of the questions.

Uncertainty. This code captures the concept of the unknown from the participant's perspective. As expected, it was identified regarding treatment outcomes (*"Not knowing if its gonna work if you're doing all this for no reason."*) but also regarding the *severity* of the treatment-emergent adverse events that were experienced:

- And I slept a lot! And I still sleep a lot! I sit here, and think, when am I going to get my energy back? Because I could still sleep a 12-hour day in a heartbeat.
- And part of that is because I'm old or because I mean, you slow down. How much of it is THAT or how much of it is... you know, like I had all this other happen and now I'm not gonna be 100%. I don't know.
- I kept wondering – when is this gonna hit me?

This was somewhat unexpected as participants were seen daily throughout their course of radiation therapy by a variety of medical professionals (e.g., radiation therapists, nurses, radiation oncologists). This should have provided substantial opportunity to address uncertainty and provide reassurance. A potential strength of the SDM tool would be to provide a trend over time for adverse events of interest, which could provide reassurance for individual patients as well as provide key foundational information for treatment and recovery as a whole.

Variability by patient. Five of the six participants acknowledged the individuality of patients undergoing therapy and that each would have unique experiences. The majority of the quotes were variations of a common statement regarding "everybody's different," but one quote stood apart from the rest: *"Listening to the patients... the patients know their bodies. They know what is going on inside their bodies and what isn't. And that, to me, is one of the first things a doctor needs to listen."* This quote ties the patient and provider together through communication and individuality. Ostensibly, the shared decision-making tool addresses this individuality by allowing the patient to identify the signs/symptoms of concern, addressing the concerns unique to each individual.

Categories

Activities of daily life. This category captures codes that align with activities of daily life as listed in the Common Terminology Criteria for Adverse Events (CTCAE). Eating and walking were the commonly identified. ADLs were not specifically queried during the interviews. Although a category, activities of daily life was a *proscribed* category created to gauge the impact of symptoms and other factors on ADL.

Anticipated events. Anticipated events are those recalled by the participant as side effects or symptoms that were to be expected during the course of therapy. Some were explicitly mentioned (e.g., alopecia, nausea, vomiting) but it also includes broader concepts:

- I knew what was coming, their explanation of what was gonna happen to me was very precise and helpful
- They had explained the series of chemo and at what point I would not start feeling well or I could start looking for signs of not feeling well this way or that way or the other way
- I took some medicine and I had a horrendous diarrhea and it wasn't supposed to affect it the opposite way.

Recalled anticipated events are significant because they provide insight into what information made a lasting impression, resulting in retention. Of note, *weight loss* was not an anticipated event recalled by participants despite being described as both an anticipated and *significant* treatment emergent adverse event.

Factors & context. This category captures codes that either impact symptoms (factors) or provide detail regarding the event (context). This includes sudden onset (*"One minute – you can be just...fine...doing what you're doing. And then all of a sudden, it's just like...your body is just dropped to nothing."*), delayed events (*"My symptoms from the radiation didn't really show up until it was all over with."*), intensive care (*"I spent the night in intensive care because my oxygen level wasn't high enough for me to go home."*), persistent symptoms (*"They gave it to me in the E.R. It didn't make my symptoms go away."*), as well as not concerned (*"He did a very good job listening to me and my concerns. I really didn't have any."*).

Patient reported outcome. Slightly different than a patient reported symptom, a patient reported outcome is a result in the opinion of the participant. This can be a treatment outcome (*"...But that was the day that the tumors had shrunk down completely. Hardly just spots."*), a symptomatic outcome (*"I really did not have any problems with my radiation. I mean everything went so smoothly with that. It went so smoothly." "I didn't lose my hair."*), as well as an overall assessment of the treatment journey (*"And I'm better than I was, I'm doing better than I was."*). Some patient reported outcomes overlap with symptoms; the primary dividing line is having it be an outcome or consequence of treatment rather than a concurrent event.

Patient reported symptom. The largest category, this group of codes is comprised of adverse events/symptoms as reported by the participants. This category includes baseline symptoms (*"...I could tell every week I was getting worse. Ended up having almost about a liter of fluid behind my lung."*), treatment emergent events (*"...my throat started getting worse 2 to 3 weekends ago... yesterday's meal was quite harsh trying to swallow that one."*), adverse events due to concurrent events (*"I got sick in the bathroom and the nurse took me to the E.R. I spent 8 hours there and they said, 'We're gonna take your gallbladder out.'" as well as generalized adverse events ("I've, uh, just been dealing with mainly the side effects from chemotherapy are mainly what messed with me."*). This category provides the customary rich and thick detail of the patients' experiences during the treatment journey. This becomes key to the shared decision-making tool to provide the context required to increase pragmatism and patient-level understanding. For example, one participant noted, *"Unbelievable amount of sleep... watching a movie... I don't think I've seen four shows in the last week from beginning to end."* This is not reflected well in the only PRO-CTCAE question for fatigue (In the last 7 days, what was the SEVERITY of your FATIGUE, TIREDNESS OR LACK OF ENERGY at its WORST? None, Mild, Moderate, Severe, or Very severe) but PROMIS item bank has the question *How often were*

you too tired to watch television? Thus, this pivots question selection *away* from the NCI's developed PRO-CTCAE and *toward* the more granular questions that align with a patient's daily experience while undergoing treatment.

Upper Level Categories / Conceptual Categories

COMMUNICATION. Shared decision making is an intersection of SYMPTOMS and COMMUNICATION; the interaction between the two upper level categories is a bilateral association. Of interest, patients conveyed understanding that communication regarding side effects / symptoms was critical for their care. One participant likened this communication to a safety net ("*...you're coming every day for radiation, and that was also sort of a safety net. Because if you didn't feel good from one day to the next, you knew you were coming back. And you could ask somebody the question...*"). Another admitted they failed to communicate as they should have and that led to emergency care ("*And if you got problems and you need help, you as the patient have to ask because they don't know. And if you don't ask, like I don't sometimes, they're not gonna know that there's a problem.*"). Participants had a favorable view of MyChart and were critical of individuals who failed to use it ("*Those are things out there for people to use to reduce the time. But if they don't use them, they need to stand in line.*") "*Toughed it out,*" is the code within symptoms that confounds communication and shared decision making, representing a concept of self-reliance that becomes detrimental to the patient. This was described by three participants:

- They kept saying a lot of this stuff was gonna happen but it never happened until I got home. And then I said, "Well, it's happening now." It happened like they described it. I just felt it and got over it.
- I should have [called the doctor] when I got sick on the pills (laughs boisterously). I just thought, 'You know, I have a really bad stomach anyways.'
- I sorta limped along

This concept is most likely influenced by the concepts of burden and self-reliance. It is apparent from the interviews (50%) that the *toughed it out* concept was as strong, or stronger, than the knowledge a patient must communicate with a provider. Instituting a shared decision-making tool to identify and quantify adverse events of special significance provides *normalcy* and *expectation*, shifting symptoms from a compliant to a rote process. With this pivot, reviewing and communicating regarding symptoms is acknowledged as anticipated, acceptable assessment to succeed in therapy. Thus, the SDM tool may tilt communication patterns away from *toughing it out* back to information sharing.

TREATMENT. Treatment refers to the antineoplastic therapy and not for adverse events or symptoms. Treatment is directly associated with symptoms logically as well as through description by the patient participants. In practice, symptoms associated to treatment are termed *treatment emergent events*; for the purposes of this research, treatment associated are the patient-recalled 'anticipated events,' which were collected through direct query during the interviews. Anticipated events represent a small fraction of the symptoms described by participants but are of interest for the shared decision-making tool, as they suggest treatment would need to be modified and/or paused if the symptoms are too severe. Again, it is also interesting what anticipated events were recalled by participants compared to which side effects providers consider to be the most important or concerning.

SDM IMPLEMENTATION. This upper level category focuses on the science and strategy behind implementation of the shared decision-making tool. How the SDM tool will interact with all the upper level categories is unclear, but the goal is that the SDM will positively impact communication through information sharing. Implementation of the SDM will impact documentation of symptoms / side effects; if implemented as designed, it should provide consistent documentation, using standardized definitions of severity and harmonized terms.

SDM FORMAT. This upper level category focuses on the graphical design of the SDM tool, including the presentation of data. Symptoms provide the key information for the SDM tool, with six symptoms / goals collected on the tool (3 from the patient, 3 from the provider). In addition to the symptoms, participants identified granularity as important, commenting that PRO-CTCAE was too general as well as timeframe. For example, participants questioned how to categorize the framing of “the past seven days,” – did it include weekends or holidays? Most interestingly, despite the favored viewpoint of MyChart, participants preferred to have paper to hold and take with them from provider to provider:

- You can just hand it to them and they could go over it with you.
- This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don’t. This could have been a reference for all the other doctors this would be helpful.
- That way if I’m home, and I had a piece of paper, and all of a sudden I hit that side effect I could say, ‘Oh, this and.... Hmmm, call in!’

Representative Codebook

Arranged alphabetically, definitions are provided for the codes shown in the SYMPTOMS depiction above. Categories are listed in **bold** with upper level categories in UPPERCASE. In general, a code is the most basic concept or construct present in an interview transcript. A category reflects a grouping or pool of constructs with a common idea. An upper-level category reflects the largest amalgamation of information, a pool or sea comprised of rivers of thought. Categories can serve as codes as well, dependent upon the concept/construct.

Code	Comment
acceptance	Accepting the situation, information, or occurrence; no longer attempting to change the situation.
accomplishment	Synonymous with completion or achievement.
Activities of daily life	Category and code. Activities performed daily by the patient. This can include Instrumental ADL (e.g. preparing meals, shopping for groceries or clothes, using the telephone, managing money) as well as self-care ADL (e.g., bathing, dressing and undressing, feeding self, using the toilet, taking medications)
alopecia	Defined in CTCAE 4.03. Hair loss.
anorexia	Defined in CTCAE 4.03. Loss of appetite.
anticipated events	Adverse events or side effects that were expected to occur in the opinion of the patient, caregiver, or provider.
arthralgia	Joint pain; MedDRA term
baseline symptoms	Symptoms that are present prior to the initiation of treatment; consistent with underlying disease, age, and/or other.

Code	Comment
burden	The subjective opinion or feeling that the patient is causing extra work, effort, or cost to family and caregivers.
burning	CTCAE, other: subjective sensation similar to being scalded by hot water or injured by a hot surface.
caregiver identified medical need	A need (physical, psychological, social, emotional) identified not by the patient but by a caregiver.
chemotherapy reaction	An adverse event directly attributed to chemotherapy by the patient, caregiver, or provider.
chest pain	Defined by CTCAE 4.03: discomfort in the chest; may or may not be related to a cardiac issue
cognitive disturbance	A disorder characterized by a conspicuous change in cognitive function.
commitment	Resolved to do something; expended energy or effort to complete.
COMMUNICATION	Upper level category representing the totality of medical experience, foreknowledge, academic information as well as commercial information sources.
communication expectation	Expectations regarding communication whether it is patient, caregiver, or provider.
concerning symptom	An adverse event that is concerning to the patient, caregiver, or provider and most likely requires notification or intervention.
constipation	Defined in CTCAE 4.03: use of laxatives or nutritional intervention to stimulate bowels.
coping	Synonymous with "cope with." Deal with and attempt to overcome problems and difficulties. Primarily patient construct; could be used with caregiver as appropriate.
cough	Defined in CTCAE 4.03: A disorder characterized by sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs and usually accompanied by a distinctive sound.
dehydration	Defined in CTCAE 4.03: excess loss of water from body.
dermatitis radiation	Defined in CTCAE 4.03: cutaneous inflammatory reaction occurring as a result of exposure to biologically effective levels of ionizing radiation.
diarrhea	Defined in CTCAE 4.03: an increase of at least 4 stools per day over baseline.
dysphagia	Defined in CTCAE 4.03: difficulty in swallowing.
dyspnea	Defined in CTCAE 4.03: shortness of breath
dyspnea PROMIS	Dyspnea questions using PROMIS question bank
edema - limb	Defined in CTCAE 4.03: swelling due to excessive fluid accumulation in the upper or lower extremities.
esophagitis	Defined in CTCAE 4.03: inflammation of the esophageal wall
Factors & context	Category encompassing things and situational context that impact symptoms positively or negatively.
fatigue	Defined in CTCAE 4.03: state of generalized weakness with a pronounced inability to summon sufficient energy to accomplish daily activities.
fever	Defined in CTCAE 4.03: body temperature of at least 38°C

Code	Comment
Format of SDM tool / SDM FORMAT	Upper level category representing pool of information regarding the format, design, and graphical layout of the shared decision making tool
gagging	adverse event associated with the sensation of choking when swallowing or eating.
gastroesophageal reflux disease	synonymous with acid reflux and GERD. Occurs when stomach acid frequently flows back into the tube connecting your mouth and stomach (esophagus).
generalized adverse reaction	A side effect or adverse event that is non-specific but attributed to a treatment, drug, or device.
hypokalemia	Defined in CTCAE 4.03: a potassium level below the lower limit of normal.
hypoxia	Defined in CTCAE 4.03: an oxygen saturation of less than 88% with exertion and/or indication for supplementation
lifestyle activity	Patient's lifestyle; may be pre-treatment, during treatment, or post-treatment
lifestyle food	Eating habits pre-treatment, post-treatment, and during treatment
lung infection	Defined in CTCAE 4.03: active infection of the lung, connotatively consistent with pneumonia
malaise	Generally unwell; synonymous will ill feeling, unwell, and / or felt ill.
memory impairment	Inability to remember; may or may not be related to chemotherapy.
mucositis oral	Frank adverse event to capture oral sores within the mouth often associated with antineoplastic therapy. MedDRA term.
nausea	Defined in CTCAE 4.03: queasy sensation with or without urge to vomit
new normal	A lifestyle, activity level, or physical issue (taste, cough) that is not consistent with life prior to the disease or treatment.
obstruction	Subjective obstruction due to tumor
odynophagia	pain with swallowing
out of town	Patient lived outside of town where treatment center was located.
pain	marked discomfort
patient abilities	The physical, emotional, or social abilities of a patient. These are typically queried in quality of life assessments as well physical examinations. Should not be confused for Activities of Daily Life which are those specific activities that are assessed for adverse event severity and criteria.
Patient reported outcome	Category and code. An outcome (disease outcome, treatment outcome) as reported frankly by the patient. This may include an adverse event if the event aligns with a final outcome (e.g. weight gain, hair loss) rather than a treatment emergent event. Often, this is in summary or retrospect and in the framing of a response to therapy; can also include a lack of response to therapy.
Patient reported symptom	Category and code. Patient's reported symptom that may or may not be endorsed by the physical exam or provider. Typically, treatment or disease related and is an unwanted side effect.
prior normal	The lifestyle, activities, or physicality (taste, strength, for example) that existed prior to the cancer or treatment

Code	Comment
prolonged effort	An increased amount of time, effort, or both to accomplish an activity as compared prior to disease and/or treatment.
provider to patient question	Questions directed to the patient from the provider, as per patient
radiation related symptoms	Adverse events known to be related to radiation therapy.
recall	The patient's ability to recall - or strategy to recall - information. This is different than memory impairment or cognitive disturbance, which are adverse events/symptoms.
relationship	Social or romantic relationship
routine illness	An illness that is deemed common and not considered associated to cancer, the pandemic, or side effects of treatment - for example, the common cold.
SDM IMPLEMENTATION	Upper level category representing pool of information regarding implementation of a shared decision making tool for patients diagnosed with lung cancer undergoing radiation therapy at a Midwestern academic hospital.
self-care	Patient taking care of self during treatment and after. Includes proactive treatment to reduce symptoms, side effects, or stress as well as care to maintain or improve the domains of health: physical, psychological, social, emotional, spiritual.
self-reliance	Patient relying on self through treatment and post-treatment
SYMPTOMS	Upper level category representing pooled information regarding symptoms, side effects, and adverse events.
throat pain	sore throat
thromboembolic event - superficial	Defined in CTCAE 4.03: blood clot not requiring emergent intervention
treatment / TREATMENT	Upper level category and code. Medical treatment, including surgery, radiation therapy, chemotherapy, nutritional support, and emergency care for the lung cancer.
uncertainty	Uncertainty regarding treatment outcomes, side effects, or the future.
variability by patient	Individuality of patients impacting treatment, diagnosis, and shared decision making.
verbal communication	Verbal communication
vomiting	Defined in CTCAE 4.03: emesis occurring at least once in a 24 hour period
weight gain	weight gain of more than 5% from onset of treatment or disease.
weight loss	Loss of at least 5% during the treatment.
white blood cell decreased	Defined in CTCAE 4.03: white blood cell decreased to less than the lower limit of normal.
working through	Maintaining an outside job or career during treatment

Treatment is linked to the patient experience, and thus shared decision making, through symptoms and patient reported outcomes. This reminds us that the impact of shared decision making on treatment is secondary and influenced by the lens of patient reported outcome measures (symptoms, treatment outcomes). This aligns with the research question, which seeks to identify the collaborative decision-aid tool regarding side effects and symptoms (not treatment).

- So, they immediately jumped on you know, “We need the medicine for this and that. You need to do this and that.” It’s not like they ignore you when you say there’s something wrong. They check it out.
- They suggested Lubriderm, which is what I put on it. And that took care of ... they’re like, “We’re gonna dry your skin out.”
- They had me on 3 different pills of medication to help with the nausea so I never noticed it.
- They were gonna get me in right away to find out what the infection was. So, they were gonna schedule me for some procedure the next day...Okay, fine. And then they called back: “We can’t do that procedure because you have to have a COVID test.”

Analytic Memos

In total, forty-six codes and categories are linked to treatment. However, there are only 13 direct links to treatment of which 5 are source links (i.e. originating from treatment) and 8 are target links (i.e. moving to treatment). Of these links, of these, 7 are codes, 1 is a category, and 1 is an upper level category. These 13 are described below.

Codes

Choice is key to patient autonomy for treatment. In the interviews, choice was touched upon regarding treatment for symptoms but was not explicitly recalled for treatment of the tumor. Logically, as well as legally, autonomy and choice are critical for any treatment decision, most notably for the therapy for the tumor. A common sentiment expressed by most participants was that they were sure there *had* been a discussion regarding antineoplastic treatment but they could not remember it. Only one participant had the opinion there was no choice for primary treatment (“*[T]hey say this is what you need to do. And that was about it.*”). Most subjects described being offered choices for treatment for side effects/symptoms; this is notable as it is the focus of this research and the target of the shared decision making tool. Examples include:

- The tums, like I said, and they were available to give me something else if that didn’t work but that worked fine.
- The nurse was, she was really sympathetic about it, but then at the end she’s like “You are either up here today or you are in Fairfield. One or the other. You have no options.”
- One of those nurses would say to me, If you have any problems with this, that or this, vomiting or whatever, and you think it is unusual, do not hesitate to call these numbers. And actually, when I, you know and we were early on and I got that infection we DID call the number because it’s like, “Oh my gosh my temperature’s over 101.5°F.”

It is interesting that participants discussed treatments for symptoms / symptom management organically (i.e., without direct query) but did not recall discussions regarding their primary antineoplastic treatment despite direct query. Patients were certain they had the discussion

but could not recall direct information provided to them. Although this is interesting, the absence of recall regarding primary therapeutic decision is out of scope of the research question. It is also interesting, and supportive of the research question, that patients recalled the choices provided to them regarding symptom management. This suggests a sense of control the patients have in these treatment decisions as well as being part of the treatment team. This supports an environment that is ready for implementation of a shared decision making tool, as both providers and patients are comfortable with patient-directed choice to manage side effects of treatment and symptoms of disease.

Clinical Trial. Of the patients interviewed, one was considered for a clinical trial and two others were treated on a clinical trial. These three patients were comfortable and well versed in aspects of the clinical trial, including the required staging to enter into a clinical trial (“*[F]or this study they staged me as a III...They changed the staging criteria for me to go into their study.*”), the investigational drug being withheld due to adverse events (“*I couldn’t have my [study drug] that day because my temperature was too high.*”), the significance of a placebo control and its impact on their treatment (“*But the placebo is a pretty strong thing there, you know?*”) and the ability to stop research treatment at any time (“*Same with this [points to study infusion]. Said I could stop at any time if I wanted.*”). Although – again – the key rationale or discussion for consenting to trial participation is absent, this recall of key legal elements of consent suggests the clinical trials team is providing *effective* and *continual* informed consent for these patient participants. Mirroring this strategy when implementing the shared decision making tool could lead to an earlier determination of the impact (if any) of the SDM on outcomes of interest.

Delay in seeking treatment is a concept that negatively impacts treatment as it represents an acknowledged (deliberate) delay in seeking treatment for the cancer (“*That Friday of... of our last day of school I went to the doctor at that point. And uh that’s when they said they thought it was bronchitis and that’s how they treated me for it. Um, and then, you know ... I didn’t get better...*”) or adverse events (“*So I finally called and then got yelled at by them. (laughs). Not really yelled at...but, I should have called them the very first day.*”). This code is only present twice but represents a strong concept of denial as well as intertwining with the code of **Toughed It Out**, which is similar but not synonymous. The shared decision making tool may be able to address this barrier by (1) providing an objective assessment to guide the patient / caregiver when to call in as well as (2) preventing escalation of symptoms through proactive identification.

Doing better is a patient assessment that compares change over time for a symptom, side effect, or generalized health. It is associated with treatment and creates the bridge between **goal** and **treatment**. This highlights a concept for consideration of the shared decision making tool: changes in symptoms over time, not simply for prevention of a serious adverse event but also to provide progress toward a goal. “*You don’t realize how bad you were until...you’re a little bit better. And you realize how...how difficult it was.*”

Expedient treatment is a property of treatment and it positively affects patient approval, which then influences communication. This creates a bridge and indirect relationship between *treatment* and *communication*. This is summarized best in the quotation “*Things went quickly for me. And I appreciate that.*” This is related with the code **immediate response**, which addresses a similar yet slightly different concept. This code focuses on the patient’s treatment.

Immediate response is a part of *treatment* and the result of a *concerning symptom*. Logically, a concerning symptom is identified by the treating physician or allied healthcare team; for the purposes of this project, a concerning symptom was one which the patient was instructed to

call in for should it occur (*"If it was something that spooked me or something, I could call and talk to someone on the team."*). This code captures the healthcare provider's immediate response to assess or address a symptom or initiate treatment: *"He goes, uh, 'I'm gonna have you run down to do this scan.' The girl put me in the wheelchair and it was right close to five and they wanted to get me there before 5. She like literally ran pushing me in this cart."* Although this code creates a link between concerning symptoms and treatment, it does not otherwise appear with the other upper level categories.

Prognosis influences **treatment** but otherwise does not appear to provide significant interaction for shared decision making tool, as it resides in the foundation of **diagnosis** and **prognosis**, which then feeds into **treatment**. Logically, one could argue that **prognosis** is influenced by compliance with **treatment**, **self-care**, and **symptoms**; however, this was not a connection described by the patients.

Self-care is associated with **treatment** but is also associated with **symptoms** as well as being a part of **activities of daily life**; **patient abilities** is a code that is responsible for **self-care**. None of these codes tie back to communication except through **symptoms**. This again emphasizes the need to recognize the relationship between communication and symptoms to address appropriate treatment, which addresses the research question for shared decision making (*"What he suggested and I followed his guidance which was spot on and very good."*)

Toughed it out is a part of **coping** and associated with **self-reliance**, **self-care**, and **treatment**; most notably, it is a cause of **emergency care**. **Toughed it out** is the concept of a patient *knowing* they should address a symptom or side effect with their healthcare provider but instead *choosing* to shoulder through and suffer through the effects, rather than address them and/or ask for help. Not surprisingly, this resulted in emergency care for patients endorsing this behavior. The rationale or reason for this action is unknown; patients describing this behavior also acknowledged that they should not have engaged in it and should have sought attention earlier. (*"And she goes, 'You should have called me the first day, not now.' I said, 'I realize this.'"*). Logically, **toughed it out** could be thought to serve as a nexus between **symptoms**, **communication**, and **treatment** – a negative concept that could entangle all three. This was not described by patients other than choosing to tolerate their symptoms rather than acknowledge their severity (or, perhaps, not believing they were severe enough to acknowledge). With this framing, the shared decision making tool could impact both **toughed it out** and **treatment**, as it provides a rote mechanism to describe the impact of **treatment** and the **symptoms** of disease – allowing evaluation and discussion without the judgement of 'severity,' or the connotation of, 'complaining,' or being 'needy.' In this framing, the SDM tool could be an equalizer, creating a psychological safe space to openly discuss what the patient is experiencing so the patient does not feel judged or demanding.

Treatment non-compliance is a barrier negatively impacting treatment as well as negatively impacting patient to provider communication. Only two patients described non-compliance, one regarding not calling in severe nausea/vomiting after not being able to take the prescribed antiemetics and the second not picking up a prescription to address a side effect. This is similar to **toughed it out** with the exception that it captures *not* taking a medication as prescribed. For adverse events of concern (nausea, vomiting, esophagitis), it may be reasonable the SDM tool also have a checkbox to assess if patients have been taking medication to address the symptom (simply yes/no). This will enable a provider to assess if further intervention is needed and/or communication.

Trust in provider positively impacts **treatment** but also positively impacts information sharing; the codes **intelligence**, **provider held knowledge**, **direct**, and **provider personality** also positively impact **trust in provider**. Lastly, **provider-to-provider communication** influences trust in provider as does the code/concept **team**. This creates a relatively complex association for **trust in provider** when extending to **treatment**, which is the only upper level category it connects to directly. Thus, to positively impact **treatment**, the trust in provider must be impacted. To do this, we must increase **provider held knowledge** and, preferably, that should be provided **directly** to the patient. The shared decision making tool should increase direct transfer from patient to provider, increasing provider held knowledge which should then impact treatment.

Categories

Patient reported outcome. Slightly different than a patient reported symptom, a patient reported outcome is a result in the opinion of the participant. This can be a treatment outcome ("*...But that was the day that the tumors had shrunk down completely. Hardly just spots.*"), a symptomatic outcome ("*I really did not have any problems with my radiation. I mean everything went so smoothly with that. It went so smoothly.*" "*I didn't lose my hair.*"), as well as an overall assessment of the treatment journey ("*And I'm better than I was, I'm doing better than I was.*"). Some patient reported outcomes overlap with symptoms; the primary dividing line is having it be an outcome or consequence of treatment rather than a concurrent event.

Upper Level Categories / Conceptual Categories

SYMPTOMS. An adverse event is defined by FDA as an untoward medical event that occurs during the contact of a clinical trial; this is then extended to an event that occurs during routine clinical care. There is a subtle nuance for this study that patient-reported symptoms are those that the patient reported but have not been confirmed by physical exam. Additionally, anticipated events are those side effects a provider noted were possible but may not have been realized. **Concerning symptoms** are those that necessitated urgent intervention, emergency care, or intensive care. **Symptoms** can also be present at baseline, consistent with the underlying disease or another comorbidity. **Symptoms** serves as a critical upper level category for the research question, as it is partnered to **communication** to create the shared decision making tool. Special interest was taken in the symptoms that were most commonly commented on by participants (fatigue, dyspnea, nausea, vomiting) as well as those that appeared to significantly interrupt their daily life (fatigue, edema, cognitive impairment). It is interesting to note participants consistently noted prompting about symptoms across providers. This provides an opportunity for the SDM tool to capture this information consistently. **Symptoms** is the only upper level category connected directly to **treatment**; thus, in order to impact treatment, the shared decision making tool must impact **symptoms**.

Representative Codebook

Arranged alphabetically, definitions are provided for the codes shown in the TREATMENT depiction above. Categories are listed in **bold** with upper level categories in UPPERCASE. In general, a code is the most basic concept or construct present in an interview transcript. A category reflects a grouping or pool of constructs with a common idea. An upper-level category reflects the largest amalgamation of information, a pool or sea comprised of rivers of thought. Categories can serve as codes as well, dependent upon the concept/construct.

Code	Comment
academic medicine	Medical care provided through the educational apprenticeship method (e.g. student, resident, fellow).
Activities of daily life	Category and code. Activities performed daily by the patient. This can include Instrumental ADL (e.g. preparing meals, shopping for groceries or clothes, using the telephone, managing money) as well as self-care ADL (e.g., bathing, dressing and undressing, feeding self, using the toilet, taking medications).
approval	to speak or think favorably of; pronounce or consider agreeable or good; judge favorably
characteristics & context	Category encompassing characteristics & situational context of communication.
choice	Ability to choose or option to choose. May be patient, caregiver, or provider.
clinical trial	A therapeutic option involving an investigational medical product or device. Aligns to the NIH definition.
COMMUNICATION	Upper level category representing the totality of medical experience, foreknowledge, academic information as well as commercial information sources.
concerning symptom	An adverse event that is concerning to the patient, caregiver, or provider and most likely requires notification or intervention.
coping	Synonymous with "cope with." Deal with and attempt to overcome problems and difficulties. Primarily patient construct; could be used with caregiver as appropriate.
COVID-19	Disease caused by SARS-CoV-2; this can refer to the frank disease or pandemic precautions due to COVID-19.
delay in seeking treatment	Patient delays seeking care despite indications it was medically necessary.
direct	Direct communication strategy and/or methods; using direct language.
doing better	Subjective assessment that frank symptoms of disease or treatment emergent adverse events are improving or have improved. This assessment can be made by patient, caregiver, or provider.
emergency care	Requiring emergency care, may be at a local facility or at emergency room.
examination	Physical exam by provider for medical evaluation or determination.
expectancy	anticipation of results or outcome.
expedient treatment	Treating quickly but not due to an emergent need.
goal	Synonymous with aim; the desired end-result treatment
HEALTH LITERACY	Upper level category ; defined by Institute of Medicine as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.
immediate response	Patient, caregiver, or provider responded immediately.
information sharing	Information sharing (back and forth) between at least two parties: provider, patient, caregiver.
intelligence	Smart; having high mental acuity.

Code	Comment
isolation	Frank or subjective separation from caregiver, family, or other providers.
medicine by committee	Negative connotation regarding the use of multiple providers in providing a single treatment.
multiple providers	Healthcare requiring multiple providers, whether they are within the same clinic, the same center (e.g., Cancer Center, Pulmonary), or institution.
new information	New medical information regarding treatment or side effect.
patient abilities	The physical, emotional, or social abilities of a patient. These are typically queried in quality of life assessments as well physical examinations. Should not be confused for Activities of Daily Life which are those specific activities that are assessed for adverse event severity and criteria.
Patient reported outcome	Category and code. An outcome (disease outcome, treatment outcome) as reported frankly by the patient. This may include an adverse event if the event aligns with a final outcome (e.g. weight gain, hair loss) rather than a treatment emergent event. Often, this is in summary or retrospect and in the framing of a response to therapy; can also include a lack of response to therapy.
patient to provider communication	Communication initiated by the patient to the provider, as per the patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider "information sharing."
persistent symptom	Context and/or factor of adverse event. Symptom persists despite treatment, self care, or intervention. May, or may not, increase in severity from initial presentation.
prognosis	Expected trajectory and outcome of therapy.
provider held knowledge	Information about the disease and/or treatment that the provider holds and needs to share.
provider held power	Power that the provider has over the treatment.
provider personality	The personality of the provider and its impact in communication.
provider to provider communication	Communication between the providers, as per patient.
recall	The patient's ability to recall - or strategy to recall - information. This is different than memory impairment or cognitive disturbance, which are adverse events/symptoms.
SDM IMPLEMENTATION	Upper level category representing pool of information regarding implementation of a shared decision-making tool for patients diagnosed with lung cancer undergoing radiation therapy at a Midwestern academic hospital.
SDM: treatment matrix	Regarding the SDM treatment matrix (the table of outcomes and adverse events).
self-care	Patient taking care of self during treatment and after. Includes proactive treatment to reduce symptoms, side effects, or stress as well as care to maintain or improve the domains of health: physical, psychological, social, emotional, spiritual.

Code	Comment
self-reliance	Patient relying on self through treatment and post-treatment.
SYMPTOMS	Upper level category representing pooled information regarding symptoms, side effects, and adverse events.
team	Positive connotation regarding the multiple providers involved in the treatment and care of patient. This is the opposite of medicine by committee code. One of the facets of TEAM is if the subject describes decisions as "we," rather than "they," and/or describes a seamless interchangeability with the providers.
toughed it out	The patient forcing themselves to experience an adverse event until its natural resolution; often, declining to seek support or help.
treatment / TREATMENT	Code and Upper level category . Medical treatment, including surgery, radiation therapy, chemotherapy, nutritional support, and emergency care.
treatment noncompliance	patients failing to comply with treatment or supportive care as prescribed by their provider.
trust in provider	Trusting in the providers for treatment, diagnosis, prognosis, and managing care.

Patients described a useful shared decision making tool as one that is paper-based, providing detail regarding side-effects and symptoms, with a time-frame that addresses weekends and holidays as well as provides information for providers across multiple clinics. Patient interviews identify a need for the tool to be simple to address slow reading skills, modifiable to address poor health literacy, and provide direct instructions to address concerning symptoms.

- You don't want to ask too many questions.
- [The PRO-CTCAE] is too general!
- I don't have any usual or daily activities...so... it really doesn't interfere with anything. All I do is watch TV.
- This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don't. This could have been a reference for all the other doctors this would be helpful.
- [I]f I'm home, and I had a piece of paper, and all of a sudden I hit that side effect I could say, "Oh, this and.... Hmmm, call in!"
- [The PRO-CTCAE] are pretty wide open...I mean, [the questions] could go back to prior to you being ill. While you were being sick. So, if you were a patient and you really wouldn't know what you were answering. I know in the last 7 days... but what about prior, right now I'm **not**, but back then I **did**.

Analytic Memos

In total, fifty-one codes and categories are linked to **SDM Format**. Of these 21 are direct links to **SDM Format**, of which 2 are source links (i.e., originating from SDM Format) and 19 are target links (i.e., moving to SDM Format). Of these links, of these, 15 are codes, 3 are categories, and 3 upper level categories. These 21 are described below.

Compared to the other analyses [treatment, symptoms, communication, health literacy], these codes are more spartan and far more functional. There is little interpretation and more directness regarding what should be present, per the patient, to make this functional.

Codes

Context – positive is a code that captures a positive patient reaction to the context of sample questions provided for review: *"I have trouble starting..." yeah, it kind of explains what you are looking for."*

Details is a code that identifies a patient's positive reaction to the details in a question. *"Yeah, yeah, it gets a little more...a little more in depth, you know, about what you're able to do."*

EORTC fatigue is a code that indicates a patient's comment, or preference, regarding the EORTC fatigue question items. *"I would have been too tired to do household chores."*

Granularity; synonymous with **details**. **Details** should be merged into granularity.

Information sharing was mentioned by patients as influencing the format of the shared decision making tool. Examples include *"You mean for [the doctor] to just...take some notes and then give me those notes?"* and *"Well, I guess a lot of it depends on... what do YOU want to know?"*

Paper: graphics identify areas of transcripts where patients described using a graphic image to depict information. This was used once only and in the context of prognosis, which is beyond

the scope of this SDM tool: *“The 40 / 60 thing. There you got your circle and there your pie chart. Not that I need help with 40 / 60 but there are some people who...you know.”*

Paper: neutral captures neutral or apathetic feedback regarding the SDM tool as proposed as a paper chart. This was captured for one subject: *“Query: For example, this would be a prompt to talk about things that the doctor is concerned about. Would this have helped if he had a chart? Response: Yeah, probably.”*

Paper: positive captures positive feedback or positive reactions regarding the SDM tool as proposed as a paper chart. Responses from patients include suggestions for use (*“That would work. Then you can just hand it to them and they could go over it with you. You could just answer it without going through everything over again. That’d work.”*) as well as simple emotional responses (*“Query: If he had a chart of side effects and what you did for it – would that be helpful? Response: Oh yeah!”*)

Questionnaire review is not a code, *per se*, but a tag regarding a detailed review / comparison of the questionnaires. This review provides rich and thick detail about the thought process behind answering the questions:

- “Since I don’t have any usual or daily activities...or anything to do...it really doesn’t interfere with anything. All I do is watch TV.” [regarding PRO-CTCAE question: how much did FATIGUE, TIREDNESS, OR LACK OF ENERGY INTERFERE with your usual or daily activities?]
- “Can’t say I was frustrated doing things that I wanted to do, cause there really wasn’t to do. I don’t have a gal or anything here with me, so...that would have made a difference!” [regarding PROMIS question: I was frustrated by being too tired to do the things I wanted to do.]

This thoughtful detail provides a logical rationale for answering the patient reported outcome measures in a manner that is contradictory to the question’s intent. For example, the participant answered “not at all,” for the PRO-CTCAE question regarding fatigue – the context and framing is wrong. Depending upon the patient’s interpretation (if I did have usual activities – would it have interfered?) the answer will be consistent with intent. It is reasonable the question is answered in the *opposite* of its intention – that the patient answers “not at all,” with regard to fatigue because the fatigue has eliminated usual/daily activities in the prior weeks (and the question is only querying the past 7 days). Fundamentally -what *are* usual or daily activities when a cancer patient is undergoing aggressive multimodality therapy? The reference is off. As one of the patients stated there is no ‘normal.’

Reading captures instances when patients describe reading for the purposes of their self-education or cancer treatment. Two patients described reading packets of printed information from their radiation oncologist. Reading is also associated with **academic information, printed education documents, information sharing** and **slow reader**. Reading is a core concept for the SDM tool from the patient’s perspective (*“I got a lot of paperwork too. And, you know, the MyChart thing... there would be explanations or the test results anyway on there that you could read.”*) as well as from a logical perspective which supports reading as a foundational requirement for a text-based shared decision making tool.

SDM: treatment matrix was originally a table of options and morphed into a matrix with choice. Should be reviewed and possible removed as a code. Non-contributory.

Slow reader is a barrier to reading and influences the format of the SDM tool. For the patient who acknowledged he was a slow reader, it took 56 seconds to read and internalize the PRO-

CTCAE questions (n=2) for fatigue. **This highlights two aspects of the SDM for slow readers: text should be kept to a minimum and the text should be consistent from week to week.**

Specific is a code that intertwines with context and framing. When reviewing questions, not only did patients like details/granularity but specificity that reflects their *current* activities, lifestyle, or situation. This is highlighted in **questionnaire review**, which identifies the impact the lack of *aligned* specificity can have on capturing patient reported outcome measures.

Timeframe – negative is a code that directly influences the SDM format but also contributes to the category **Question Timeframe**. This code captures aspects of the timeframe (e.g., in the past week, in the past 7 days) of the PROM queries. Because of the potential for negative impact on the PROM query, it is linked directly to SDM format as well as the category (“*I know in the last 7 days... but what about prior, right now I’m not, but back then I did.*”).

Written record is a single instance capturing information that the provider *holds, verbally* provides to the patient, and would be beneficial to have *written* for the patient: “So actually just writing it down rather than just in his head? Because he comes in and he’s ...got it. And I’m sure it’s written down somewhere.” Facets of this information could be captured in the SDM tool.

Categories

Activities of daily life. This category captures codes that align with activities of daily life as listed in the Common Terminology Criteria for Adverse Events (CTCAE). Eating and walking were the commonly identified. ADLs were not specifically queried during the interviews. Although a category, activities of daily life was a *proscribed* category created to gauge the impact of symptoms and other factors on ADL. Activities of daily life can be queried on the SDM tool, similarly to symptoms, if these are of priority to provider or patient.

PRO-CTCAE is a category marking conversation regarding the PRO-CTCAE, the NCI’s patient reported outcomes measure. In general, feedback regarding the PRO-CTCAE was that the questions were too broad. When asked which question style was preferred, none of the patients selected the PRO-CTCAE question samples for fatigue or dyspnea. (“*[PRO-CTCAE], which would be the most vague. You’re just asking me very much in general how my fatigue was.... Period.*”)

Question timeframe. This collects information regarding the timeframe prompts for patient reported outcome measures. The codes **timeframe-important**, **timeframe-negative**, and **timeframe-interruption** pool into this category, influencing **SDM format** as well as **SDM usefulness**.

Upper Level Categories / Conceptual Categories

SYMPTOMS. An adverse event is defined by FDA as an untoward medical event that occurs during the contact of a clinical trial; this is then extended to an event that occurs during routine clinical care. There is a subtle nuance for this study that patient-reported symptoms are those that the patient reported but have not been confirmed by physical exam. Additionally, anticipated events are those side effects a provider noted were possible but may not have been realized. **Concerning symptoms** are those that necessitated urgent intervention, emergency care, or intensive care. **Symptoms** can also be present at baseline, consistent with the underlying disease or another comorbidity. **Symptoms** serves as a critical upper level category for the research question, as it is partnered to **communication** to create the shared decision making tool. Special interest was taken in the symptoms that were most commonly commented on by participants (fatigue, dyspnea, nausea, vomiting) as well as those that appeared to significantly interrupt their daily life (fatigue, edema, cognitive impairment). It is

interesting to note participants consistently noted prompting about symptoms across providers. This provides an opportunity for the SDM tool to capture this information consistently. **Symptoms** is the only upper level category connected directly to **treatment**; thus, in order to impact treatment, the shared decision making tool must impact **symptoms**.

SDM IMPLEMENTATION. This upper level category focuses on the science and strategy behind implementation of the shared decision-making tool. How the SDM tool will interact with all the upper level categories is unclear, but the goal is that the SDM will positively impact communication through information sharing. Implementation of the SDM will impact documentation of symptoms / side effects; if implemented as designed, it should provide consistent documentation, using standardized definitions of severity and harmonized terms.

HEALTH LITERACY. This upper level category captures not only medical literacy but also individual concepts/factors that impact an individual's use of medical information. For example, commitment, proactive, comparison, printed education documents, and reading. The SDM tool format should accommodate varying levels of health literacy to enable generalizability as well as implementation.

Representative Codebook

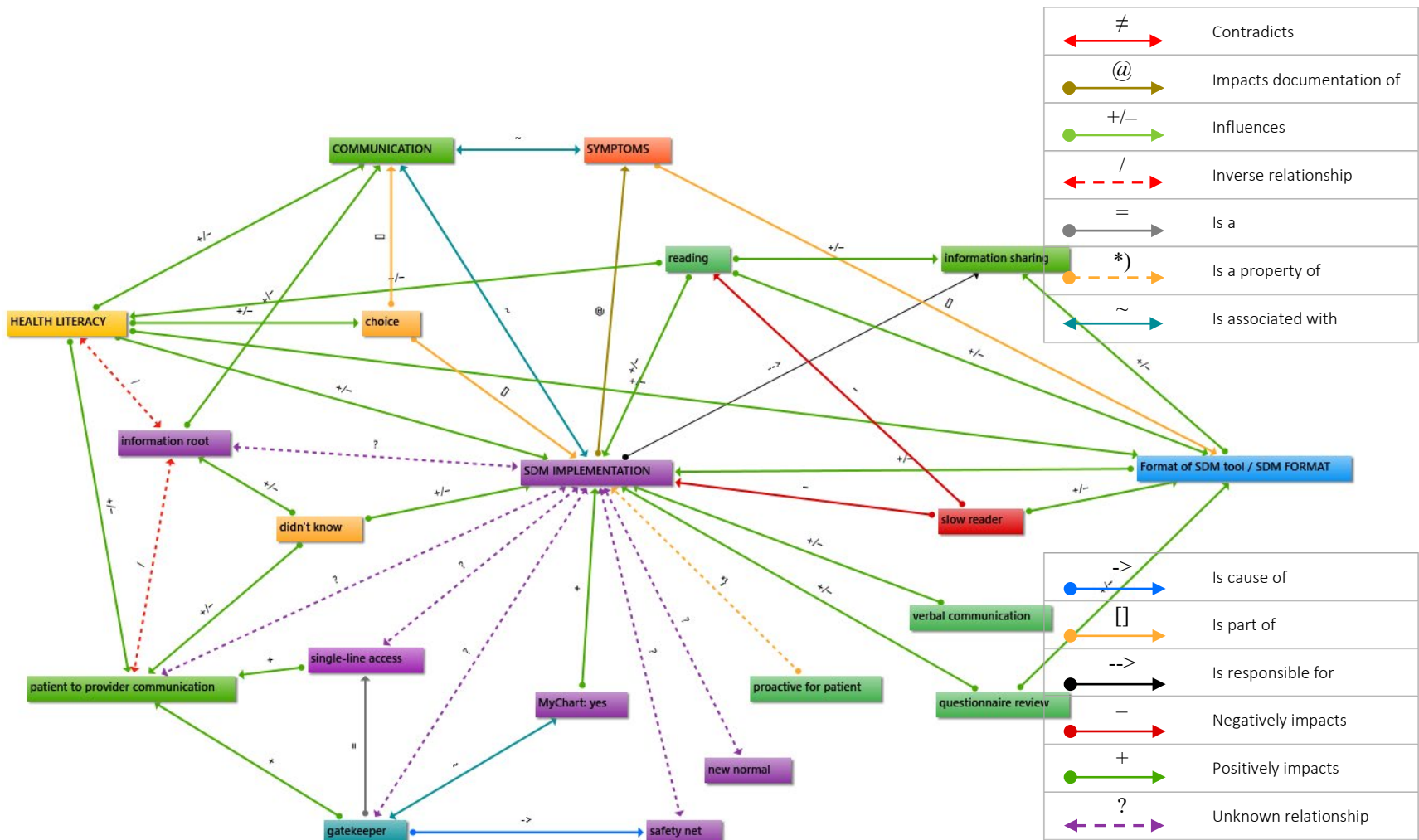
Arranged alphabetically, definitions are provided for the codes shown in the SDM FORMAT depiction above. Categories are listed in **bold** with upper level categories in UPPERCASE. In general, a code is the most basic concept or construct present in an interview transcript. A category reflects a grouping or pool of constructs with a common idea. An upper-level category reflects the largest amalgamation of information, a pool or sea comprised of rivers of thought. Categories can serve as codes as well, dependent upon the concept/construct.

Code	Comment
academic information	Medical information obtained from an accredited academic institution (e.g. Mayo, UIOWA, MSKCC).
accomplishment	Synonymous with completion or achievement.
activities of daily life	Activities performed daily by the patient. This can include Instrumental ADL (e.g. preparing meals, shopping for groceries or clothes, using the telephone, managing money) as well as self-care ADL (e.g., bathing, dressing and undressing, feeding self, using the toilet, taking medications).
burden	The subjective opinion or feeling that the patient is causing extra work, effort, or cost to family and caregivers.
choice	Ability to choose or option to choose. May be patient, caregiver, or provider.
context - positive	Positive reaction or feedback to sample item bank questions (PROCTCAE, PROMIS, EORTC) when discussing the SDM tool.

Code	Comment
details	Granularity of questions when discussing the SDM tool.
dyspnea PROMIS	Dyspnea questions using PROMIS question bank.
EORTC fatigue	Fatigue questions using EORTC question bank.
Format of SDM tool / SDM FORMAT	Upper level category representing pool of information regarding the format, design, and graphical layout of the shared decision making tool
granularity	Detailed context.
HEALTH LITERACY	Upper level category ; defined by Institute of Medicine as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.
information sharing	Information sharing (back and forth) between at least two parties: provider, patient, caregiver.
Information traffic	Category encompassing verbal signals or messages for communication.
intelligence	Smart; mental acuity.
lifestyle activity	Patient's lifestyle; may be pre-treatment, during treatment, or post-treatment.
lifestyle food	Eating habits pre-treatment, post-treatment, and during treatment.
no frustration	frustration was not present with the encounter.
no normal	Activity, lifestyle, or physical symptoms are changing such that a new baseline or expectation cannot be met. Nothing is predictable.
no questions	Patient and/or caregiver did not have questions or concerns regarding the disease, treatment, or outcomes.
out of town	Patient lived outside of town where treatment center was located.
paper: graphics	Positive feedback regarding the use of graphics (pie charts, circles) in the SDM tool.
paper: neutral	Neutral feedback regarding the use of paper SDM tool.

Code	Comment
paper: positive	Positive feedback regarding the use of paper SDM tool.
patient abilities	The physical, emotional, or social abilities of a patient. These are typically queried in quality of life assessments as well physical examinations. Should not be confused for Activities of Daily Life which are those specific activities that are assessed for adverse event severity and criteria.
printed education documents	Education materials in printed format provided to the patient and/or their caregiver.
prior normal	The lifestyle, activities, or physicality (taste, strength, for example) that existed prior to the cancer or treatment.
PRO-CTCAE	Category and code. Feedback regarding the PRO-CTCAE fatigue and dyspnea questions.
PROCTCAE fatigue	Fatigue questions using PROCTCAE question bank.
provider held knowledge	Information about the disease and/or treatment that the provider holds and needs to share.
Question timeframe	Category capturing thoughts and concepts regarding the timeframe for questions soliciting patient reported outcome measures [PRO-CTCAE, PROMIS, EORTC]
questionnaire review	A section of transcript with detailed review by a subject on how he would answer the questions from the 3 different QoL groups.
reading	Information that was conveyed by reading and/or the preference to read.
recall	The patient's ability to recall - or strategy to recall - information. This is different than memory impairment or cognitive disturbance, which are adverse events/symptoms.
relationship	Social or romantic relationship.
SDM IMPLEMENTATION	Upper level category representing pool of information regarding implementation of a shared decision-making tool for patients diagnosed with lung cancer undergoing radiation therapy at a Midwestern academic hospital.

Code	Comment
SDM: treatment matrix	Regarding the SDM treatment matrix (the table of outcomes and adverse events).
SDM: usefulness	Whether the SDM tool is useful.
self-care	Patient taking care of self during treatment and after. Includes proactive treatment to reduce symptoms, side effects, or stress as well as care to maintain or improve the domains of health: physical, psychological, social, emotional, spiritual.
slow reader	Having a slow reading speed, limiting reading functionality
specific	granularity associated with questions, shared decision making prompts, and evaluations.
SYMPTOMS	Upper level category representing pooled information regarding symptoms, side effects, and adverse events.
timeframe - important	The timing / framing of the timing is important in the SDM tool.
timeframe - interruption	Interruptions for holidays and weekends - or treatment breaks - need to be addressed in the framing for the question.
timeframe - negative	Problems regarding the timeframe; negative aspects that need to be considered.
trend over time	pattern of change in symptom, side effect, adverse event over time. Context / property of SDM tool.
trust in provider	Trusting in the providers for treatment, diagnosis, prognosis, and managing care.
uncertainty	Uncertainty regarding treatment outcomes, side effects, or the future.
vague	Related to SDM tool and item questions. Nonspecific or nongranular questions
working through	Maintaining an outside job or career during treatment
written record	Written record of anticipated outcomes, side effects due to lung cancer therapy.



\neq	Contradicts
@	Impacts documentation of
+/-	Influences
/	Inverse relationship
=	Is a
*	Is a property of
\sim	Is associated with

\rightarrow	Is cause of
[]	Is part of
\rightarrow	Is responsible for
-	Negatively impacts
+	Positively impacts
?	Unknown relationship

Simplified view:
SDM Implementation

Patients described implementation of an SDM tool as multi-disciplinary, enabling consistent sharing regarding of patient-reported side-effects and symptoms. If effectively implemented, the SDM tool could support the *gatekeeper* function, serving as a single source of information to the multidisciplinary committee as well as a resource for the patient to know when to escalate situations and who to contact during holidays and weekends.

- This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don't. This could have been a reference for all the other doctors this would be helpful.
- Then you can just hand it to them and they could go over it with you...without going through everything over again.
- Maybe you just want to know from week to week whether it's getting better. It was REALLY BAD and oh, now it's not quite so bad, and you know so you can see the trend that it's getting better and better.
- We need somebody that has direct input into the committee who knows what's going on. Like a gatekeeper. One person I talk to and they direct me.
- You're coming every day for radiation, and that was also sort of a safety net. Because if you didn't feel good from one day to the next, you knew you were coming back and you could ask somebody the question.

Analytic Memos

In total, 54 codes and categories are linked to **SDM Implementation**. Of these 18 are direct links to **SDM Implementation**, of which 6 are source links (i.e., originating from SDM Implementation) and 12 are target links (i.e., moving to SDM Implementation). These links consist of 14 codes and 4 upper level categories. These are described below.

Compared to the other analyses [treatment, symptoms, communication, health literacy], these codes are more spartan and far more functional. There is little interpretation and more directness regarding what should be present, per the patient, to make this functional.

Codes

Choice is one of the key ethical tenets in medicine and defines patient autonomy. Choice was not directly linked by patients to SDM implementation but is considered, logically, to be a property of shared decision making. Curiously, patients could not recall treatment options and/or rationale for choosing their cancer treatment but could recall being given options to treat side effects (“[T]hey were available to give me something else if that didn't work but that worked fine.”)

Gatekeeper captures the concept that a single person serves as the communication conduit. Patients alluded to SDM implementation serving this function by providing after hours instructions as well as serving as the common information source across clinic visits:

- That way if I'm home, and I had a piece of paper, and all of a sudden I hit that side effect I could say, “Oh, this and.... Hmmm, call in!” or “drink some milk!” or “get some ice cream.”
- Some doctors take good notes and other doctors don't. This could have been a reference for all the other doctors this would be helpful.

Information root is a complex concept that has a broader information deficit than “I don’t know.” The information root encompasses not even knowing what to ask, what to research, or where to begin. Information root also includes – somewhat - a lack of self. This is because none of the responses to the question “What did you think was important for your radiation oncologist to know?” were based in *self* and instead reflected on an information gap. Logically, this significantly impacts the shared decision making tool. If a patient cannot identify their goals or the minimum quality of life they would like to maintain during therapy, this hobbles a patient-centered patient reported outcome measure paradigm. Thus, implementation needs to incorporate a strategy to cross the information root, to tease out the patient’s preferred patient reported outcome measures.

Information sharing occurs when there is a back and forth between a healthcare provider and the patient. The presumption at study design was that the SDM tool would increase information sharing, based on the peer-reviewed literature. Thus, this relationship in the diagram reflects that posited by peer-reviewed literature [Cochrane Database of Systematic Reviews. 2011. PMID: 21975733]

MyChart: yes has a positive impact on the SDM tool implementation as per patient comments. Patients commented positively on MyChart and its immediate access and link to providers. Although patients indicated they wanted the SDM tool itself to be provided in paper, positive association with MyChart indicates the questions can be submitted to the patient through the MyChart portal, creating a smooth implementation workflow:

- You sign up for MyChart, it’s there. You get home you forgot something you can look at it.
- So when I got to Fairfield they already knew what was going on because of the MyCharts and everything was transferred back to them...
- And, you know, the MyChart thing... there would be explanations or the test results anyway on there that you could read.

New normal is a patient described concept that their life and lifestyle – as they knew it – had ended. This captured – primarily – their lack of physical ability and how it impacted their life, but also tangentially their lack of knowledge about their healthcare condition as well as its treatment and, lastly, the unknown of if they would get better. Ultimately, it captures the fact that they don’t know if they can ever ‘go back,’ to how they were prior. This intertwines with SDM implementation as the ‘new normal’ is so new, it may be difficult to identify goals during treatment.

- [B]ut that’s just something I do now...
- It’s been a life changing experience, I’ll tell you that much. And there’s times when I can see why folks do give up and they fail with it. Because the stress that comes with it.

Sometimes I can go most of the day and not have a problem. Then there are days that 3 or 4 o’clock I’m done.

Patient to provider communication captures communication initiated by the patient to the provider. It is a one-sided communication. For the SDM implementation tool, patients provided comments that can impact its implementation for communicating to the provider:

- If it was something that spooked me or something, I could call and talk to someone on the team.

- I would do the research and write down a question, like, my particular diagnosis, and the staging, is what I wrote down
- And if you got problems and you need help, you as the patient have to ask because they don't know. And if you don't ask, like I don't sometimes, they're not gonna know that there's a problem. So the biggest thing is the patient has to be upfront with the doctor also. It's true though, if you're not upfront with the doctor, they don't know how to take care of it. And they assume you're okay.

For this reason, a text prompt has been added to the SDM tool to enable patients to ask questions or comment on a problem not directly queued in the pre-built SDM tool.

Proactive for patient is the code that captures the physician acting on the patient's behalf, proactively, but from *the patient's point of view*. This is represented as a property of the SDM implementation through patient feedback as part of the plan for the patient:

- [M]aking sure that I was not having any pain.
- What he suggested and I followed his guidance which was spot on and very good.
- And then those two worked together making a plan for what was best for me.

Questionnaire review is a code identifying a thoughtful review of the sample questions provided for the shared decision making tool. It is something that should be reviewed when implementing the SDM tool:

- [regarding PRO-CTCAE fatigue]: Since I don't have any usual or daily activities ...or anything to do... it really doesn't interfere with anything. All I do is watch t.v. (chuckles).
- [regarding PROMIS fatigue Q1] I would have been too tired to do household chores...
- [regarding PROMIS fatigue Q3] Can't say I was frustrated doing things that I wanted to do, cause there really wasn't to do. I don't have a gal or anything here with me, so... that would have made a difference!
- [regarding EORTC fatigue Q1] Yeah, I definitely have problems carrying uh... heavy things. Walking ain't bad but as soon as a I start using more muscles and then my legs ... makes it harder to breathe. (4 sec pause) ...
- [regarding EORTC fatigue Q2] ...only went on one semi-long walk.
- [regarding EORTC fatigue Q3] Short walk is no problem. I usually take the stairs when I go out of the hotel. I took them once when I went up...but it's just as much energy as it is to walk down to the elevator and back as it is to go down the stairs.
- [regarding EORTC fatigue Q4] Yeah, I'm pretty much in... laying down most of the day these last couple of weeks
- [regarding EORTC fatigue Q5] And I don't need help with the eating, dressing, washing.

This questionnaire review provides insight into how patients read the questions and apply them to their daily actions – but it also provides a critical look at how “the new normal,” impacts the answers to those questions. Here, the patient was removed from his home and living at a hotel (due to COVID, Hope Lodge was closed) and away from friends and family. As he stated, he didn't have anything to do – so PROMIS Q3 does not apply and neither does the PRO-CTCAE question regarding fatigue. The review also points to a binary response: walking up stairs only once. Taking a long walk only once. This goes against the standard patient

reported outcome measure tools, changing it from a gradient to a binary response. This also impacts SDM tool implementation.

Reading codes to the amount of reading a patient is expected to engage in, did engage in, or completed. What was striking was the amount of reading – and returning to the information provided – that patients described:

- Little one [packet], about 10 pages or so. Listed it all and everything.
- I like the explanation the way he explained it to me is good, but then when I get home... I would pull that out and re-read it.
- They actually provided stuff like this about the symptoms. I could review it at home and if something else come up – I could pull that out and look through it.

Safety net is described by patients as the comfort from daily radiation treatments (i.e., interaction with someone on the healthcare team). This is critical for implementation of the SDM tool and, eventually, generalizability – as the tool will be designed for a therapy that is rooted in daily treatments, not the prolonged schedule of chemotherapy treatment (one visit every 2 to 4 weeks).

- Because if you didn't feel good from one day to the next, you knew you were coming back. And you could ask somebody the question...

Single-line access codes to gatekeeper; no other single line access was identified by patients (i.e., group email, group phone call). Other single line access could be provided (MyChart, receptionist, email) but this was not discussed or identified by patients. Patients identified a single person as the gatekeeper, as the “go to.”

Slow reader to a patient's ability to read and/or the impact of reading on the patient's intake and processing of information. One subject openly commented on being a slow written processor, having information read to him rather than reading himself. This is a reminder the tool must be implemented to accommodate all reading strengths.

Verbal communication codes for verbal communication as a strategy for information sharing by the provider / healthcare team to the patient. This reminds us that the implementation must still have a verbal communication component, not simply relying on paper.

- Well, in the morning when I come in... mostly talking with Heather & Megan and they are pretty informative.
- I think verbal plus the research part like this would be helpful, you know.
- I like the explanation the way he explained it to me is good, but then when I get home... I would pull that out and re-read it.

Categories

None.

Upper Level Categories / Conceptual Categories

COMMUNICATION. Shared decision making is an intersection of SYMPTOMS and COMMUNICATION; the interaction between the two upper level categories is a bilateral association. Of interest, patients conveyed understanding that communication regarding side effects / symptoms was critical for their care. One participant likened this communication to a safety net (“...you're coming every day for radiation, and that was also sort of a safety net.

Because if you didn't feel good from one day to the next, you knew you were coming back. And you could ask somebody the question..."). Another admitted they failed to communicate as they should have and that led to emergency care (*"And if you got problems and you need help, you as the patient have to ask because they don't know. And if you don't ask, like I don't sometimes, they're not gonna know that there's a problem."*). Participants had a favorable view of MyChart and were critical of individuals who failed to use it (*"Those are things out there for people to use to reduce the time. But if they don't use them, they need to stand in line."*) *"Toughed it out,"* is the code within symptoms that confounds communication and shared decision making, representing a concept of self-reliance that becomes detrimental to the patient. This was described by three participants:

- They kept saying a lot of this stuff was gonna happen but it never happened until I got home. And then I said, "Well, it's happening now." It happened like they described it. I just felt it and got over it.
- I should have [called the doctor] when I got sick on the pills (laughs boisterously). I just thought, 'You know, I have a really bad stomach anyways.'
- I sorta limped along

This concept is most likely influenced by the concepts of burden and self-reliance. It is apparent from the interviews (50%) that the *toughed it out* concept was as strong, or stronger, than the knowledge a patient must communicate with a provider. Instituting a shared decision-making tool to identify and quantify adverse events of special significance provides *normalcy* and *expectation*, shifting symptoms from a compliant to a rote process. With this pivot, reviewing and communicating regarding symptoms is acknowledged as anticipated, acceptable assessment to succeed in therapy. Thus, the SDM tool may tilt communication patterns away from *toughing it out* back to information sharing.

SDM FORMAT. This upper level category focuses on the graphical design of the SDM tool, including the presentation of data. Symptoms provide the key information for the SDM tool, with six symptoms / goals collected on the tool (3 from the patient, 3 from the provider). In addition to the symptoms, participants identified granularity as important, commenting that PRO-CTCAE was too general as well as timeframe. For example, participants questioned how to categorize the framing of "the past seven days," – did it include weekends or holidays? Most interestingly, despite the favored viewpoint of MyChart, participants preferred to have paper to hold and take with them from provider to provider:

- You can just hand it to them and they could go over it with you.
- This would be helpful for me because they could have referenced this stuff. Some doctors take good notes and other doctors don't. This could have been a reference for all the other doctors this would be helpful.
- That way if I'm home, and I had a piece of paper, and all of a sudden I hit that side effect I could say, 'Oh, this and.... Hmmm, call in!'

HEALTH LITERACY. This upper level category captures not only medical literacy but also individual concepts/factors that impact an individual's use of medical information. For example, commitment, proactive, comparison, printed education documents, and reading. The SDM tool format should accommodate varying levels of health literacy to enable generalizability as well as implementation.

SYMPTOMS. An adverse event is defined by FDA as an untoward medical event that occurs during the contact of a clinical trial; this is then extended to an event that occurs during routine clinical care. There is a subtle nuance for this study that patient-reported symptoms are those that the patient reported but have not been confirmed by physical exam. Additionally, anticipated events are those side effects a provider noted were possible but may not have been realized. **Concerning symptoms** are those that necessitated urgent intervention, emergency care, or intensive care. **Symptoms** can also be present at baseline, consistent with the underlying disease or another comorbidity. **Symptoms** serves as a critical upper level category for the research question, as it is partnered to **communication** to create the shared decision making tool. Special interest was taken in the symptoms that were most commonly commented on by participants (fatigue, dyspnea, nausea, vomiting) as well as those that appeared to significantly interrupt their daily life (fatigue, edema, cognitive impairment). It is interesting to note participants consistently noted prompting about symptoms across providers. This provides an opportunity for the SDM tool to capture this information consistently. **Symptoms** is the only upper level category connected directly to **treatment**; thus, in order to impact treatment, the shared decision making tool must impact **symptoms**.

Representative Codebook

Arranged alphabetically, definitions are provided for the codes shown in the SDM IMPLEMENTATION depiction above. Categories are listed in **bold** with upper level categories in UPPERCASE. In general, a code is the most basic concept or construct present in an interview transcript. A category reflects a grouping or pool of constructs with a common idea. An upper-level category reflects the largest amalgamation of information, a pool or sea comprised of rivers of thought. Categories can serve as codes as well, dependent upon the concept/construct.

Code	Comment
academic information	Medical information obtained from an accredited academic institution (e.g. Mayo, UIOWA, MSKCC).
caregiver	A person who provides support to the patient during treatment.
characteristics & context	Category encompassing characteristics & situational context of communication.
choice	Ability to choose or option to choose. May be patient, caregiver, or provider.
COMMUNICATION	Upper level category representing the totality of medical experience, foreknowledge, academic information as well as commercial information sources.
comparison	Patient-specific attribution
COVID-19	Disease caused by SARS-CoV-2; this can refer to the frank disease or pandemic precautions due to COVID-19
didn't know	Lack of background knowledge (medical, health), context, or electing to deprioritize in the face of other decisions or information requirements. Often associated with 'information root,' which is the nebulous concept around the goals of treatment and defining the patient's desired new normal.

Code	Comment
Factors affecting communication	Category encompassing things that impact communication negatively or positively. Not to be confused with characteristics & context, which are properties and/or traits.
familiarity with provider	Knowing the name and/or clinic of the provider.
fear	unpleasant emotion associated with anxiety, sense of foreboding or danger.
foreknowledge	A patient's or caregiver's familiarity with cancer, the healthcare system, or medicine in general.
Format of SDM tool / SDM FORMAT	Upper level category representing pool of information regarding the format, design, and graphical layout of the shared decision making tool
gatekeeper	Individual who provides a single line of information between patient, caregiver, and providers.
HEALTH LITERACY	Upper level category ; defined by Institute of Medicine as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions
information root	The recognition that the information is not available to the patient or provider and they cannot act due to the lack of information. The information root is missing.
information sharing	Information sharing (back and forth) between at least two parties: provider, patient, caregiver.
Information traffic	Category encompassing verbal signals or messages for communication.
isolation	Frank or subjective separation from caregiver, family, or other providers.
medicine by committee	Negative connotation regarding the use of multiple providers in providing a single treatment.
multiple clinic	Healthcare provided through multiple clinics; this is different than multidisciplinary clinic which is one physical clinic with multiple providers. This construct is multiple physical locations.
multiple providers	Healthcare requiring multiple providers, whether they are within the same clinic, the same center (e.g., Cancer Center, Pulmonary), or institution.
MyChart: yes	Agreed to use MyChart (electronic EHR portal system), used, or has positive connotations with MyChart.
new information	New medical information regarding treatment or side effect.
new normal	A lifestyle, activity level, or physical issue (taste, cough) that is not consistent with life prior to the disease or treatment.
no questions	Patient and/or caregiver did not have questions or concerns regarding the disease, treatment, or outcomes.

Code	Comment
patient abilities	The physical, emotional, or social abilities of a patient. These are typically queried in quality of life assessments as well physical examinations. Should not be confused for Activities of Daily Life which are those specific activities that are assessed for adverse event severity and criteria.
patient to provider communication	Communication initiated by the patient to the provider, as per the patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider 'information sharing.'
printed education documents	Education materials in printed format provided to the patient and/or their caregiver.
proactive	Self-actuation or care; patient putting self first to ensure best treatment, best outcomes.
proactive for patient	Provider construct to put patient first to receive the best care or outcomes.
provider cares	Verbal communication, physical interaction, or other indication that the provider cares personally for the patient as a person, beyond medical obligation.
provider held knowledge	Information about the disease and/or treatment that the provider holds and needs to share.
provider held power	Power that the provider has over the treatment.
provider prompting	Provider's prompting for further information and/or communication.
provider support	Providers providing support on a personal level, beyond the stereotypical patient/provider relationship.
provider to patient communication	Communication centered around, or from, the provider to the patient - as per patient. This is a one-way conversation; for quotes where both parties discuss (i.e. patient is responding to provider, or provider then responds to patient) consider 'information sharing.'
questionnaire review	A section of transcript with detailed review by a subject on how he would answer the questions from the 3 different QoL groups.
reading	Information that was conveyed by reading and/or the preference to read.
recall	The patient's ability to recall - or strategy to recall - information. This is different than memory impairment or cognitive disturbance, which are adverse events/symptoms.
safety net	something, or someone, that is reassuring to the patient
SDM IMPLEMENTATION	Upper level category representing pool of information regarding implementation of a shared decision-making tool for patients diagnosed with lung cancer undergoing radiation therapy at a Midwestern academic hospital.

Code	Comment
SDM: treatment matrix	Regarding the SDM treatment matrix (the table of outcomes and adverse events).
SDM: usefulness	Whether the SDM tool is useful
single source	Construct that only one person is hearing the verbally communicated information.
single-line access	single line of communication or access to providers
slow reader	Having a slow reading speed, limiting reading functionality
stress	bodily or mental tension
SYMPTOMS	Upper level category representing pooled information regarding symptoms, side effects, and adverse events.
team	Positive connotation regarding the multiple providers involved in the treatment and care of patient. This is the opposite of medicine by committee code. One of the facets of TEAM is if the subject describes decisions as "we," rather than "they," and/or describes a seamless interchangeability with the providers.
treatment / TREATMENT	Upper level category and code representing medical treatment, including surgery, radiation therapy, chemotherapy, nutritional support, and emergency care.
treatment noncompliance	patients failing to comply with treatment or supportive care as prescribed by their provider
trust in provider	Trusting in the providers for treatment, diagnosis, prognosis, and managing care.
verbal communication	Verbal communication

APPENDIX M: SDMCQ QUESTIONS AND COLLABORATIVE DECISION AID

Nausea (feeling like you could vomit or be sick to your stomach)

Since the last time I saw a radiation doctor:

- I have vomited (thrown up).
- I have nausea but haven't vomited.
- I have not had nausea or vomited but I'm not that hungry.
- I have not had nausea or vomited but I'm not eating.
- I can't be around food – the smell or looking at it.
- I have not had nausea or vomited.
- [separate checkbox – not drop down] I am using medicine for nausea

Cough

Since the last time I saw a radiation doctor:

- I am coughing stuff up (snot, sputum, blood).
- I cough when I try to talk or breathe deeply.
- I get lightheaded when I cough.
- I may cough but it doesn't bother me.
- I have not coughed.
- [separate checkbox – not drop down] I am using cough medicine

Chest pain

Since the last time I saw a radiation doctor:

- My chest hurts – it feels like burning.
- My chest hurts – it feels tight and/or hurts when I breathe.
- My chest hurts, but only when I try to eat.
- My chest hasn't been hurting.
- [separate checkbox – not drop down] I am using medicine for chest pain

Fatigue

Since the last time I saw a radiation doctor:

- I have not been able to watch a TV show without falling asleep.
- I am okay sitting but needed a wheelchair to get to my appointments.
- I walk only to my appointments from the car/taxi/valet.
- I went for a short walk (about a block).
- I'm as active as I was before I started radiation therapy.

Breathing

Since the last time I saw a radiation doctor:

- I can't walk 10 steps without stopping to catch my breath.
- I can't walk to my appointments without stopping to catch my breath.
- I use a wheelchair because I become so short of breath.
- I feel lightheaded when I try to walk or when I stand up.
- I feel the same as before I started radiation therapy.
- [separate checkbox – not drop down] I am using oxygen

Collaborative Decision Aid Tool - Example

Question	Baseline (June 7, 2021)	July 5, 2021	Today
Nausea (feeling like you could vomit or be sick to your stomach):	I have not had nausea or vomited	I have not had nausea or vomited but I'm not that hungry.	I can't be around food – the smell or looking at it.
I am using medicine for nausea	Yes	Yes	Yes
Cough:	I have not coughed.	I am coughing stuff up (snot, sputum, blood)	I may cough but it doesn't bother me
I am using cough medicine:	No	Yes	Yes
Chest pain:	My chest hasn't been hurting	My chest hurts – it feels tight and/or hurts when I breathe	My chest hurts, but only when I try to eat
I am using medicine for chest pain:	No	Yes	Yes
Fatigue:	I am okay sitting but needed a wheelchair to get to my appointments.	I am okay sitting but needed a wheelchair to get to my appointments.	I have not been able to watch a TV show without falling asleep
Breathing:	I can't walk to my appointments without stopping to catch my breath.	I can't walk to my appointments without stopping to catch my breath.	I can't walk 10 steps without stopping to catch my breath.
I am using oxygen:	No	No	No
Weight:	78 kg	74.8 kg (96% baseline)	71.73 (92% baseline)
Question:	None	None	Do I need oxygen

APPENDIX N: SDMCQ RESPONSES DURING FIRST IMPLEMENTATION CYCLE

Symptom	Descriptor	Count
Nausea	I have not had nausea or vomited but I'm not that hungry	3
	I have not had nausea or vomited	17
Cough	I may cough but it doesn't bother me.	11
	I get lightheaded when I cough	1
	I cough when I try to talk or breathe deeply	1
	I am coughing stuff up (snot, sputum, blood)	1
	I have not coughed.	6
Pain	My chest hurts, but only when I try to eat.	4
	My chest hurts, it feels tight and/or hurts when I breathe	1
	My chest hasn't been hurting.	15
Fatigue	I am okay sitting but needed a wheelchair to get to my appointments	2
	I have not been able to watch a TV show without falling asleep	1
	I walk only to my appointments from the car/taxi/valet	3
	I went for a short walk (about a block)	3
	I'm as active as I was before I started radiation therapy.	11
Breathing	I feel lightheaded when I try to walk or when I stand up.	3
	I feel the same as before I started radiation therapy.	17