UNDERSTANDING GOALS OF CARE FOR PATIENTS UNDERGOING CHIMERIC ANTIGEN RECEPTOR T-CELL THERAPY: A QUALITATIVE DESCRIPTIVE STUDY

UNDERSTANDING GOALS OF CARE FOR PATIENTS UNDERGOING CHIMERIC ANTIGEN RECEPTOR T-CELL THERAPY: A QUALITATIVE DESCRIPTIVE STUDY

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TITLE: Understanding Goals of Care for Patients Undergoing Chimeric Antigen Receptor T-Cell Therapy: A Qualitative Descriptive Study

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ABSTRACT

Background: Chimeric Antigen Receptor (CAR) T-cell therapy is a relatively novel treatment in Canada for relapsed and refractory leukemias and lymphomas. Limited evidence is available on patient experiences when undergoing this treatment, and there is no research regarding patients' goals of care (GOC) when undergoing this treatment.

Aims: This study aimed to explore patients' experiences undergoing CAR T-cell therapy, particularly as it related to their GOC.

Methods: A qualitative descriptive approach was employed. Information was gathered via semi-structured interviews and medical chart review. Interviews were transcribed and analyzed using content analysis to identify key themes.

Results: Six regional patients participated in this study. Ten key themes were identified, highlighting patients' identified GOC, a lack of implicit GOC discussions, challenging transitions throughout care, and a lack of nursing involvement in GOC discussions.

Conclusion: Patients undergoing CAR T-cell therapy have clearly identified GOC (simply to survive) but have not explicitly discussed these goals with their healthcare providers. Overall, patients had positive experiences in receiving care during CAR T-cell therapy but there was opportunities identified to improve care, related to facilitating GOC discussions, increasing support during transitions in care, and optimizing the role of the nurse within GOC conversations. Future research should aim to investigate the experiences of a more varied group of patients including those who were offered and declined receiving CAR T-cell therapy, the perceptions of healthcare providers regarding GOC discussions within CAR T-cell therapy, and the role of nurses in GOC discussions.

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LIST OF ABBREVIATIONS

CAR	Chimeric Antigen Receptor
CRS	Cytokine Release Syndrome
DLBCL	Diffuse Large B-Cell Lymphoma
FL	Follicular Lymphoma
GOC	GOC
HHS	Hamilton Health Sciences
HrQoL	Health-Related Quality of Life
ICANS	Immune Effector Cell Associated Neurotoxicity Syndrome
JHCC	Juravinski Hospital and Cancer Centre
MAiD	Medical Assistance in Dying
ODS	Oncology Day Services
PRO	Patient Reported Outcome
SICP	Serious Illness Conversation Program

DECLARATION OF ACADEMIC ACHIEVEMENT

I, Danielle Jones, declare that this work is my own and, if not, I have acknowledged the original source using APA or another approved citation format.

Date: October 2024

Graduate Thesis: Understanding Goals of Care for Patients Undergoing Chimeric Antigen Receptor T-Cell Therapy: A Qualitative Descriptive Study

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CHAPTER ONE: INTRODUCTION

In 2023 an estimated 22,300 people were diagnosed with a new hematological malignancy in Canada (Canadian Cancer Society, 2023). While many options exist for first line treatments, until recently there were very few options for further curative treatment following recurrence or refractory disease (Ernst et al., 2021; Harris et al., 2021). The rise of immunotherapy has significantly changed the treatment landscape, offering many more options for subsequent and curative lines of treatment (Cable et al., 2021). One such treatment is Chimeric Antigen Receptor (CAR) T-cell therapy, which offers a chance at cure for patients with relapsed or refractory B-cell leukemias and lymphomas, who previously would have been ineligible for further treatment (Alexander et al., 2021; Ellis et al., 2021). CAR T-cell therapy has the potential to improve survival for patients with hematological malignances, but as detailed below there is still much to be learned about this treatment, especially as it relates to patient experience.

The remainder of this chapter will provide a brief overview of the indications for CAR T-cell therapy, followed by a more specific description of how this treatment is provided at the Juravinski Hospital and Cancer Centre (JHCC), where this research took place. Common side effects and toxicities associated with CAR T-cell therapy will be described. This will be followed by information on the focus of this thesis, including the research question and problem statement guiding its completion.

CAR T-Cell Therapy Process

CAR T-cell therapy is a form of adoptive immunotherapy (a therapy which stimulates the immune system to mount a response against cancer cells) that is indicated

for patients with relapsed or refractory CD19 + B-cell leukemias, B-cell lymphomas, and mantle cell lymphomas (Holstein & Lunning, 2020). This therapy was first approved for use in Canada in 2018, and is currently available in Ontario, Quebec, Alberta, and British Columbia. Currently, there are three CAR T-cell products being used at the JHCC: Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), and Tecartus (brexucabtagene autoleucel). These products are intended for the treatment of relapsed/refractory B-cell leukemias and lymphomas (Ellis et al., 2021). At the time of initial recruitment for this thesis, approval had only been granted for Kymriah and Yescarta, and as such the pool of eligible participants was limited to those receiving these agents. The eligibility criteria for CAR T-cell therapy expanded during this research, and is expected to further expand in the near future to include other hematological malignancies (with clinical trials ongoing for CAR T-cell therapy to treat multiple myeloma) and solid tumour malignancies (Holstein & Lunning, 2020).

Within Ontario, the JHCC was one of the first centres to offer CAR T-Cell therapy. Given the scarcity of centres providing CAR T-cell therapy (the only other two centres offering this to adult patients in Ontario are Princess Margaret Hospital and The Ottawa Hospital), the JHCC provides treatment both for local and regional patients. Regional patients are those who have been treated at an outside cancer centre upfront (often as far away as Windsor) but are referred to the JHCC for CAR T-cell therapy. The treatment process for CAR T-cell therapy at the JHCC is like that reported in other studies, beginning with a rigorous review of the patient's eligibility from both a medical and psychosocial perspective (Foley, n.d.). See Appendix A for an overview of the

eligibility criteria. Next is the collection of T-cells via apheresis which are sent for manufacturing and expansion. The manufacturing process involves the incubation of patients' T-cells with CAR-encoding viral vectors, which will ultimately allow the engineered T-cells to recognize and target cancer cells expressing the CD19 antigen (Boyiadzis et al., 2018; Dudley et al., 2019). Upon confirmation of an acceptable number of CAR T-cells, the product is transported back to the JHCC for infusion. Patients receive lymphodepleting chemotherapy in the days prior to receiving the reinfusion of CAR-T cells. This is generally three days of chemotherapy provided 3-5 days prior to the reinfusion. Some patients may have also received bridging chemotherapy or radiotherapy while awaiting the delivery of their CAR T-cells if there were concerns regarding disease progression.

Reinfusion occurs on an outpatient basis, with patients monitored closely for any adverse reaction (most commonly chills or rigors) during the 15 minute reinfusion time (Dudley et al., 2019). Post-reinfusion, patients are followed on an outpatient basis with daily visits for the first 10 days after their reinfusion, and then two-three times per week until 30 days post reinfusion. If patients develop any symptoms indicating a potentially severe side effect or toxicity, they will be admitted to hospital until resolution of their symptoms and normalization of their neutrophil counts. If patients are discharged from the hospital and have no further neutropenia by 30 days post reinfusion, they are then transferred back to their home hospital for follow-up care or if they live locally in the Hamilton region will have routine appointments at the JHCC.

Common Side Effects and Toxicities of CAR T-Cell Therapy

Patients are closely monitored for any adverse effects following their reinfusion, as side effects and toxicities are common with CAR T-cell therapy due to the heightened immune response created by the introduction of chimeric T-cells to the body (Garcia Borrega et al., 2019). This stimulates apoptosis in the targeted cancer cells but can also create overactive immune responses which may cause collateral damage to healthy cells and tissues (Garcia Borrega et al., 2019). By far the most common and dramatic toxicities are cytokine release syndrome (CRS) and neurotoxicity in the form of immune effector cell associated neurotoxicity syndrome (ICANS), which are both potentially life-threatening or permanently life-altering (Brudno & Kochenderfer, 2016). The incidence rates for CRS and ICANs are 3-47% and 3-31% respectively, which are close to the overall response rates to therapy of 40-60% (Yassine et al., 2020).

Cytokine Release Syndrome

CRS is a common toxicity associated with CAR T-cell therapy, caused by an overactivation of the immune system (Garcia Borrega et al., 2019). CRS tends to occur most often within 7 days of reinfusion, and rarely occurs past 14 days post reinfusion (Alexander et al., 2021). Initial presentation can be mild with patients experiencing fevers, headaches, and general malaise. This can rapidly progress to affect multiple organ systems, resulting in severe hypotension, tachycardia, disseminated intravascular coagulation, and vascular leakage (Garcia Borrega et al., 2019). For this reason, patients receiving CAR T-cell therapy at the JHCC are closely monitored for any fevers or other indications of early CRS and are admitted to hospital promptly if these symptoms

develop. Management of CRS depends on its severity and can include the use of supportive measures (such as IV hydration and anti-pyretics), medications to block further cytokine release (i.e. tociluzumab and/or corticosteroids), and ICU admission for vasopressors, cardiac monitoring, and/or intubation (Foley, n.d.; Garcia Borrega et al., 2019).

Immune Effector Cell Associated Neurotoxicity Syndrome

ICANS is also an important toxicity to monitor for following CAR T-cell therapy. Similar to CRS, it often occurs shortly after a reinfusion, but with a later onset (Garcia Borrega et al., 2019). Unlike CRS, the exact cause of ICANS is unclear, but thought to be related to an overactivation of the immune system. While CRS follows a predictable progression of symptoms, ICANS can appear suddenly or gradually, with symptoms ranging from mild cognitive changes to a severe decrease in level of consciousness necessitating ICU admission (Garcia Borrega et al., 2019). At the JHCC, patients are screened for early cognitive changes every 12 hours for the first 10 days following their reinfusion, with early symptoms requiring prompt attention and medical intervention to prevent severe neurotoxicity (Foley, n.d.; Garcia Borrega et al., 2019).

Thesis Focus

While it is an extremely promising treatment, only about 50% of patients will achieve a long-term cure or remission after CAR T-cell therapy (Yassine et al., 2020). In fact, the probability of cure is equal to the probability of developing life-threatening side effects while undergoing treatment (Garcia Borrega et al., 2019; Yassine et al., 2020). For most patients the only other available treatment option is pursuing palliative or supportive

care (Boyiadzis et al., 2018; Holstein & Lunning, 2020). The decision to receive CAR T-cell therapy may draw heavily upon patients' goals of care (GOC), defined in this thesis as the patient's goals for their health and healthcare that have been developed in collaboration with their clinicians to forge mutual patient-clinician understanding about the intended goals of medical treatments (Elias & Odejide, 2019; Naik et al., 2016; Secunda et al., 2019 Stanek, 2017).

Thus far, research surrounding CAR T-cell therapy has focused heavily on symptom management and guidelines for clinicians – often at the cost of under-reporting on outcomes important to patients, such as quality of life (Foster et al., 2020). Minimal research evidence is available on the experiences of patients undergoing CAR T-cell therapy, with no research available regarding GOC and how they are addressed during the treatment decision-making process. Similarly, the role of the registered nurse in caring for patients receiving CAR-T cell therapy has not been fully investigated. While recommendations are available on how to adequately prepare oncology nurses to care for patients in the acute reinfusion phase (Whisenant et al., 2021), there is no research available thus far on patients' perceptions of the nursing care received or nurses' involvement in GOC conversations and the treatment-decision-making process.

Given the complexity of such decisions and the limited research evidence, it is essential to improve our understanding of patient experiences in receiving CAR T-cell therapy and whether patients' experiences match both their overall understanding of this treatment and their personal goals for health and healthcare. It is important to assess patients' understandings of the aims and potential impact of this treatment options, how

well this option fits with patients' personal goals for their health, and if patients have discussed their GOC with clinicians during the process of making a treatment decision. An improved understanding of GOC within the context of CAR T-cell therapy will help ensure that patients are receiving care aligned with their goals, and that they have been adequately counselled on their treatment options before proceeding to treatment. This may prove to be particularly important as it relates to the oncology nurse, as it has been well documented that nurses who provide care to patients receiving treatments not aligned with their goals are likely to experience moral distress (Canzona et al., 2018). Thus far, the role of the nurse in supporting treatment decision making or discussing GOC in the context of CAR T-cell therapy is unclear. This thesis was intended to gather information from adult patients regarding their experiences in receiving CAR T-cell therapy, with an emphasis on understanding their self-identified GOC and perception of treatment intent and expected outcomes. It also aims to gain a greater understanding of the role of the nurse in GOC discussions surrounding CAR T-cell therapy, as well as their role in treatment overall.

Problem Statement

There is a paucity of research examining GOC in relation to patient decision-making about CAR T-cell therapy and about patient experiences in receiving this new form of treatment. CAR-T cell therapy can provide a lifeline to patients who have exhausted all other lines of curative therapy (Bartosch, 2021; Buitrago et al., 2019), yet little is known about how patients view their experience of pursuing and receiving this treatment, or if their experiences were consistent with their expectations of the treatment.

Both patients and clinicians would benefit from a more nuanced understanding of both how patients describe their GOC and experience of receiving CAR T-cell therapy and where there are potential gaps or areas for improving how care is provided, including nursing care.

The overarching aim of this thesis was to provide information that will improve GOC conversations and allow nurses and other clinicians to better prepare their patients for what they may experience when receiving CAR T-cell therapy. A secondary aim of this thesis was to better understand the role of nurses in relation to GOC and patient experiences during CAR T-cell therapy.

Thesis Overview

This chapter has provided a brief introduction to the role of CAR T-cell therapy and the intended aims of this thesis. Chapter Two will detail the literature search informing this thesis including search strategies, a synthesis of key findings, and an analysis of the current body of literature including strengths and limitations. Two distinct literature searches were performed: one focused on patients experiences with CAR T-cell therapy, and a second focused on GOC discussions in the oncology setting. Chapter Three will follow, detailing the methodology (qualitative description) used for this research. Chapter Four provides a thick description of the research participants and the study findings. Chapter Five provides a discussion of the results, along with implications for policy, practice, research, and overall concluding remarks. This chapter will also remark on study strengths and limitations, and reflections on the role of the researcher throughout this study.

CHAPTER TWO: LITERATURE REVIEW

To inform this thesis two distinct literature searches were performed: one to understand patient experiences with receiving CAR T-cell therapy, and a second to understand the current status of GOC discussion in cancer care. This literature search was performed initially prior to beginning data collection and updated during data analysis to provide further context to the findings.

Patient Experiences with CAR T-Cell Therapy

An initial literature search was conducted to gain an understanding of the patient's experience with receiving CAR T-cell therapy, aimed to discover what patients undergoing CAR T-cell therapy are likely to experience over the course of their treatment. A literature search was performed across multiple databases including PubMed, OvidMedline, and Web of Science. Search terms used were "patient experience" or "quality of life" or "patient reported outcome" and "CAR T-cell" or "chimeric antigen receptor" or "Kymriah" or "Yescarta." The search was limited to English language speaking studies. An initial search also included the term "qualitative," yet this yielded only 5 results and as such was removed. This search was limited to articles published within the last 11 years (as the search was repeated one year after being initially performed). Please see Appendix B for a detailed breakdown of the search strategy, and further information on included articles.

Studies were excluded if they were: not yet conducted in human trials (i.e., mouse studies), or were focused on pediatric cases, expansion of CAR T-cell treatment to areas outside of those currently approved in Canada (B-cell leukemias and lymphomas), the

manufacturing of CAR T-cells, specific biochemical markers or adjunct treatments, or cost effectiveness. Studies were also excluded if they did not fit the operational definition of patient experience - a description of a patient's interaction with the healthcare system that is reported directly from the patient (Cheng et al., 2021; Oben, 2020).

Overall, the search of the literature identified very few articles that examined patient experiences in receiving CAR T-cell therapy. A total of 29 articles (see Appendix B) were included in the review, with over half (n = 19) utilizing patient reported outcome measures (PROs) for data collection. One article utilized case studies with limited input from patients (Kersten et al., 2019). Nine articles employed a qualitative approach to research which provided holistic information on patient experience. As will be discussed below, this body of literature is limited and has many gaps. A synthesis of the consulted literature will now be discussed, including information on PROs in CAR T-cell therapy, and patients' experiences of receiving CAR T-cell therapy.

Patient Reported Outcomes in CAR T-Cell Therapy

Most of the literature surrounding CAR T-cell therapy is written from the clinician's perspective, with the primary inclusion of the patient voice in the form of PROs. PROs have been used to assess quality of life, psychiatric or emotional distress, and incidence of toxicities in patients receiving CAR T-cell therapy (Kamal et al., 2021). Available findings suggest that from baseline, patients are likely to experience adverse effects and worsened quality of life in the first 14-30 days following reinfusion, with some improvement or a return to baseline levels by 90 days post reinfusion. Adverse effects commonly reported in PRO based studies include worsened cognition, decreased

appetite, nausea, fatigue, insomnia, and joint pain (Bar et al., 2019; Barata et al., 2021; Hoogland et al., 2021; Jim et al., 2018; Kamal et al., 2021; Ruark et al., 2020; Sidana et al., 2019).

It is important to note that an improvement in symptom burden and quality of life is typically only observed in patients with a lasting and strong response to treatment (Hoogland et al., 2021; Maziarz et al., 2020). The experience of patients who have not responded to therapy has not yet been investigated. In most PRO-based studies examining long term effects, the data is limited to patients who have responded to therapies or those who did not know yet if the treatment was effective (Hoogland et al., 2021; Maillet et al., 2021; Maziarz et al., 2020; Sidana et al., 2019). In many studies, participants who did not respond to therapy died or were lost to follow-up prior to completion of follow-up surveys.

Overall, the research literature on patient experiences with CAR T-cell therapy is relatively new and incomplete. There has been limited time for longitudinal studies or qualitative studies as the priority has thus far been on evaluating safety and efficacy of CAR T-cell therapy. While a valuable tool, PROs do not fully capture the range of experiences associated with CAR T-cell therapy. PROs allow patients to self-report their symptoms and are useful for guiding clinical decisions and treatments, but they do not allow for clarification of responses or to gather in-depth information on what is being reported. From a patient perspective, the current evidence provides limited insight for patients about what to expect from a practical standpoint during treatment; the available

literature thus far speaks more so to clinician perspectives and the clinical management of toxicities and symptoms throughout the acute post-reinfusion period.

Patient Experience of Receiving CAR T-Cell Therapy

Eight articles provided descriptions of the process of preparing for and receiving CAR T-cell therapy from the perspective of the patient (Cheng et al., 2021; Jenei et al., 2021; Mao et al., 2023; Matthews et al., 2019; Stenson et al., 2021). Five articles that were fully available for review investigated patient perceptions of CAR T-cell therapy based upon Reddit postings (Jenei et al., 2021), individual interviews (Akinola et al., 2023; Bixby et al., 2023; Mao et al., 2023; Whisenant et al., 2021) and focus group interviews (Cheng et al., 2021) to understand health related quality of life across the treatment continuum. These were qualitative studies; however, none specifically identified the qualitative methods employed at the outset of the study. Two sources were only available in the form of abstracts, which investigated patient and caregiver experiences with receiving CAR T-cell therapy though the use of qualitative interviews (Matthews et al., 2019; Stenson et al., 2021).

These articles and abstracts provided insight into both the perceptions of CAR T-cell therapy prior to treatment, and the experience of receiving CAR T-cell therapy. Despite the uncertain curative nature and side effect profile, patients consistently reported a positive mindset entering into therapy (Bixby et al., 2023; Jenei et al., 2021; Mao et al., 2023; Matthews et al., 2019). When reviewing Reddit postings surrounding CAR T-cell therapy, patients reported anxiety and uncertainty about whether or not they would be eligible or able to afford the therapy but once approved they described an overwhelming

sense of excitement to begin treatment (Jenei et al., 2021). This is further described in Matthews et al.'s 2019 findings from their qualitative interviews – once approved for CAR T-cell therapy, many patients were focused primarily on their chance at cure and reported feeling blindsided by negative side effects or toxicities.

While limited, available evidence suggests that patients are not fully prepared for the range of experiences that are possible with receiving CAR T-cell therapy (Matthews et al., 2019; Stenson et al., 2021), and that significantly impacted their overall functional abilities (Whisenant et al., 2021). This may be due to the newness of this treatment and the limitations of current research evidence to inform the development of comprehensive patient information and self-management support interventions and resources. It could also be related to patients having higher than are reasonable expectations for treatment. It is thus far unclear if patients who are undergoing CAR T-cell therapy have had discussions about their GOC with cancer care providers to prepare them for the practical aspects of their treatment. As further literature is published on the experiences of patients, clinicians will be better able to provide their patients with an understanding of what to expect.

GOC Related to Cancer Care and Malignant Hematology

A second literature search was performed to gain information on the discussion of and conceptualization of GOC in cancer care. 'GOC' is a term used broadly to represent a variety of different concepts – as such, the first step of this literature review was to establish an operational definition of GOC as the foundation for this study. Of the 30 articles consulted in the literature review, three comprehensive definitions were identified

(Elias & Odejide, 2019; Naik et al., 2016; Secunda et al., 2019). For further clarity, additional literature was also consulted after performing a more targeted search for GOC definitions specifically (Stanek, 2017). These definitions are provided below as well as the context for the articles.

Table 1

Definitions of GOC in Literature

Citation	Context	GOC definition
Elias & Odejide, 2019	Overview of treatment options for older adults eligible for immunotherapy	"Patient's goals, values, and preferences regarding their treatment… in the context of the individual patient's medical condition and prognosis"
Naik et al., 2016	Qualitative study investigating GOC of patients newly diagnosed with cancer	"The desired outcomes of a particular healthcare service, therapy, or procedure"
Secunda et al., 2019	Systematic review and qualitative discourse analysis across healthcare	"The overarching aims of medical care for a patient that are informed by patient's underlying values and priorities, established within the existing clinical context, and used to guide decisions about the use of or limitation(s) on specific medical interventions"
Stanek, 2017	Concept analysis; nursing	"[Mutual] desired health expectations [between patients and clinicians] that are formulated through the thoughtful interaction between a human being seeking medical care and the healthcare team in the healthcare system and are appropriate, agreed on, documented, and communicated"

These definitions describe GOC as being contextually driven and developed in collaboration between patients and clinicians. However, only Stanek's definition

explicitly notes that GOC are constructed jointly between the patient and the clinician – this is an important distinction as it captures the influence that the clinician has on the patient's understanding and insight into the intended aims of their treatment. It also acknowledges that the best treatment decision for a patient is the one that aligns with their GOC. Each of these definitions brought forward a different aspect of GOC that was adapted into one new, cohesive definition. This was deemed necessary to proceed with clarity and given that a full description of GOC considering patient and clinician opinions, the context of the GOC, and the need for mutual understanding while recognizing the patient has ultimate autonomy over their decisions.

Moving forward, GOC will be conceptualized as the patient's goals for their health and healthcare that have been developed in collaboration with their clinicians to forge mutual patient-clinician understanding about the intended goals of medical treatments. This definition was utilized to perform a further literature search on GOC discussions in oncology. A literature search was performed across multiple databases including PubMed, OvidMedline, and Web of Science. Search terms used were "GOC" or "prognostic understanding" and "CAR T-cell" or "oncology" or "hematology" or "cancer care." The search was limited to studies published in English within the last 11 years (2013-2024).

Studies were excluded if they focused on pediatric or adolescent populations, palliative care or end of life care exclusively, or patient populations other than oncology. Studies were also excluded on conducting full text screenings if authors conceptualized GOC simply as a discussion regarding preference for code status, or if the purpose of the

study was only to identify ways to prevent hospital admissions. On a thorough full text screening, studies which were editorial, or opinion pieces were also excluded, as were studies that were not generalizable to the oncology population as a whole. Detailed information on the search strategy and a summary of selected articles can be found in Appendix C.

A total of 41 articles were included in this review. Broadly, these articles addressed the implementation of GOC discussions in cancer care, patient understanding of treatment intent, and patient identified GOC. Each of these areas were essential to formulating background knowledge for this proposal, and key findings for each are discussed below along with analysis and implications of the available literature.

Implementation of GOC Discussions in Cancer Care

Nineteen articles included in the literature review covered how GOC are discussed, with key findings summarized below. The articles contained in this section of the literature review were generally of high quality and balanced across research paradigms (five articles were qualitative in nature, six were quantitative and reliant upon survey data or nominal data obtained via chart reviews, and eight were review articles drawn from a variety of sources). However, only two of the articles specifically mentioned the discussion of GOC for the patient with a hematological malignancy (Apostol et al., 2015; Elias & Odejide, 2019), and no articles mentioned the discussion of GOC in patients preparing for CAR T-cell therapy.

Despite recognition that GOC discussions are essential to supporting patient autonomy and informed decision making (Boucher, 2021; Elias & Odejide, 2019), these

discussions still tend to be initiated close to end-of-life, and often focus primarily on code status rather than a true discussion of patient's overall goals of their care (Brazee et al., 2021; Frey et al., 2017; Wittenberg et al., 2016). Clinicians report multiple barriers to performing GOC discussions including a lack of time, fear of eliminating patient hope, perceived unpreparedness of patients and families to engage in these conversations, and difficulty obtaining accurate prognostic information (Dillon et al., 2021; Dulaney et al., 2017; Elias & Odejide, 2019; Schulman-Green et al., 2018). This can leave patients without valuable information about their diagnosis, prognosis, and treatment plans (Frey et al., 2017; Pompa et al., 2016), and can result in patients having overly optimistic views for their treatments (Canzona et al., 2018).

Of six articles describing the content of GOC discussions, four focused on whether patients would like to receive life-prolonging interventions such as additional chemotherapy, cardiopulmonary resuscitation, or mechanical ventilation as part of their care (Apostol et al., 2015; Emiloju et al., 2020; Frey et al., 2017; Schulman-Green et al., 2018). The remaining two articles more closely investigated overall GOC outside of treatment options, including quality of life, time spent with family, and physical well-being (Boucher, 2021; Pintova et al., 2020). As discussed further below, GOC discussions which do not explore patients' overall goals and values can leave patients with misunderstandings of their treatment intent and are perhaps part of the reason why patients receiving CAR T-cell therapy may feel unprepared for the range of experiences that may occur.

Patient Understanding of Treatment Intent

Consisting of almost one third of the consulted literature, nine articles described patients' understanding of treatment intent and prognostic awareness. Of the nine articles, seven were directed at capturing information about patients diagnosed with solid tumour malignancies (Douglas et al., 2019; Kim et al., 2015; Lennes et al., 2013; Pompa et al., 2016; Roldan et al., 2020; Winner et al., 2017), and two articles included patients with hematological malignancies in their sample (George et al., 2020; Tulsky et al., 2021). Information was gathered primarily via survey methods and was often limited to investigating GOC across a continuum from curative to palliative care. Of six studies relying on survey data, four characterized GOC as either completely curative or completely palliative, and the remaining two studies did not provide a description of how GOC were characterized.

As highlighted above, many gaps exist in the current practice of discussing GOC which can leave patients with overly optimistic views of their chance of cure across multiple treatment modalities such as radiation, surgery, and chemotherapy (Douglas et al., 2019; Dulaney et al., 2017; George et al., 2020; Kim et al., 2015; Lennes et al., 2013; Roldan et al., 2020; Tulsky et al., 2021). In seven studies investigating patient and physician agreements on treatment intent, there was a degree of discordance in each study, where patients and clinicians had different perceptions on the role of treatment and the possibility of cure (Douglas et al., 2019; George et al., 2020; Kim et al., 2015; Lennes et al., 2013; Roldan et al., 2020; Tulsky et al., 2021; Winner et al., 2017).

Where this discordance existed, patients were more likely to have an optimistic view of their treatment intent and were much more likely to believe their treatment had a curative intent even when clinicians had advised them otherwise**.** Even in the case of palliative radiation where the treatment intent is simply to improve quality of life, up to 35% of patients thought that the treatment was intended to cure their cancer entirely (Roldan et al., 2020). This finding has important implications for patients considering CAR T-cell therapy as there is no guarantee for cure. Approximately 40-60% of patients may have a chance for cure or a long-term remission following this therapy, and as such it is important to assess whether patients have clear expectations about treatment effectiveness and outcomes.

Patient-Identified GOC

There were very few studies identified which focused on patient-identified GOC, consisting of six articles in total (Apostol et al., 2015; Bernacki, Paladino, et al., 2015; Bickel et al., 2020; Frey et al., 2017; Pintova et al., 2020; Secunda et al., 2019). These articles were primarily based upon survey data and may not capture the full spectrum of patient identified goals - it was unclear whether all surveys had the ability for open responses or if they had to choose from a pre-populated set of options.

It has been noted that an implicit bias exists in healthcare systems towards curative therapies (Secunda et al., 2019), but living longer is not necessarily the top priority for patients with advanced cancer (Bernacki, Paladino, et al., 2015). Patients often placed a higher or equal value upon maintaining quality of life versus achieving a cure, particularly when progressing through multiple lines of treatment (Bernacki,

Paladino, et al., 2015; Douglas et al., 2019; Frey et al., 2017; Naik et al., 2016). In a study by Frey et al. (2017) an online survey was distributed to women diagnosed with ovarian cancer, and asked questions regarding their disease status, treatment intent, and how tolerable they found the symptoms arising from their current treatment regimes. Women who were receiving treatment with a curative intent reported that they would be willing to tolerate a wide variety of symptoms or hospitalizations and procedures, yet these same events were rated much less tolerable by women who were receiving treatment with a palliative intent (Frey et al., 2017).

Given the unique position of CAR T-cell therapy as a potentially curative option, it is important to understand how patients have made decisions regarding the likelihood and tolerability of the severe side effects and toxicities that are associated with the therapy. These decisions may reflect a trade-off like that described by women with ovarian cancer, yet no research has thus far been conducted in this area. There is the opportunity to gain valuable insight into the GOC of this unique patient population, that may offer strategies for improving GOC discussions and treatment decision-making.

Implications for Nursing Practice and Research

While the role of clinicians (e.g., physicians, nurse practitioners) has been discussed broadly in relation to GOC discussions (Douglas et al., 2019; Schulman-Green et al., 2018), it is also important to recognize the role of the registered nurse in this process. Nurses are positioned to provide support and health teaching to patients and their families and often advocate on their behalf to meet their goals for health and healthcare (Boucher, 2021; Canzona et al., 2018; Strachan et al., 2018; Whisenant et al., 2021). They

also have the opportunity to help patients identify what is important to them, to clarify their understanding of the treatment and treatment process, and to identify situations where treatment intent does not align with patients' GOC (Boucher, 2021; Wittenberg et al., 2016). While multiple articles have highlighted the importance of nursing support throughout CAR T-cell therapy (Alexander et al., 2021; Foster et al., 2020; Taylor et al., 2019), no studies have investigated patient perceptions of the role of nurses throughout their treatment experience or in relation to GOC.

In both the current healthcare environment with the COVID-19 pandemic, and in oncology and palliative care settings historically, registered nurses report feeling a sense of moral distress when caring for patients whose expectations or GOC are discordant with those of the clinicians managing their treatment and care. Registered nurses play a pivotal role in the delivery of CAR T-cell therapy, both in the direct delivery of care and in a system navigation/case management role (Dudley et al., 2019). This leaves registered nurses in a position where they are likely to face emotional distress upon caring for patients whose CAR T-cell therapy does not appear to be concordant with their GOC.

Conclusion and Research Questions

This literature review was performed to summarize the current evidence about CAR T-cell therapy and GOC discussions in oncology. Multiple evidence gaps were identified related to both patient's experiences with CAR T-cell therapy and the role of the nurse in GOC discussions. There is limited qualitative literature available on patient experiences with CAR T-cell therapy and no literature at all on GOC discussions prior to receiving CAR T-cell therapy. Available evidence regarding GOC discussions was

further developed with both qualitative and quantitative research studies to review, but the role of the nurse within these discussions has not been examined. Given the identification of multiple knowledge gaps, there are multiple aims of this study – both to better understand how to improve GOC conversations and preparing patients for what they are likely to experience throughout treatment, and to get a sense of the role of nurses in relation to GOC and patient experience. The research questions were as follows:

1. What are patients' perceptions of GOC broadly and in relation to CAR T-cell therapy?
2. What are patients' experiences in receiving CAR T-cell therapy and how do these experiences align with their GOC?
3. What are patients' perceptions of the role of registered nurses regarding their GOC and healthcare experiences during CAR T-cell therapy?

This chapter has provided a detailed description of the literature review performed as part of this thesis and identified the research questions. The next chapter will discuss how these research questions were investigated, using qualitative descriptive methodology.

CHAPTER THREE: METHODOLOGY

This chapter will discuss the methodology used to complete this thesis. It will begin by detailing the study design (qualitative descriptive research), followed by descriptions of the sample and sampling strategies, the recruitment process, data collection including the formation of an interview guide, data analysis, and how ethical issues were addressed. The chapter concludes with an overview of the strategies used to enhance rigor throughout the study, particularly as it pertains to analysis.

Study Design

This thesis utilized a qualitative descriptive design (Bradshaw et al., 2017; Sandelowski, 2000, 2010). This approach is often referred to as an exploratory method of research, which aims to gain a deeper understanding of a question or phenomena by gathering information from those deeply immersed in the experience. It is well suited to questions arising from clinical practice and as such is often used in qualitative health research, particularly in the discipline of nursing (Bradshaw et al., 2017). It is an accessible form of research which aims to understand and analyze a phenomenon by performing analysis rooted in the words of the participants (Sandelowski, 2000). In contrast to more theoretical or abstract approaches such as qualitative interpretive, grounded theory, or phenomenology, qualitative descriptive studies do not aim to build a new theory or to further translate the meaning of the data, but rather they aim to provide a detailed and nuanced description of a clinical phenomenon – in this case patient experiences and GOC in relation to CAR T-cell therapy (Bradshaw et al., 2017; Luciani et al., 2019; Sandelowski, 2000).

The goal with analysis in the qualitative descriptive method is to identify themes within the data while staying close to the participant's own words with minimal abstraction (Luciani et al., 2019). Compared to interpretive descriptive methodology, qualitative descriptive research produces themes which are more deeply rooted in the words of the participants. This was selected as the most appropriate research methodology for this research given the lack of available relevant literature to build a theoretical scaffolding to perform analysis, which would be a hallmark of interpretive descriptive design (Luciani et al., 2019).

Study Setting

This study took place at the JHCC in Hamilton, Ontario. Approval to proceed with this study was obtained by the appropriate research ethics board, seen in Appendix D. The JHCC is part of Hamilton Health Sciences (HHS), an academic health system affiliated with McMaster University. The JHCC is a regional centre for complex malignant hematology, treating patients with a variety of hematological malignancies and with multiple treatment modalities (chemotherapy, immunotherapy, targeted therapies, radiation therapy, and stem cell transplantation). Starting in December 2019, the JHCC became one of only three centres offering CAR T-cell therapy across Ontario. Currently, there is capacity at the JHCC to offer this treatment to three to four patients per month. Care is provided across both the inpatient and outpatient settings.

Sample and Sampling Strategies

The population involved in this study was patients eligible for CAR T-cell therapy at the JHCC. At the time of this research, this population was limited to patients over the

age of 18 with B-cell leukemias and lymphomas whose disease has progressed or relapsed through at least two lines of therapy. Patients who met the inclusion criteria to participate in this study were those either planning to receive CAR T-cell therapy at the JHCC and deemed medically eligible (see Appendix A for a review of the criteria for medical clearance) or who were within 100 days of the reinfusion of their CAR T-cells. Patients were excluded from participating if they were unable to partake in interviews for any reason, including language barriers, pre-existing cognitive or developmental disorders, or physical or psychological limitations. In addition, to avoid any conflicts of interest, patients who had received direct nursing care by the student researcher were not eligible to participate. Study eligibility was assessed by the patient's cancer care team (see Appendix E for clinician referral instructions), and by the student researcher when contacting the patient to provide study information prior to receiving informed consent.

A purposeful approach to sampling was utilized (Palinkas et al., 2015; Sandelowski, 2000). Purposeful sampling is a hallmark of qualitative research, as the aim of recruitment is to create a sample of participants who have experienced the phenomena under investigation (Bradshaw et al., 2017). Patients with varied perspectives and experiences regarding GOC and CAR-T cell therapy were recruited. This included variation among social demographics, diagnoses, and treatment that may impact overall patient experience such as the underlying disease, prior treatments, and whether severe toxicities were encountered after reinfusion.

Sample Size

Sample sizes within qualitative research vary based on the nature of each study, with few clear guidelines in place for determining an appropriate sample size at the outset of a study (Morse, 2000). Appropriate sample sizes in qualitative research are difficult to determine in advance since the ultimate goal is to gather enough information to develop a thorough and nuanced understanding of the phenomena under examination (Bradshaw et al., 2017). Given the nature of data collection techniques used in qualitative research (for example, observation, interviews, focus groups), a large volume of rich data can be collected from each individual participant. This study utilized in-depth individual interviews, with a planned sample size of 8 to 10 participants, which is consistent with other similar studies in qualitative health research (Accardi-Ravid et al., 2020; Chin, 2017; Eriksson et al., 2018). The final decision to end recruitment was intended to occur on the basis of data saturation, which is the point in analysis where additional interviews do not add any additional information to answer the research questions (Bradshaw et al., 2017). However, significant challenges within the recruitment process were encountered (see further below) and recruitment was stopped at six participants.

Recruitment Strategies

The recruitment of patient participants involved working closely with the multidisciplinary team at the JHCC using a variety of different strategies. The student researcher began by attending tumour board meetings at the JHCC to present on the study and to outline recruitment criteria. Members of the patients' primary care teams (physicians, nurse practitioners, social workers, transplant coordinators, and registered

nurses) were asked to identify potential eligible patients, provide them with brief information about the study, and ask if they would be willing to be contacted by the student researcher to receive more information about the study. A document was created and shared with clinicians to guide them through these steps, seen in Appendix E. Patients who expressed interest were provided with a letter of information (see Appendix F), and clinicians emailed the student researcher the patient's name and contact information (either phone or email dependent on patient preference) so that they could be contacted to receive more information about the study. When this approach did not provide enough participants, the student researcher spoke with the nurse clinician within the CAR T-cell program who provided a list of physicians who were seeing eligible patients for CAR T-cell therapy and the dates they would be present at the JHCC for appointments. The student researcher then contacted clinicians on the day of their appointments with patients following CAR T-cell therapy and asked either for an introduction to the patient with their consent, or for the clinician to introduce the study and advise the student researcher whether the patient was agreeable to being contacted with further information. There was also the opportunity for patients to refer themselves to the study – recruitment posters (see Appendix G) were displayed in areas of high traffic for patients undergoing CAR T-cell therapy (e.g., outpatient clinic waiting rooms and Oncology Day Services [ODS]) with a letter of information attached. It noted on the recruitment poster that interested participants could contact the student researcher directly by phone or email. There were not any participants recruited in this manner.

Once the student researcher was provided with patient's contact information and confirmation that they were interested in learning more, they were contacted via phone or email to review the letter of information, obtain and document verbal consent, and plan for how and when the interview would occur. For patients who were initially contacted via email, a phone conversation was scheduled to review the letter of information and obtain and document verbal consent. Verbal consent was documented both electronically in the patient tracking excel file in Appendix H and on paper on the consent form seen in Appendix I. After obtaining and documenting verbal consent, an interview was scheduled for a date and time that is convenient for the participant. Scripts for these conversations can be found in Appendix J.

Feasibility and Implementation

Decisions regarding the sampling and recruitment plan were discussed in tandem with the research committee which includes the head of the CAR T-cell program at the JHCC, Dr. Ronan Foley. The proposed sample size for this study was 8-10 participants, and in the 12 months prior to study initiation 16 participants had received CAR T-cell therapy at the JHCC amounting to an average of 2 infusions per month. If this pattern was true for the duration of the study recruitment period (six months), there was predicted to be an upfront sample pool of six patients with an additional twelve participants over the next six months. In order to meet the estimated sample size of 8-10 participants, approximately half of the projected 18 patients would need to agree to participate, which was felt to be a reasonable goal. However, recruitment was slow and ultimately took 8 months. While most participants approached (six of nine) were eager to participate in the

research, there were a number of patients undergoing CAR T-cell therapy within the window of recruitment who were too unwell to be approached. Demands on clinicians were also quite high throughout the recruitment period given ongoing staffing challenges and high patient loads which may have contributed to decreased referrals being made. In order to boost recruitment, the study was reintroduced to clinicians on multiple occasions throughout the recruitment window. The nurse clinician within the CAR T-cell program at the JHCC was identified as an excellent point of contact for patients and was able to assist in boosting recruitment. Recruitment began in September 2022 and was completed by June 2023 with a total of six participants consented to partake in the study.

Data Collection

Data was collected primarily via semi-structured individual interviews conducted by the student researcher, with information about the participant's course of treatment collected via the medical health record. Interviews were selected as the best method of data collection modality due to the sensitive nature of the topic, and the need to gain an understanding of the phenomena directly from those experiencing it (Kallio et al., 2016). The interviews also permitted a more thorough understanding of participants' experiences by allowing them time and space to provide nuanced explanations of their thoughts. Interviews were conducted virtually via Zoom or via phone calls. In-person interviews were not performed due to ongoing concerns with the COVID-19 pandemic and the immunocompromised status of this patient population.

Interviews were scheduled between day 30 to 100 post reinfusion of CAR T-cells. By day 30 post reinfusion, participants had completed and were recovering from the

treatment, with the next planned follow-up in the clinic at day 100. During this time period the majority of acute side effects would have resolved for most participants (Chakraborty et al., 2019; Kamal et al., 2021), allowing for a decreased burden to be placed upon participants. On approximately day 100 following their reinfusion, patients have an appointment at the JHCC to review their response to treatment based on a PET-CT scan. An outer limit of 100 days was selected so that participants participating in the study would not be aware of whether or not the CAR T-cell therapy had been effective. It was anticipated that if patients were already aware of whether their CAR T-cell therapy had been effective, their perceptions of the treatment would be different. Patients were also expected to have good recall of their healthcare experiences during the time period for data collection.

After the participants provided informed consent and prior to the interview, clinical data were collected from the medical health records to capture relevant information about the nature of the participant's underlying diagnosis and treatment experience. These data were collected by the student researcher by performing a chart review in Epic, the electronic medical health record used by HHS. This information was captured in an Excel spreadsheet seen in Appendix K (which was password protected and stored on a secure server) and later imported into NVIVO. These data were then linked to the corresponding participant transcript, allowing for cross-referencing of themes with this information.

Demographic and clinical data relevant to the receipt of CAR T-cell therapy at the JHCC were collected to inform purposeful sampling and to provide a context for data

analysis. A detailed description of the sample is also necessary to allow other healthcare professionals and researchers to determine whether findings from this study are applicable in other clinical contexts. Demographic information (age, gender, living distance in kilometres from the JHCC, highest level of education obtained, income level, marital status, and employment status) was self-reported by patients during the interview. These variables were selected as they were expected to influence participant's experiences in receiving treatment.

Clinical information (i.e. disease type, date of initial diagnosis, previous lines of treatment, and information about the course of treatment with CAR T-cell therapy including hospitalization and use of supportive medications) was collected from the patient's medical chart to ensure that a range of varied patient experiences and contexts were captured within the sample. For example, patients who have received a prior stem cell transplant may view their GOC and experience with CAR T-cell therapy different than those who have not (Sidana et al., 2019). Similarly, information on the use of supportive medications (i.e. tociluzumab and corticosteroids) will provide important clinical context as they are only indicated for patients with severe ICANS or CRS. Patients who experience side effects and toxicities as a result of CAR T-cell therapy may feel differently towards their overall treatment experience and perceived fit with their GOC.

Interview Guide Development and Interview Process

The development of the interview guide was informed by a framework outlining five phases of development: determining suitability of the project for an interview,

seeking knowledge, formulating preliminary interview guide, pilot-testing the interview guide, and finalizing the interview guide (Kallio et al., 2016). The interview was structured into two sections. The first section includes questions to examine participants' initial perceptions of CAR T-cell therapy, understanding of GOC as a concept and identification of their personal GOC, and how GOC were addressed during the treatment decision-making process. Of note, no specific questions about prognosis were asked as this could cause unwarranted distress. Instead, participants were asked to describe their understanding of the intended effect of CAR T-cell therapy on their cancer. Full information was still gleaned on participants' understanding of treatment intent and prognosis regardless, as will be discussed later. In the second section, interview guide questions examine participants' experiences in receiving CAR T-cell therapy and how these experiences matched their expectations. This section also aimed to gather more information on the role of registered nurses in the CAR T-cell care process, including whether nurses were involved in GOC discussions. In total, the interview guide consisted of eleven open-ended questions with prompts and follow up questions available for each.

Prior to use in the study, the interview guide was refined based on feedback from three patients who had undergone CAR-T cell therapy at the JHCC. Patients were invited to provide written feedback on the clarity, comprehensiveness, and acceptability of the interview guide questions (see Appendix L for evaluation forms). These patients were identified by a member of the clinical team (the physician lead) and asked for their permission to be contacted by the student researcher. The student researcher was then provided with participant's contact information and emailed them a copy of the

evaluation form. Responses were reviewed by the student researcher to make modifications to the study. The three patients interviewed had no concerns regarding the content of interview questions, although were all unclear on the meaning of GOC. This was noted, and a clear definition of GOC was provided to patients moving forward. The interview guide was also pilot tested in a mock interview with nursing peers to assess the need for further changes, under the guidance of the Local Principal Investigator (LPI). The interview guide was not deemed to need further revisions after this mock interview, but interview techniques were reinforced for the student researcher. The final interview guide can be found in Appendix M. The interview guide questions were slightly modified along the data collection and analysis process as new and common themes emerged (Bradshaw et al., 2017). For instance, after noting that many participants expressed the difficulties they had travelling back and forth to the hospital for their follow-up visits in the acute reinfusion period, the interview guide was adapted to gather more information on this experience.

Participants were offered the choice between taking part in an interview using a secure online platform (Zoom; utilizing the student researcher's institutional license through McMaster University), or by telephone call – this decision was made with the participant when arranging a date and time. All participants chose to participate in phone interviews. Interviews occurred in a private location within the JCC in a private office where participants could not be overheard and were audio-taped via digital recorder. Telephone calls were performed using the office phone – this prevented inadvertent storage of participant phone numbers and ensured participants would not have access to

the student researcher's personal phone number. The audiotaped interviews were then transcribed with removal of information that could identify the participant or other individuals (including specific locations, names of specific individuals, or references to specific dates or events that will be easily identified by the healthcare team). The student researcher transcribed audio files, which were deleted by the student researcher following review of transcription for accuracy.

Approach to Analysis

Content and thematic analysis occurred simultaneously with data collection, as this is a hallmark of qualitative descriptive methods (Bradshaw et al., 2017; Sandelowski, 2000). Once transcribed, interviews were read several times to refamiliarize the researcher with the context of the interview and the discussion which took place (Bradshaw et al., 2017), and then read with the intent of coding the data. In qualitative research, codes are words or phrases that capture the meaning of a selected portion of the data (Saldaña, 2020). This allows researchers to identify and categorize the different themes or meaning units covered within interviews and permits the data to be grouped into relevant categories for further analysis. This process was iterative and inductive, and as such the codes and categories were refined as additional interviews were conducted. NVIVO 12 software was used to store, manage, and analyze both the transcribed interview and chart review data. This process occurred in collaboration between the student researcher and LPI initially as a form of researcher triangulation. All interviews were coded in tandem between the student researcher and LPI. Once codes had been agreed upon, themes were generated in the context of the three research questions for the

study. Demographic data was analyzed quantitatively (i.e. by producing frequency counts, means, range scores, and standard deviation) using descriptive statistics via the use of SPSS.

Strategies Used for Enhancing Rigor

Rigor (or trustworthiness) in qualitative research involves the use of strategies to maintain credibility, transferability, dependability, and confirmability (Krefting, 1991; Morse, 2015). For further definition of the meaning of these terms and an overview of relevant techniques applied to this study please see Table 2. The techniques used included reflexivity, researcher triangulation, peer review, and dense description.

Reflexivity occurred throughout the research process. This involved a process of ongoing self-awareness and constant reflection on how the researcher's position has impacted their relationship with the research (Finlay, 2002). This was particularly important in this instance given the student researcher's prior role as a registered nurse within the hematology program at the JHCC. A reflexive journal was maintained, and care was taken to ensure that data analysis was not shaped by the researcher's personal values or biases – research triangulation similarly helped to maintain bias free analysis, as described below (Pillow, 2020).

Researcher triangulation refers to the process of two or more reviewers independently performing analysis on the same data and then discussing their findings to assess for consistency across strategies or coding techniques (Morse, 2015). Transcripts were independently reviewed and coded by both the student research and research supervisor (LPI). They met to discuss the initial coding and to come to agreement on the

coding scheme, including the development of a codebook. Independent reviews and meetings continued until it was felt there was consistency in the coding between the student researcher and LPI.

Peer review is a separate concept from researcher triangulation; it involves working with impartial outside researchers to review research methodology and findings. For this study, peer review was conducted regularly with members of the student researcher's committee. This involved reviewing the research proposal and study design (including the interview guide) prior to starting data collection. Once data was collected, this involved reviewing the codebook and themes with the research committee.

Thick description involves closely detailing aspects of the study that would allow health care professionals and other researchers to determine if the results are applicable in a different context (Morse, 2015). This was performed both by describing the context of the study (e.g., delivery of CAR-T cell therapy at the JHCC and the demographic and clinical characteristics of study participants, as well as by closely describing the methodological decisions made throughout the research process.

Table 2

Techniques for Enhancing Rigor

Component	Definition	Techniques
Credibility	Also referred to as 'truth value', refers to how accurately the findings reflect the experience under investigation (Krefting, 1991)	Reflexivity, researcher triangulation, peer review
Transferability	Describing the study in such a way that readers can	Thick description

	determine if results are applicable to other contexts (Morse, 2015)	
Dependability	Performing the study in such a way that variability between participants' experiences can be explained (Krefting, 1991)	Peer review, thick description
Confirmability	Performing the study in such a way that sources of bias are identified and minimized (Krefting, 1991)	Reflexivity, researcher triangulation

Ethical Considerations

There were many important ethical considerations in the design and implementation of this study. The topic area (i.e., GOC) is extremely sensitive, thus care was taken to ensure that interviews would not be harmful or cause emotional stress. Participants who appeared distressed during the interview process were offered a timeout or break as needed. This was offered to one participant, however they advised they were okay to continue. It was decided that if the student researcher was concerned about the participant's mental health following the interview, resources would be provided at the end of the interview including a recommendation to reach out to the care team. Resources included information about the psychosocial oncology team at the JHCC, information about local cancer support organizations such as Wellwood, or recommendations for how to access local programs through their family doctor. A script for reviewing recommendations after identifying distress can be found in Appendix N. This was used in one instance and the participant was offered to be connected to resources, but advised

they were already well supported. Participants were reminded that they could pause or stop the interview at any time and could choose not to answer any of the questions asked.

Verbal consent was obtained prior to scheduling the patient for an interview and was reaffirmed multiple times throughout the remainder of the study process. Verbal consent was selected over written consent given all interactions with participants including interviews were conducted virtually to minimize exposure of this vulnerable population to COVID-19. Informed consent was still obtained, with participants being provided a letter of information which contained all the information needed to make an informed decision about participating in the study. Participants were required to review this prior to consenting to participate, and this information was also reviewed verbally with the student researcher.

Many steps were taken to protect participant privacy. Only one master file existed that contained participants' names, contact information in the form of phone numbers and/or email, and their unique participant identification (ID) number. Identifying information (email and phone number) was deleted upon dissemination of study findings to the participant if requested – if this was not requested by the participant their information was be deleted upon completion of interviews. All other information (transcripts, audio recording, demographic information, and chart review information) was linked only to the participant ID number and did not contain any other identifiers. Audio recordings were deleted upon transcription. Prior to deletion of audio files, the audio recorder was stored in a locked cabinet in a locked office within the research unit of the LPI at the JCC, to which only the student researcher had the key. Documentation of

verbal consent as seen in Appendix I was also stored in this location. All electronic data was stored and password-protected in a folder located on the HHS secure server, which was accessible only by the student researcher. Only de-identified data was imported into NVIVO for analysis and remained password protected.

Care was taken to ensure that identifying information was not included within any publications or shared results of the study, including the removal of potentially identifying statements, comments, or description of people or places mentioned throughout the interview process. Demographic and chart review information were only shared in aggregate form. Full transcripts were only reviewed by the student researcher and principal investigator – information shared with the research committee was shared in excerpts rather than full transcripts.

Conclusion

This chapter has provided an overview of the methods used to perform this study, as well as the steps taken both to promote rigor in this project and to ensure the ethical conduct of the research. In the next chapter, research findings are presented.

CHAPTER FOUR: FINDINGS

This chapter provides a detailed description of the study participants and results. Information regarding study participants includes demographic and clinical information collected via chart review and the interviews. Study findings will be presented in relation to identified themes relevant to the three research questions. Detailed descriptions of each theme will be provided along with key quotes from participants.

Demographic and Clinical Information

A total of nine patients were invited to participate in this study, of which six consented and completed an interview. A detailed description of the demographic and clinical characteristics of the participants are found in Table 3 and Table 4 respectively. In summary, this was a very homogenous group of participants. All six participants were male and living far enough away from the JCC that they were considered to be a regional patient, meaning they were referred from an outside care centre for treatment. All six participants had pursued higher education, were married, and had a total household income above $60,000. There was more variance in their clinical characteristics, which described both their underlying disease and prior treatments, and their experiences with receiving CAR T-cell therapy. Four participants had an underlying diffuse large B-cell lymphoma (DLBCL), and 2 had an underlying follicular lymphoma (FL) transformed to DLBCL. They had received between two to four prior lines of treatment, with two participants having previously received a stem cell transplant (SCT). All six participants were hospitalized throughout the course of their CAR T-cell therapy, but only one participant required an ICU admission. Four participants developed toxicities (CRS or

ICANS) requiring tocilizumab, with three developing severe toxicities necessitating the use of corticosteroids.

Table 3

Demographic Data

Demographic Characteristic	**Parameters**	**N (%)**
Age in years	51-60	1 (17)
	61-70	3 (50)
	71-80	2 (33)
Gender	Male	6 (100)
Distance from JHCC	40-60 km	1 (17)
	60-80 km	3 (50)
	> 80 km	2 (33)
Highest level of education received	College diploma	2 (33)
	Bachelor's degree	3 (50)
	Master's degree	1 (17)
Total household income in Canadian dollars	$60,000-$89,999	4 (67)
	>$90,000	2 (33)
Marital status	Married	6 (100)
Employment status	Off work	3 (50)
	Retired	3 (50)

Table 4

Clinical Information

Clinical Characteristic	**Parameters**	**N (%)**
Underlying diagnosis	DLBCL	4 (67)
	FL transformed to DLBCL	2 (33)
Number of previous lines of treatment	2	1 (17)
	3	3 (50)
	4	2 (33)

Prior SCT	Yes	2 (33)
	No	4 (67)
Hospitalized during CAR T-cell therapy	Yes	6 (100)
ICU admission	Yes	1 (17)
	No	5 (83)
Total doses of tociluzumab received	0	2 (33)
	1	1 (17)
	2	2 (17)
	4	2 (33)
Received corticosteroids	Yes	3 (50)
	No	3 (50)

DLBCL = Diffuse large B-cell lymphoma, FL = Follicular lymphoma

Study Findings

A total of 10 main themes identified related to the three research questions with associated subthemes and are summarized below in Table X. These themes and subthemes will be presented in more detail starting with those related to research question 1.

Table 5

Themes and Subthemes

Research Question	**Themes**	**Subthemes**
1) What are patients' perceptions of GOC related to CAR T-cell therapy?	CAR T-cell therapy offers another shot at living	Lack of explicit GOC discussions Patients are not familiar with the term GOC
	When making a treatment decision, CAR T-cell therapy is the only real option	Factors considered in treatment decision making Comfort with treatment decision

	Patients have a good understanding of CAR-T cell therapy	
2) What are patients' experiences in receiving CAR T-cell therapy and how do these experiences align with their GOC?	Patients felt prepared to receive CAR T-cell therapy	
	Patients engaged in self-management	
	Coping and the psychological impact of CAR T-cell therapy	
	Experiences with treatment	Reinfusion process Side effects of CAR T-cell therapy Physical recovery Being a regional patient
	Healthcare experiences	Positive perceptions of the healthcare team Challenging aspects of care Transitions in care
	Family caregivers played an important role	
3) What are patients' perceptions of the role of registered nurses regarding their GOC and healthcare experiences during CAR T-cell therapy?	Nursing care throughout CAR T-cell therapy	

Themes and Subthemes Related to Research Question 1

Three major themes were identified related to patients' perceptions of GOC and CAR T-cell therapy. These themes will now be discussed further below.

CAR T-cell therapy offers another shot at living

When asked about their GOC, all patients identified a goal to treat their cancer. This meant different things to different people with some specifically wishing to cure their cancer, some hoping for more time, and some stating they wished to fight their cancer. While there are subtle differences between these self-identified goals, they all speak to the hope that CAR T-cell will provide them with additional time. Patients spoke of the hope that CAR T-cell offered, with one patient stating as follows: "The only thing I was concerned about is the cancer came back, but I was happy they had another potential solution…At least I had another shot at living… at making it a few more months, anyway" (CG02). Another patient described CAR T-cell therapy as a "ray of hope", further clarifying later that it was a treatment which offered the possibility to cure their cancer. As will be discussed later on, patients did identify that it was not ensured CAR T-cell would offer a durable response however it is clear that patients assign a great deal of hope to this treatment.

Patients are not familiar with the term GOC

A notable finding from this study was that most patients were not familiar with the term GOC. This is a commonly used term in healthcare (Stanek, 2017), however only one of six participants was familiar with this term and believed he had actually come across it in his work in the medical field.

Lack of explicit GOC discussions

Despite being able to clearly articulate their goals and the way CAR T-cell therapy would meet their goals, patients did not recall having an explicit conversation

with the healthcare team about their GOC. When asked, four of six patients stated that they had not openly discussed their goals for their health with the team at the JHCC. However, they described an implicit understanding between themselves and the team, with one participant describing that they felt their healthcare team "know what I'm all about" (CG06), and another stating that their GOC were not explicitly discussed, but "understood" (CG02). Another described that they did not feel a need to "waste time" with a GOC discussion, as their team "clearly understood from the beginning… that this was something that I was 100% in for" (CG04). There was not the opportunity to perform chart reviews or speak with treating clinicians about their recall of having had a GOC discussion, but it was clear from speaking with patients that they did not recall an explicit discussion about their GOC.

When making a treatment decision, CAR T-cell therapy is the only real option

When asked about their decision to pursue treatment with CAR T-cell therapy, patients described they never really viewed it as a choice that needed to be made. They explained that they were aware that there were no further curative options, and did not view pursing palliative or supportive care alone as a viable choice. As one participant stated:

> "Yeah – well, [laughs] it's funny. There was no decision or – this was the therapy. Cause I had failed the previous three therapies…It made it more comfortable I suppose, but there was no question whether of – of not doing the therapy, in my mind at that point." (CG03)

Another participant further clarified that by the time they were referred to see the team at the JHCC, their decision to pursue treatment had been made clear to the team there. They did not feel they were presented with any decision to be made:

> "See now, you keep saying 'deciding to have it', I don't think there was this – I don't think I was given a decision… it was just offered as the next treatment… Nobody said 'Do you want to have this', it's like 'This is what we're going to do.' So, I never really felt that I had a clear [pause] choice… I don't know what the alternative would be – like you wanna do this or you wanna do that; it would be you wanna do this or you wanna die? So, it was never given to me as, you know, 'Do you want to do CAR-T?'. It was like 'We're going to give you stem cell, you're now eligible for CAR-T.' That was the conversation, not 'Would you want to have this?' (CGO3)

Even when participants did feel as there was a choice, they described that there were no real alternatives to pursing treatment. One participant in particular captured this feeling well, asking "So faced with the choice between something that could - that might save my life and certain death, what would anybody choose?" (CG05). Although there were no other potentially curative treatments available, it is not clear whether patients were aware that pursuing best supportive care was an option particularly given that patients did not recall having explicit GOC discussions with their healthcare team.

Factors considered in treatment decision making

Although there was not the perception of a decision to really be made, patients were able to reflect on factors that were congruent with their receipt of CAR T-cell

therapy. These factors included the limited eligibility for the treatment, comments from family and healthcare providers, and weighing of risks and benefits. Participants were aware that they were part of a small subset of patients eligible for treatment with CAR T-cell therapy, and multiple participants described that they felt "lucky" (CG03) to even have the option for this treatment. Some also described their trust in the healthcare team influencing their decision, asking "But on what basis would I ever contradict you know a doctor if they think that CAR T therapy is the right one for me?" (CG05). Others described reviewing their options with trusted family members, who were all in consensus that proceeding with CAR T-cell therapy was the best path forward.

As voiced by patients, even the potential risks of severe treatment-related toxicities did not deter their assessment that CAR T-cell therapy was the only treatment option. As one participant explained, they balanced the risks associated with CAR T-cell therapy with their knowledge that they had a life-threatening cancer:

> "They said you know this could happen, that could happen, you know. You know, worst case scenario I could die. They didn't you know say you know [trails off]. I said, well, I'm going to die if I don't get this fixed so. I mean, I'm going…" (CG06)

It became clear when discussing treatment decision making that participants did not need to spend much time considering their options, as they did not feel there were any other options so proceed with CAR T-cell therapy was not a choice they felt they had to make.

Comfort with treatment decision

Although participants did not feel there was a treatment decision to make since there were no other options, post-treatment they felt comfortable with their decision to receive CAR T-cell therapy. When asked, participants reported that although they experienced a high degree of side effects during treatment, they would make the same decision over again. One participant stated as follows:

> "For me, it was horrible but like I said it's a process that I know I had to go through so. You know I wasn't expecting to go through, or I didn't expect it to be so tough, but looking back like I said I'd do it all over again." (CG01)

This is an important finding, since most participants (n=5) at this time did not yet know if their treatment had been effective against their cancer. The same participant (CG01) did state that their answer may change once they knew whether the CAR T-cell worked. However, for one participant who unfortunately had early disease progression post treatment, he still advised that even with this knowledge, he would opt to get the treatment over again. This speaks to the comfort that patients have with their decision, and that it appeared to have aligned well with their goals for their health – which were to live longer, survive, or cure their cancer.

Patients have a good understanding of CAR T-cell therapy

In order to ensure that a treatment aligns with a patient's self-identified GOC, they must have an accurate understanding of the expected aims and benefits of a treatment. Overall, the comments from each of the participants indicated that they have a good understanding of CAR T-cell therapy. This includes both a thorough understanding of

how the treatment works to treat cancer as well as the realistic likelihood that it would work. Participants were all able to accurately describe the mechanism of action for treatment in their own words.

Perhaps most importantly, participants expressed their knowledge that CAR T-cell therapy did not guarantee a cure. One participant stated "I know it's only 40% chance that it works. And that's not a huge number. But I just kind of hang on to the positive" (CG01). Another stated that their chance of response was "at best 50/50" (CG02). Another described their understanding of potential benefits as follows:

> "I think it was a very explicit understanding you know that I'll go through this treatment, and we're gonna see if it takes and if it doesn't – if it takes it could be a permanent cure, or it could be just a big improvement, or it could be nothing. And you know, I [pause] I'm prepared to roll the dice." (CG05)

It is clear that patients are able to articulate their knowledge that CAR T-cell therapy has a relatively low chance of cure. However, they still felt (as described above) that this was their only option and so felt comfortable overall with their decision to pursue treatment. They viewed CAR T-cell therapy as the only option in which they could achieve their goals of cure or living longer and were willing to take the potential benefit over the potential risks of the treatment.

Themes and Subthemes Related to Research Question 2

Six themes were identified related to patient's experiences with receiving CAR T-cell therapy. This was the question which produced the most information, as patients

provided very detailed insights into their experiences with receiving this complex therapy. These themes are discussed further below.

Patients felt prepared to receive CAR T-cell therapy

Participants described being well prepared to start their treatment, having received a lot of information from the healthcare team. As one participant explained, "when you're, when you're ready for anything, there's not much surprise" (CG05). Participants advised that they were provided a "holistic view" (CG03) of what was going to unfold. For some participants, they handled this well with no issues:

> "Well, uh [sighs]. I [pause] I look at it, I always tell my family yeah you know whatever the universe throws at you, you can handle because you have no choice. So, whatever they told me, uh, as far as the risks didn't really bother me, I mean it was - it's, it's proceeding with a curative option which, which hopefully is the case. Um, and it was the kind of last chance to achieve that." (CG06)

Others found that the level of information provided was overwhelming and at times triggered significant anxiety:

> "That's what it was the complications, the potential complications are what scared me. And I don't know if they could tell me this doesn't happen to people, and I don't know the words to use – but it didn't happen [sighs]. I don't know. I'm glad I knew the complications, but [trails off]. That was the biggest part of this CAR T, was the concern about the complications 2-3 days beforehand. And it just, everything was sort of banging at the door, thinking 'Oh my god, this could really go badly', you know." (CG03)

Overall, while patients described feeling well prepared for the process of receiving treatment, different patients perceived the provided information differently. They also responded to this information differently and used different coping skills to manage this.

Patients engaged in self-management

Throughout the process of receiving treatment, participants engaged in self-management strategies. This included information-seeking, monitoring for side effects, and managing medications. Information seeking took place most often prior to treatment starting. Participants had varying opinions on the utility of researching information about CAR T-cell independently – some preferred to look online for additional information while others relied on the healthcare team to provide them with information. Another participant described his experience using the available patient portal to review his notes from his clinic visit, which helped clarify misunderstandings about his disease status. One participant described reviewing written information provided by the healthcare team about CAR T-cell therapy in the days leading up to his reinfusion, which ended up triggering a lot of anxiety about whether it was truly worth the risk for him to undergo treatment.

Monitoring for side effects occurred most often when participants were discharged after their reinfusion, particularly monitoring for any fevers. Participants described having been instructed to closely monitor for and call the healthcare team if a fever occurred. This task often fell to family caregivers as this participant described:

> "My temperature was like 37.2, and then it was 37.3 so we were just watching it and thinking 'Oh, what's next?' So, at 37.5 my wife phoned, saying 'What should we be doing?', you know." (CG03)

There was little mention of monitoring for side effects once admitted to hospital, however on discharge managing medications was challenging for some patients. As one participant described:

> "They're changing your meds so there's a lot of preparatory work to be done and my wife had to really keep on top of it. We must have had 20 medications in there all to be taken at different times." (CG04)

There were multiple new medications introduced over the course of treatment, which was a lot of work for participants to manage.

Coping and the psychological impact of CAR T-cell therapy

The psychological impact of CAR T-cell therapy was described by participants and presented in multiple ways. As one participant described, he spent the days prior to his reinfusion thinking about his fears that the treatment could end his life rather than extend it:

> "This could kill me. If it couldn't kill me, maybe I'll be a vegetable in ICU. And that would be not good either and so I was thinking - would it be better to just die from my lymphoma? You know it's slow growing, it could take a couple years; or just be a vegetable in ICU. So, you know that was going through my mind." (CG03)

In addition to anxiety encountered prior to treatment, patients also described the difficulties they faced while receiving treatment. This was particularly evident when taking about hospitalization – one participant spoke about how difficult it was to be away from his family for extended treatments, as well as feeling "alone" and "pretty helpless" (CG01) when deconditioned from treatments. Another participant described the fear they felt after developing neurological toxicities and thinking they had experienced a stroke.

Participants were offered to be connected to a social worker as part of their treatments, but one participant declined and another reported he had already been connected to a team previously, at his home hospital. There were few references to seeking support from the healthcare team, however participants were able to identify coping strategies they found useful, which are described below.

Coping strategies described were similar across participants, and centred primarily around practicing acceptance, maintaining optimism, and finding the positives in a negative situation. As described above, participants had an excellent understanding both of their disease status and the goals of their treatment. When this knowledge about the potential risks of treatment led to distress or anxiety, participants described reminding themselves that they did not have other options – so what would happen would happen:

> "I think I just talked myself through it – I have to do this, because there's really no question about going through with it. Like, rational me stepped in and said we have to do this, but irrational me thought this is scary. But rational me said you have to do this." (CG03)

Another participant described that their approach to life in general was to accept the things they could not change, "For me, it's just do what you gotta do, that's all. My position is there's no point in getting upset about things you can't control" (CG02). Similarly, another participant described receiving treatment as a "passive" (CG05) experience, and that he had to take things as they came while knowing he could not control the outcomes.

As well as describing a sense of acceptance of their circumstances, participants also described maintaining hope despite their knowledge of the uncertain nature of treatment response. Finally, many participants spoke to finding the positives in their situation. This primarily centred around gratitude to their access to treatment. As one participant explained,

> "I felt fortunate that [CAR T-cell therapy] was an option for me, and they had already proceeded, that is [TREATING PHYSICIAN] and [NURSE CLINICIAN] had already proceeded to fund my treatment and I would be a fool not to take it – to take advantage of it." (CG04)

Participants referenced their gratitude for the quick access to treatment, approved funding, and even just the existence of the treatment. They were aware that this is a newer treatment, and something that would not have been available to them a few years ago, so some were grateful just to have this option.

Experiences with treatment

This theme focuses specifically on patients experiences with their reinfusion, and aspects of their recovery from this. Participants provided detailed descriptions of their

experiences that fell into four subthemes: reinfusion, side effects, recovery, and the experience of being a regional patient. Each subtheme will be discussed further below.

Reinfusion process

The reinfusion process varied significantly between participants. The majority of participants (four of six) experienced a smooth reinfusion with no side effects, with one participant describing it as anticlimactic:

> "Easy! I was, uh, so anticlimactic. They should have a band or something that walks in playing the big drums. Because it's like 'that's it?' Anti-climatic. It's you know, we planned for this for 8 weeks or 9 weeks or something and it's like that's it? Even the taking the cells was so dramatic – you've got that fancy machine with the whirling dials and the spinning wheels and the lights flash – that's really impressive. And then you just hang an IV and get it back in – you gotta get a machine with lights, or flashing lights or something… it was easy, no issues." (CG03)

Two participants developed infusion reactions during or shortly after their reinfusion, involving fevers, chills, and rigors. This required the use of medications to control symptoms. Both of these participants described their surprise at how quickly the reaction developed:

> "I wasn't expecting to react to it. It's hard how my body reacted… I wasn't expecting to have a physical reaction to the actual infusion… I knew it was possible to react to the T-cells but I wasn't expecting an immediate – and I think it was morphine that stopped the reaction." (CG01)

Side effects of CAR T-cell therapy

Multiple different side effects were described by participants, including fevers, gastrointestinal upset, fatigue, cardiotoxicity, cognitive changes, and neurological toxicity. Participants focused heavily on descriptions of their fatigue and associated weakness, with one participant describing as follows: "I just remember lying in bed…not being able to do very much. Like not even really to shift myself in bed because I was so weak… not being able to get out of bed" (CG01). This was a significant change in function for most participants. Fevers were also mentioned by many participants, and this was the reason for unplanned hospital admissions. Only one participant described neurological toxicity, however this was very frightening and dramatic for them, as below:

> "I knew I was in trouble, I was going 'I'm in trouble here, what's going on?' Yeah. I knew I was in trouble. I was thinking 'Did I have a stroke?' .... I did think that I had a stroke when I couldn't talk. It was frustrating cause he was asking me these questions and I'm going – I'm just shaking my head like 'I'm sorry, I can't answer you.' Yeah. It was weird. Scary, actually." (CG06)

Physical recovery

Despite the wide range of side effects experienced during the acute reinfusion period, physical recovery for most participants began quickly after returning home (which occurred approximately 30 days after reinfusion). This was reassuring and provided hope that the treatment was working. Participants tracked their progress, reporting that they felt "better and stronger everyday" (CG01). One participant described an improvement in

physical functioning which restored mobility to better than his pre-treatment baseline. This again provided hope that the treatment was working as intended.

Being a regional patient

The last aspect of treatment experiences described were aspects of treatment that were unique to being a regional patient. All participants in this study lived greater than 60 kilometres away from the JHCC, meaning they were regional patients who were receiving care at another cancer centre before being referred to the JHCC for CAR T-cell therapy. Aspects of treatment that were described included having to travel for care, being away from family, having to stay in a hotel after reinfusion, and having to meet a new healthcare team to receive treatment. Participants had little to say about the hotel, describing it as 'no big deal' (CG02). They also described that they were initially introduced to the idea of CAR T-cell by their primary oncologist, however most of the information provided came from the team at the JHCC. This meant having to travel to a new centre and meet an entirely new team prior to starting treatment. This could have been a source of distress for some, but participants in this study all reported having lots of faith in the team at the JHCC, as described below.

Healthcare experiences

The previous theme was focused on participants' descriptions of their treatment experiences. This theme examines participants' perceptions of their overall healthcare experiences. These perceptions were categorized into three subthemes: positive perceptions of the healthcare team, challenging aspects of care, and transitions in care. All subthemes will be discussed further below.

Positive perceptions of the healthcare team

Overall, participants described very positive perceptions of their healthcare team. As one participant stated:

> "The whole experience, the whole CAR T experience was a big warm blanket. They wrap around me, my wife, even our family. And we felt so taken care of – yeah, a big warm blanket. For the whole period from the day [TREATING PHYSICIAN] said you need CAR T-cell to the harvesting, to the infusion. That was about 2 months. No, we felt very, very embraced the whole time. The whole time." (CG03)

Five of six participants described similar overall perceptions of their interactions with the healthcare team, describing them as "gentle and understanding" (CG04), "outstanding" (CG02), and "fast at responding" (CG06). Participants were able to identify specific aspects of their interactions with the healthcare team which contributed to their positive experiences including thorough and timely care, responsiveness to questions, and provision of adequate information. However, many participants spoke more generally about their perception of their interactions, describing how warm and welcoming the team was as well as referencing the large amount of trust they had in the team to provide them with care.

Challenging aspects of care

Participants were also able to identify challenging aspects of their related to hospitalization, frequent outpatient appointments, and contacting the team after hours. Hospitalization was referenced by many participants as one of the most difficult aspects

of their treatment, due to the severity of treatment side effects and also being away from home. Descriptions of their time in hospital ranged from “unpleasant” (CG04) to “horrible” (CG01).

Once discharged from hospital, participants also referenced their difficulties with going back and forth to the outpatient unit for day visits. These visits occurred three times per week after patients were discharged from hospital until they were sent home and back under the care of their referring physician. The visits back and forth to ODS were often long days, as patients would often require transfusions, electrolyte infusions, additional bloodwork, or imaging. This was one aspect of care patients reported feeling unprepared for as they did not expect these visits to last as long as they did. They also referenced the difficulty getting up early to make it in for appointments when they were still recovering from their reinfusion and quite fatigued. The visits were described as long and draining, as one participant details below:

> “Because it was busy, more – I think we thought we’d be lounging around this hotel, you know. Calling up room service and stuff, and we were busy, you know driving up and down and being at the Juravinski. And then the day you weren’t at the Juravinski you spent the day recuperating from how busy we were.” (CG03)

The final challenge participants described throughout treatment was a lack of responsiveness and clarity when trying to get in touch with the healthcare team after hours with concerns:

> “They talk about temperatures of 38 you need to get your ass into the hospital sort of thing. My temperature was like 37.2, and then it was 37.3 so we were just

watching it and thinking 'Oh, what's next?' So, at 37.5 my wife phoned, saying 'What should we be doing?' And it took us probably all night to sort out what number to call." (CG03)

This experience was frustrating for participants, as they had been told ahead of time to call in for any issues, and that concerns would be managed promptly.

Transitions in care

Patients described being discharged home from the hospital as a significant transition in their care. This meant both that they were transitioning back to home from staying in the hotel, but also to their referring team for care. This transition required participants to adjust to less frequent monitoring and often created some uncertainty about who was managing aspects of their care, including medications. As one patient described, leaving the team at the JHCC felt like having a warm blanket removed, as they lost a lot of the support that was being provided with frequent visits and assessments:

"So, you were – you're kind of used to now, you know I was going for blood work three times a week. At [HOSPITAL] I was going for bloodwork once a week and you'd see the oncologist once a week. And now I'm down to once a month and we're going to go to once every three months and hopefully once a year." (CG03)

This perception of decreased support may have been heightened by the uncertainty patients were facing, as once discharged from hospital they still had to wait around two months before having a PET scan that would determine their response to treatment. This was anxiety-provoking, particularly without the reassurance of going into

hospital three times per week. One participant described that he spent every day wondering what the results would show (CG01). Further uncertainty existed when trying to sort out which team (JHCC or referring team) was taking over the management of medications. One participant described their difficulties sorting out who to contact for anticoagulation management:

> "We're not really [sighs] sure exactly who's doing what at this point in time for my care, I guess that's it. They've tried to explain it to me but… it's fragmented and we ask one [provider] they'll say well we didn't give it to you the first time so we're not responsible, when in fact they changed [the dose] so they are responsible and – I'm supposed to be on anticoagulation for a year because of CAR T." (CG03)

This was an issue likely unique to the patients in this group as they were regional patients, but it added a layer of complexity to their recovery process. Despite challenges in the transition, some participants did report they felt that the two teams communicated effectively, however this was not the case for all.

Family caregivers played an important role

Family caregivers were referenced multiple times throughout interviews. They were important throughout the care process, with three main aspects identified: as a motivator to pursue treatment, supporting patients with care needs throughout hospitalization, and helping with self-management. When asked about GOC, while all participants similarly cited a goal to live longer or cure their cancer, some explained that the motivation behind this goal was to spend more time with their family and to watch

their children grow up. As one participant stated, “It was all for my kids. I want to see them get older” (CG01). Participants also referenced taking their family members’ opinions into account when deciding to have CAR T-cell therapy.

Once treatment was underway, family caregivers were essential in supporting patients. It is a requirement to undergo CAR T-cell therapy that there is an assigned caregiver who is able to provide 24-hour support for the first thirty days post reinfusion. While patients were admitted to hospital, this involved frequent visits which were often long days at the hospital, as described: “[My wife] would get there around 10:30 or 11:00 in the morning and she would leave around 7:00” (CG06).

Support was also needed with self-management when not admitted to hospital. As participants described, it was family members checking their temperature, tracking their medications, and making calls to the healthcare team with concerns. This often placed a lot of responsibility on the family caregivers. They were also very important prior to treatment starting, as they were present for family meetings and helped patients keep track of all the information provided.

Themes and Subthemes Related to Research Question 3

One theme was identified in relation to the role of the nurse (registered nurse, nurse clinician, and nurse practitioner) throughout CAR T-cell therapy, described further below. There was extensive data provided about the role of nursing care throughout treatment, and participants spoke at length about the impact of nursing care on their overall experience.

Nursing care throughout CAR T-cell therapy

Patients made many references to nursing care throughout treatment. They had many positives to say about the overall care provided by nurses, nurse practitioners, and nurse clinicians. One participant described their perception of nursing care as follows:

> "The nurses there are phenomenal, really…. it's like they almost anticipate what they're, you know what's going to happen… They're always friendly, they never get rattled, they just, you know, it doesn't matter what you ask them or how many times you ask them. They, they got just really, really good personalities." (CG02)

When asked about specific examples, participants described nurses as normalizing their experience, which made them feel more comfortable. One participant also described how nurses were able to make conversation with them about their lives outside of the hospital, and find common ground.

In addition to describing overall perceptions of care, participants were able to recognize the multiple ways in which nurses were involved in their care and treatment. They described nurses as being involved in health teaching, care delivery, and care management. Prior to treatment, information was provided in collaboration by both the nurse clinician and physician. Particularly during the family meeting, participants described information being provided equally by the physician and nurse clinician. Nurses were also instrumental in providing care both during hospital admissions and ODS visits. This care included performing assessments, assisting with personal care, and performing procedures such as catheter insertions. Especially during ODS visits, nurse

practitioners were responsible for managing and coordinating care. This involved correcting abnormal electrolytes and ordering imaging for new or worsening concerns.

Overall, participants were able to identify many ways in which nurses were instrumental to their care, and overall felt that the level of care provided was quite high. They did not reference the role of the registered nurse in discussing GOC. As discussed previously, participants disclosed that they did not have formal GOC discussions with the healthcare team. However, there was not a specific interview question about whether patients had discussed their GOC with nurses – so it is possible that there was some discussion that was not mentioned during interviews.

Conclusion

In summary, this chapter presented the results from six in-depth interviews of men who were regional patients receiving CAR T-cell therapy at the JHCC. From the analysis, ten main themes and 10 sub-themes described participants' perceptions and experiences related to GOC and their healthcare experiences in receiving CAR T-cell therapy. The role of nurses and the care they provided was also illustrated. While patients did not recall explicit GOC conversations, they were able to articulate their goals to have "another shot a living" and were comfortable with their decision to have CAR T-cell therapy. The major of interview data and the results, illustrates participants healthcare experiences related to the substantive physical, psychological, and social impact of CAR T-cell therapy. Participants had very positive perceptions of their care but also identified opportunities for improving how treatment information is provided, as well as the coordination and transitions in care. Nurses were not noted to engage in GOC but were

pivotal to participants' positive healthcare experiences. The next chapter will examine the identified themes as they relate to other literature. The strengths and limitations of this study will also be discussed along with the implications of study findings for nursing practice, policy, and future research.

CHAPTER FIVE: DISCUSSION

The aim of this study was primarily to investigate the GOC of patients undergoing CAR T-cell therapy and how this related to their decision to pursue this treatment. It was found that all participants stated their primary goal was simply to survive, and they felt there were no other options for them outside of the CAR T-cell therapy that would offer the possibility to extend their life. As a result, this was an easy decision to make with some participants explaining they didn't even view it as a decision that needed to be made – just the logical next step in their treatment. While participants were able to very clearly state their GOC and understanding of how CAR T-cell therapy was intended to help them achieve this, they also reported not having formal discussions about GOC with the healthcare team. Participants did not feel an explicit GOC conversation was necessary as they had already decided to receive treatment, and some assumed the healthcare team was already aware of their goals and wishes.

Information was also gathered on the experience of receiving treatment, which highlighted perceived preparation for treatment, overall patient experiences including side effects, challenging aspects of care, and the role of self-management strategies and family support throughout treatment. Participants reported that they generally felt very well prepared to receive treatment and had a good understanding of most of what was to happen. They had very positive experiences with their healthcare teams overall. They did report challenges inherent to outpatient administration of CAR T-cell therapy, mainly in knowing how to contact the team after hours, and in having to come back for day visits frequently during their recovery period. They described using a variety of coping and

self-management strategies throughout treatment and highlighted the distinct transition that occurred when returning home once discharged from the JHCC. This is in the context of all participants having been regional patients referred from other centres.

The final aim of this study was to investigate the role of nurses in discussing GOC. An important observation is that participants did not share information about their experiences or insights on the role of nurses in discussing GOC as they related to CAR T-cell therapy. This lack of information about the nursing role may have occurred because participants did not perceive they had explicit GOC conversations, and the interview guide questions did not provide opportunity to further explore this issue. It is therefore possible that relevant data about the role of nurses in discussing GOC was not captured. Alternatively, since physicians were noted by participants to be mostly involved in discussions about treatment and CAR T-cell therapy, nurses may not have the opportunity to contribute to GOC conversations. The literature also suggests that nurses are not generally comfortable having formal GOC conversations and are more likely to engage in small or informal GOC discussions embedded within care delivery (Strachan et al., 2018). Therefore, GOC conversations with nurses may have occurred, but participants did not recognize them as such. Participants did discuss the importance of the registered nurse, nurse practitioner, and nurse clinician role in providing care during their treatment. All had different roles and were felt to have a high level of expertise and professionalism.

These findings will now be discussed as they relate to existing literature. Strengths and weaknesses of this study will then be discussed, followed by the implications that findings have on nursing practice, policy, and nursing research.

Relationship of Results to Existing Literature

Many of the results from this study have echoed what has been previously reported in existing literature (Bixby et al., 2023; Gatwood et al., 2021; Hoogland et al., 2021; Jenei et al., 2021; Mao et al., 2023; Stenson et al., 2021; Wang et al., 2021). This is seen as a strength of this study, as the results are consistent with those of larger scale studies, and even those performed in other countries. However, there were also findings from this study which have not previously been investigated in detail, and which provided insight into key areas for future research. Both similarities and differences to the existing bodies of literature will be discussed now, as they relate to each of the three primary research questions for this study.

CAR T-Cell Therapy and GOC

The first research question for this study investigated patient-identified GOC as they relate to CAR T-cell therapy. Important findings in this regard included patients' descriptions of their GOC, their understanding of treatment intent, and their recollection of GOC discussions.

Patient-Identified GOC

When asked to describe their primary goal when pursuing CAR T-cell therapy, participants unanimously cited their goal to live longer. A goal to live longer and eradicate disease is a commonly cited goal for patients undergoing treatment for a variety of different cancers (Frey et al., 2014; Naik et al., 2016; Pintova et al., 2020). Particularly early on in their treatment course, when asked their primary goal for treatment the majority of patients cited a goal to cure their cancer (Frey at al., 2014). While cure and

life prolongation were the primary goals for participants in this study, secondary goals identified were to be comfortable, spend more time with their family, or to be able to maintain a certain level of activity. These goals focused more on quality of life are also consistent with goals identified by patients in other studies (Bernacki, Paladino, et al., 2015; Frey et al., 2014, 2017; Naik et al., 2016; Pintova et al., 2020). In particular, when patients have advanced disease or are offered treatments that are no longer curative Frey et al. (2017) found that patients were less tolerant of side effects and placed a higher focus on maintaining quality of life. The participants in this study are uniquely positioned as while they do have advanced disease, but are also still eligible for curative treatment with CAR T-cell therapy. This could explain the identification of multiple different goals for their care, but it was clear that the primary goal when pursuing treatment was to get 'another shot at living'. It is also important to recognize that the participants in this study had already decided to proceed with treatment, and so we are missing the perspective of those who did not find that CAR T-cell therapy was aligned with their goals, which will be discussed later as an opportunity for further research.

Understanding of Treatment Intent

The participants in this study stood out from those in similar studies, as they all expressed an excellent understanding of the likelihood that CAR T-cell therapy had to cure their cancer. Prior research indicates that in general, patients are likely to have an inaccurate understanding of the likelihood of cure, tending to be much more optimistic than their clinicians (George et al., 2020; Kim et al., 2015; Lennes et al., 2013; Roldan et al., 2020; Tulsky et al., 2021). However, the participants in this study were able to

accurately recall the information and quote relevant statistics provided to them about CAR T-cell and the chance for a cure. This indicates that clinicians are well to ensure that patients have the information they require to make an informed treatment decision as it relates to treatment intent. It is also important to recognize that CAR T-cell therapy is unique in that it is only offered to patients who have failed multiple other lines of treatment yet remains a potentially curative option. This is different than the typical patient population included in the above referenced studies, as they focused more upon patients who no longer had curative intent treatments available to them (Kim et al., 2015; Roldan et al., 2020; Tulsky et al., 2021). It is therefore difficult to say for certain whether participants in this study truly had a better understanding of treatment intent than those in other studies given the differences in the goals of their treatment.

Recollection of GOC Discussions

One of the most interesting findings from this study, particularly the participants' detailed understanding of treatment intent, was that most did not recall having had a formal discussion about GOC with their hematologists – either from their referring cancer centre or at the JHCC. It has been previously noted across multiple studies that there are a number of clinician barriers to discussing GOC particularly in a clinic setting, including a wish to maintain hope, lack of clinic time and capacity, and a lack of comfortability holding these discussions (Gruß & McMullen, 2019; Littell et al., 2019; Schulman-Green et al., 2018). Similarly, it has also been previously found that patients often find it difficult to initiate GOC conversations with clinicians despite recognizing their importance (Frey et al., 2017). The participants in this study were unique in that they did

not feel there was a need to have a detailed GOC discussion, as they had already decided to proceed with treatment. One potential explanation for this is that the participants in this study were all patients who had received their upfront care and treatment at another cancer centre and may have had formal GOC conversations with their referring oncologist. However, it was also noted that participants were not familiar with the term GOC. It is possible that language used to introduce GOC conversations is more clinician-forward than patient-forward, and this could be causing patients to misinterpret the content or intention of these conversations. As will be discussed further below, the introduction of the Serious Illness Conversation Program (SICP) program introduced at the JHCC is intended to guide these conversations with patient facing language (Bernacki, Hutchings, et al., 2015).

Awareness of GOC

A consistent theme from available literature is that the term GOC is widely used both in research and practice by clinicians (Secunda et al., 2019; Stanek, 2017). However, there was a lack of literature regarding patients' perception of this term. Of the six participants in this study, only one had ever heard the term GOC, and this was because they worked in the medical field. Patients being unaware of the term GOC is not a finding that has previously been reported and has important implications for clinical practice. For example, given that not all patients may not be familiar with the term GOC, clinicians should assess their understanding of this concept and provide a detailed explanation of what this entails when initiating these conversations.

Patient Experience

The second research question for this study investigated patients' experiences with receiving CAR T-cell therapy. Participants' descriptions of their experiences with receiving treatment were consistent with what has been reported in the literature, both in terms of PRO data and qualitative studies. Areas of patient experience that have been researched in depth are side effects, psychological impact, and the role and perception of outpatient administration of CAR T-cell therapy. The findings of this study as they relate to these areas will be discussed further below.

Side Effects

The side effects experienced by participants in this study are all aligned with those reported in other studies. In particular, participants descriptions of acute side effects matched those which have been previously identified (Hoogland et al., 2021) including fatigue, fevers, headaches, GI disturbances, and cognitive changes. Fatigue, weakness, and fevers seemed to be the most common side effects encountered, but GI toxicity and neurotoxicity seemed to be the most distressing side effects. It is also important to note that for most patients, it has been found that side effects will lessen after the 90 day mark if their treatment has been effective (Wang et al., 2021). Participants in this study were interviewed right around this time frame, so before their symptoms had really started to improve. However, they did report they felt generally well prepared for the side effects they experienced, and felt they knew what to expect and that their care was managed well.

Psychological Impact

The psychological impact of undergoing CAR T-cell therapy has previously been reported using PRO data, and suggests that while there may be an initial worsening of anxiety or depression immediately following or preceding a reinfusion, this generally improves over time if there has been a treatment response (Bar et al., 2019; Johnson et al., 2023; Knight et al., 2022). However, this does not speak to the degree of distress which was experienced by some of the participants in this study. One participant in particular detailed their severe anxiety in the days leading up to their infusion, while they considered the real possibility that they may die from the treatment rather than their disease. Others spoke of the uncertainty they had to live with in the months following their reinfusion, while waiting for their PET scan to assess disease status. This was a common theme in other qualitative studies about patients receiving CAR T-cell therapy. In Jenei et al.'s 2021 study investigating perceptions of CAR T-cell therapy as described in online Reddit postings, patients described facing uncertainty both regarding their access to CAR T-cell therapy and their treatment experiences – particularly as it related to side effects and whether what they were experiencing was normal. Similarly, Stenson et al. (2021) reported that both patients and caregivers found the lack of certainty about response in the months following treatment difficult as it was hard to make plans for the future. Participants in our study touched upon this briefly, with one participant speaking to their renewed hope for going back to work, while recognizing that they needed to have their results first before deciding.

Uncertainty while awaiting test results is likely something that these patients had experienced previously with their other lines of treatment. However, unlike with their chemotherapy treatments which would have been given on a regular basis with interval CT scans, participants were no longer on treatment while they were waiting to find out about treatment response. This combined with the transition from the frequent visits and monitoring occurring at the JHCC to being back at home on their own could have contributed to a heightened sense of anxiety. Participants also felt that while they were generally very well prepared for their reinfusion, they did not feel well prepared for the transition back home. This is an important area to focus on in terms of improving patient care, as patients could likely benefit from enhanced support while awaiting their results, and more information about what to expect for this period upon discharge from the JHCC.

Experience with Outpatient Administration

The participants in this study all received care in both in-patient and out-patient settings. Three participants were admitted immediately following their reinfusion for a period of 10 days, while three others were treated on an outpatient basis initially following reinfusion, but readmitted when they developed fevers. This is consistent with other centres which have offered outpatient recovery to some patients (Bixby et al., 2023). The risks and benefits of an outpatient approach to treatment have been thoroughly investigated previously. Participants in other studies (Bixby et al., 2023; Gatwood et al., 2021) have advised that while the advantage of being at home is increased comfort, being

in hospital feels safer and provides access to more frequent monitoring and interventions as needed.

In a 2023 study by Bixby et al., 18 patients who had had received or been offered inpatient recovery following CAR T-cell therapy were asked to provide their thoughts on receiving inpatient or outpatient care. All participants agreed that the care they had received in hospital was excellent, and they felt that they were well taken care of and supported, consistent with what participants in our study had reported. When asked about their thoughts on outpatient recovery as an option, many were hesitant to choose this over inpatient recovery despite acknowledging that it would be less intrusive and more comfortable for them to stay at home. They cited a need for frequent monitoring, and the expertise of the healthcare team in identifying potential concerns right away as primary benefits to staying in hospital (Bixby et al., 2023). Another important consideration was the burden on family caregivers during outpatient care, as well as the increased financial burden for incidental expenses for food and travel (Bixby et al., 2023). All participants agreed that in order for outpatient recovery to be a viable option, they would need a phone number to call providing them with direct access to the healthcare team (Bixby et al., 2023).

While the participants in our study were not asked specifically about their thoughts regarding outpatient administration, they indirectly referenced many of the above findings. They spoke about the high level of care provided, and how the healthcare team was able to anticipate their needs. For those who were initially recovering as an outpatient, they spoke about the uncertainty they felt when they started developing

symptoms requiring further attention and the discussions with their caregivers about how to proceed. Although all patients were provided with a direct number to call in and speak to the team, two participants experienced significant difficulties actually getting through to the hematology team to get advice. This was quite frustrating for them. While participants did not reference costs of recovering as an outpatient (rooms in a nearby hotel were funded as a part of their treatment), they did reference the difficulty of getting to and from the cancer centre every other day when they were already fatigued. They noted the importance of caregivers in providing support to manage medications and appointments. Although it would not be possible or necessary for all patients to remain as an inpatient for the duration of their recovery, this study has highlighted important areas where care could be improved during outpatient recovery which will be discussed further below.

Nursing Role in GOC Conversations

The third and final research questions of this study aimed to investigate the role of the registered nurse in GOC discussions throughout CAR T-cell therapy. In reviewing the GOC literature available, there is little mention of the role of the nurse in these discussions. That which exists suggests nurses more often engage in informal GOC discussions embedded in the provision of care, contrasted with physicians as having formal GOC conversations (Strachan et al., 2018). There has also been research done which indicates that nurses face moral distress when providing care that does not appear to fit with the patients GOC (Canzona et al., 2018). In this study, patients did not mention the role of the nurse as it related to discussions around GOC. This was a role that fell primarily to physicians, and as mentioned patients often did not feel it necessary to have

formal discussions about GOC with the team at the JHCC. The lack of information gathered about the role of the nurse in GOC discussions represents an area for further research.

While little was learned about the role of the nurse in GOC discussions, participants spoke about the excellent care they received and the positive interactions they had with nurses throughout their treatment. This included interactions with registered nurses, nurse practitioners, and the nurse clinician. Existing literature has highlighted the importance of having a skilled nursing team to provide care to patients undergoing CAR T-cell therapy (Stenson et al., 2021; Whisenant et al., 2021). This was further highlighted throughout this study as well, with participants speaking about how nurses supported them with direct care, care management, and the provision of information.

Study Weaknesses

It is important to recognize the weaknesses of this study when discussing results. The study's most significant limitation is its small sample size and homogeneity of study participants. Only six participants were successfully recruited to participate in this study, despite many months of recruitment. This is thought to be in part owing to the nature of the time points at which potential participants were recruited – they were most often reachable on their day visits following their reinfusion. As previously mentioned, this was a time of high symptom burden and fatigue for participants, which could have contributed to the reasoning for participants opting not to participate in a study which would have been an additional burden. Of nine participants contacted, six did ultimately agree to participate. There were also additional eligible participants not able to be contacted by the

student researcher as clinicians were unable to speak with them to confirm they were agreeable to be contacted – this occurred mainly for patients who had already been discharged home and were coming to the JHCC infrequently. The six participants who did participate were also a very similar group of individuals – all were male, married, and had post-secondary education. They were all also regional patients who had received upfront treatment at another cancer centre and been transferred to the JHCC for CAR T-cell therapy.

This small and homogenous group of participants means that results of this study are unlikely to represent the experiences of all patients receiving CAR T-cell therapy. In particular women, those of lower socioeconomic status, and those who received CAR T-cell therapy from their primary cancer care team are likely to have different perspectives and experiences form the study participants. For example, study participants had already decided to proceed with CAR T-cell therapy prior to being referred to the JHCC, which may have influenced the perceived need for a GOC discussion. In addition, the participants were staying in a hotel rather than at home for the 30 days following recovery, and thus were isolated from family and friends which could have impacted their overall experience and psychological effects.

A sample size of six participants was smaller than was intended for the study, and although there are no clear guidelines for the number of participants to be included in a qualitative study such as this (Bradshaw et al., 2017), six is less than would typically be seen in a qualitative descriptive study. As stated in the methods section, typically eight to ten participants would be included. This does mean that the results are harder to

generalize to other patients receiving CAR T-cell therapy and affects the strength of the findings. However, for major themes identified in this study, participants reported similar perception and experiences, and the results are consistent with previously reported findings in the literature.

Study Strengths

While weaknesses of the study have been clearly identified, there were also clear strengths of this study. As mentioned above, the small and homogenous pool of participants makes it difficult to generalize findings to other patients undergoing CAR T-cell therapy. However, these participants represent a very unique and understudied patient population given that they were all male and from other cancer centres. It was interesting to interpret results within this context, and does provide a very thorough understanding of some of the challenges faced by regional patients when undergoing CAR T-cell therapy at another centre outside of their home community.

Despite the small group of participants, major themes were well described, and there was consistency in experiences among participants. This was particularly clear when discussing GOC, as all six participants clearly identified their goal to live longer. Furthermore, very rich and open discussions were had with participants. Participants were open to discussing all aspects of their care, and able to discuss existential questions about their GOC and their mortality. For instance, participants brought up statistics about treatment intent without being asked, and one discussed their interest in medical assistance in dying (MAiD). This participant brought up the conversations they had had with their referring provider about MAiD as an option when discussing his understanding

of his disease status. It was an unprompted remark, again highlighting the willingness of participants to discuss very difficult topics. Despite these difficult conversations, only one participant became distressed but was comfortable enough to carry on with the interview. Participants were also incredibly open and insightful about their experiences, and able to clearly articulate their thoughts about treatment and areas in which improvements in care could be made.

Finally, despite the small sample size and lack of variability within participants, results from this study were seen to align with and complement previous research and may inform the care of regional patients receiving CAR T-cell therapy outside of their home cancer centre.

Implications for Nursing Practice, Policy, and Nursing Research

Thus far the findings and their relation to existing literature, and the strengths and weaknesses of this study have been discussed. The implications of this study for nursing practice, policy, and nursing research will now be discussed in detail.

Implications for Nursing Practice

The role of the nurse in providing care throughout CAR T-cell therapy has been recognized as highly important to overall patient experience (Buitrago et al., 2019; Whisenant et al., 2021). In this study, participants described the positive impact of nurses on their healthcare experiences. However, areas of improvement were noted particularly around optimizing patient teaching and improving support for patients during the transition from the JHCC to home. It was also noted by the research team that there is a for role increasing the nursing role in GOC discussions. Throughout each of these areas,

there was also a need for enhanced psychological support. Each of these areas will be discussed further below, with proposed strategies for implementation.

Optimizing Patient Teaching

Participants described receiving a large volume of information prior to their CAR T-cell therapy, consistent with what has been reported in other literature (Jenei et al., 2021). Participants perceived the information differently, with some finding it overwhelming and some finding that it was the information they needed. One participant in particular had significant anxiety in the days leading up to his reinfusion as he ruminated on the possible side effects and toxicities he might encounter. At the same time, participants also identified areas of their care which they did not feel prepared for – mainly their outpatient visits, and the transition from the JHCC to home.

When providing patient education, it is considered best practice to perform a needs assessment and then tailor the provided information to the needs of the patient (Registered Nurses' Association of Ontario, 2012). This can be difficult to do in practice, when patients need to have a full understanding of the expected risks and benefits of a treatment to make an informed decision. Therefore, it is unlikely that patients could be provided with less information on the expected side effects and toxicities, as they need this information in advance of the treatment. The participant who expressed their anxiety over the information provided did advise that they had been provided with the exact likelihood of undergoing these toxicities, so it is clear that patients were counselled appropriately on the risks and likelihood of these risks occurring. As mentioned, there is

also a need for additional psychological support throughout the treatment course which may have provided an outlet for patients to discuss their anxieties or concerns.

However, a need for further information regarding outpatient visits and what to expect on the transition home were identified. This is likely not information that is required to be provided upfront at the initial family meeting, but could be provided later on in their treatment, around the time of preparing for attending outpatient visits and before their transition back to their home cancer centre. Multiple patients also voiced that they would have found it helpful to have been connected to a peer mentor who had also undergone CAR T-cell therapy, which they felt may have helped alleviate some anxiety. Peer mentoring has previously been found to be helpful for many patients undergoing cancer treatments, including those undergoing stem cell transplantation (Amonoo et al., 2022). This likely would have also provided them with additional information on what to expect from their visits from a patient perspective.

Increasing Support for Patients During Transitions

One transitional period where participants have identified as needing further optimization is the support provided when they are monitoring their symptoms as outpatients after their reinfusion and discharge from hospital. Particularly, they identified having difficulties knowing who to call and when. When they did call, it took them multiple tries to be connected to the correct person. This was a concern identified by participants in the study by Bixby et al. (2023) on perceptions of inpatient versus outpatient administration of CAR T-cell therapy. A more stream-lined option to contact the healthcare team after hours should be created, with clearer information on when to

call and how to get in contact with the team. It would also be helpful to provide patients with guidance on which providers to contact for which issues – as participants in this study highlighted that once discharged to their home cancer centre it was unclear which providers were managing ongoing medications.

Patients also described their difficulties with the transition back to their home care centre, particularly when they are first returning home. They also described the anxiety that can accompany their uncertainty while awaiting PET scan results. Two participants brought up their introductions to the social work team, with one having been connected at their home centre, and one not seeing the need for this connection. However, participants did describe the transition from the frequent visits to being at home quite jarring, and this could potentially be improved with built-in support at regular intervals upon discharge, even just with check-in phone calls once settled at home so patients have the opportunity to highlight any questions or concerns. It is also suspected that patients would benefit from ongoing psychosocial support on a more formalized basis, given the distress that was experienced by participants and the knowledge that anxiety and PTSD symptoms persist for up to 6 months post treatment (Johnson et al., 2023). Given that participants had already referenced feeling quite overwhelmed with their multiple visits in the acute reinfusion period, this could be accomplished by having regular check-ins with a member of the psychosocial oncology team when already at the JHCC for other appointments. Prior to their reinfusion and after discharge to their home cancer centre, these could be ongoing virtual visits, with in-person visit when participants returned for their post

treatment PET scan results appointment. By pre-arranging appointments, it lessens the burden on patients as they no longer have to call in and request an appointment.

Increasing Nursing Role in GOC Discussions

The final major implication for nursing practice identified in this study was a need to further optimize the role of the nurse in GOC discussions. It has previously been identified that although nurses can often identify when patients are not receiving goal-concordant care, they often do not feel they have the confidence or knowledge to open up GOC discussions with patients (Boucher, 2021; Canzona et al., 2018). The ways in which nurses engage in GOC discussions with patients has been found to be fundamentally different when compared to physicians, mainly as it occurs briefly within other aspects of care provision rather than a stand-alone discussion (Strachan et al., 2018). Minimal research is available on how to promote increased comfort with GOC discussions for nurses specifically, but Boucher et al. (2021) identified that nurses could benefit from accessing programs intended for clinicians broadly to increase comfort and participation in GOC discussions. It was specifically suggested that use of the SICP (Bernacki et al, 2015) is one tool that can be used.

SICP was developed initially in 2015 to help guide conversations with patients receiving palliative care about their GOC. It includes clinician training guides, conversation guides, and patient-facing materials to help prepare patients to participate in these serious illness conversations (Bernacki et al, 2015). The SICP program has been adopted within the JHCC and has been introduced initially to those working in outpatient clinics within the oncology program. If this program was to be rolled out to nurse on the

inpatient teams as well, they would likely also benefit from increased comfortability engaging in GOC conversations with patients.

Implications for Healthcare Policy

As discussed above, one of the major themes identified in this study was the lack of clear GOC discussions between patients and clinicians. Participants described making assumptions that their clinicians were aware of their GOC, when this may not have been the case. As such, implications for healthcare policy include suggestions for supporting and encouraging clinicians to engage in GOC discussions with patients prior to their CAR T-cell therapy. One such suggestion has already been made above – to roll out the SICP program to inpatient nurses to increase their comfort engaging in these discussions. The remainder of this section will be targeted at increasing physician led GOC discussions prior to CAR T-cell therapy.

Integrating GOC Discussions into Routine Care for CAR T-Cell Therapy

As with nurses, a number of barriers exist which can prevent physicians from engaging in GOC discussions with patients. These barriers often include a lack of clinic time, a lack of comfort with these conversations, a wish to maintain hope, and a lack of therapeutic relationship with the patient in question (Dillon et al., 2021; Gruß & McMullen, 2019; Hong et al., 2021; Littell et al., 2019; Schulman-Green et al., 2018). As mentioned above, the use of the SICP program (Bernacki, Hutchings, et al., 2015) is a tool already in place to reduce some of these barriers, and has already been rolled out to providers within the JHCC.

All of the patients in this study were regional patients and while they were not familiar with the concept may have had GOC discussions with their referring physician. One suggestion to ensure these conversations are happening is to ask for inclusion of a documented GOC discussion in the referral package. This would both ensure that the conversations have been introduced and would give clinicians at the JHCC a starting point from which to begin this conversation. It is also important to build the time for these important conversations – it would not be appropriate for this to occur at the first, brief meeting with a JHCC physician, nor would it be ideal to occur at the lengthy family meeting which is intended to provide a detailed overview of the treatment process and possible side effects. This would likely mean an additional visit for a full GOC discussion, which might not be possible given limited time in outpatient clinics. This is why for regional patients it would be important to ensure that their GOC have been discussed and well documented by the referring provider.

Implications for Nursing Research

The process for collecting data for this study and the results illustrate that it is possible to have open and honest conversations with patients about their GOC and understanding of treatment intent. However, only a very small group of participants were recruited to this study, and it was not a diverse or varied group of participants. As such, the first step for further research in this area would be to gather this information from a more varied and larger group of participants to further validate these findings and transferability to other patient populations receiving CAR T-cell therapy. Other areas to target for further research include understanding clinicians' perspectives on GOC

conversations within the CAR T-cell program, and the perspective of patients who opted out of receiving CAR T-cell therapy.

Clinician Perspectives on GOC Conversations

As discussed, participants reported not having had GOC discussions preceding their CAR T-cell therapy and did not feel it was necessary. They did have clear GOC identified, and expressed a thorough understanding of treatment intent and likely benefit. However, there was also room for clarification around the role of palliative care alongside CAR T-cell therapy, as one participant had believed them to be mutually exclusive. Participants also reported that they felt there was an implied understanding between themselves and the team at the JHCC regarding their GOC.

Given these findings, it is also important to understand the clinician's perspective on the GOC of patients undergoing CAR T-cell therapy. This is an important area for future research, given that participants identified they felt that the healthcare team had a good understanding of their GOC without discussing them. It would be helpful to understand whether clinicians feel this is a necessary discussion, particularly for patients who are being referred having already decided to proceed with treatment. It would also be interesting to clarify whether clinicians recall having a GOC conversation, and what these conversations entailed. It is possible that these discussions were had but were not retained by participants given the volume of other information provided.

This research should include a varied pool of clinicians – including physicians, nurses, and other members of the allied health team. This would also help further identify

barriers to other clinicians partaking in GOC discussions, and likely would help target strategies to reduce these barriers.

Patients Who Opted Out of CAR T-Cell Therapy

It has also been identified that all patients who participated in this study had already opted to proceed with CAR T-cell therapy, and this could have contributed to their perception that a GOC discussion was not needed. It is also perhaps unsurprising that the majority of participants identified similar goals of wanting to survive – as CAR T-cell therapy was the only option available to them to allow them this option. It is also important to understand the GOC of patients who were offered CAR T-cell therapy but decided not to proceed with this. This would help to provide additional information surrounding GOC and CAR T-cell therapy, by identifying patient-identified GOC that were not felt to be congruent with CAR T-cell therapy. This would also help provide further information to guide the GOC conversations for all patients considering undergoing treatment, as it may offer clinicians additional context to factors patients need to consider in their decision. It is also possible that there are patients for whom CAR T-cell therapy would have aligned with their goals, but they may have had misconceptions about treatment, or had other barriers preventing them from proceeding (for instance, patients who were unwilling to stay in a hotel or who did not have a reliable caregiver).

Conclusion

This study aimed to better understand the experiences of patients undergoing CAR T-cell therapy at the JHCC, in particular as it related to their GOC. Ten major themes were identified, providing insight into patients self-identified GOC and how this impacted

their decision to pursue CAR T-cell therapy, their overall experiences with receiving treatment, and the role of the nurse in providing this care. Key findings included the identification of a common goal of care simply to survive, a lack of formalized GOC discussions occurring, identification of ways in which to better support patients during their recovery period, and an understanding of the different transitions in care that occur and how patients perceive these transitions. This study provided new insight into the experience of patients undergoing CAR T-cell therapy and the context in which their treatment decision is made (where they felt there was no option other than to proceed with treatment). It was also identified that undergoing CAR T-cell has an impact on physical, psychological, and social well-being, with additional strategies needed to better support patients in these realms. Areas for further research have been identified, as have ways to improve care to better support patients throughout their treatment.

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Appendix A: Cancer Care Ontario/Hamilton Health Sciences Eligibility Requirements for CAR T-Cell Therapy

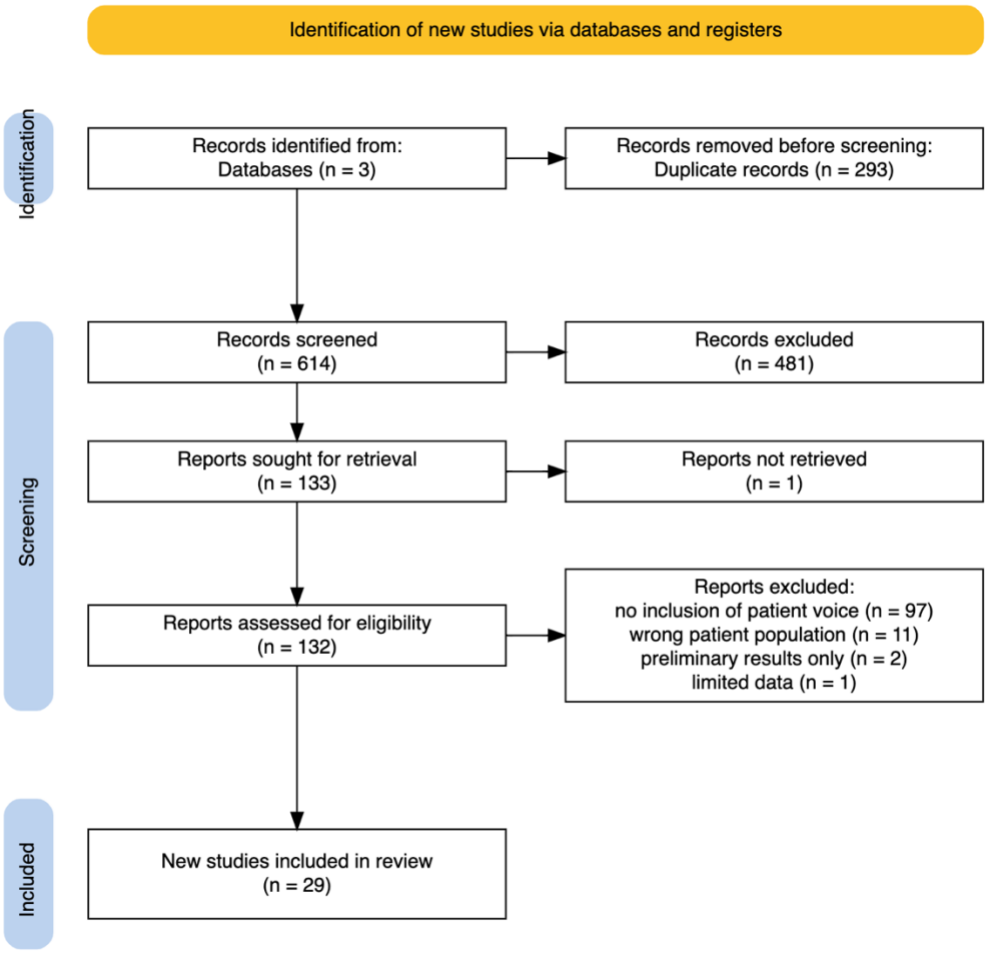
	DLBCL	ALL
Age	Patient must be ≥ 18 years of age	Patient must be between 18-25 years of age (inclusive)
Disease Status	Histologically confirmed CD19+ DLBCL with measurable disease (extranodal lesions ≥ 10mm in long and short axis) at the time of referral	CD19+ ALL; Ph+ ALL who are intolerant to/failed two lines of TKI therapy, or TKI therapy is contraindicated
Treatment History	Must include the following: - Relapsed or refractory diseased after ≥ 2 lines of chemotherapy - Failed/ineligible/did not consent for SCT (Stem Cell Transplant) - Has been off PD-L1 inhibitor treatment for at least 6 weeks	Must be one of the following: - Has refractory disease - Has relapsed after allogeneic SCT - Has experienced second or later relapse - Is ineligible for allogeneic SCT due to comorbid disease, contraindications to conditioning, lack of suitable donor, prior SCT, or declined SCT as a therapeutic option
Clinical Status	Karnofsky Performance Score is ≥ 70% AND patient has a life expectancy of ≥ 12 weeks without chemotherapy	Karnofsky Performance Score is ≥ 50% AND patient is clinically stable and expected to remain so through CAR-T cell infusion date
Organ Function*	*Renal function*: serum creatinine ≤ 1.6 mg/dL, eGFR ≥ 45mL/min/1.73m^2 *Liver function:* ALT/AST ≤ 3x upper limit of normal value for age, bilirubin ≤ 2x upper limit of normal value for age	*Renal function:* serum creatinine ≤ 150.31 μmol/L *Liver function:* ALT ≤ 5x upper limit of normal for age, bilirubin < 2.0 mg/dL

	Pulmonary function: pulse oxygenation > 91% on room air *Cardiac function:* LVEF ≥ 40% per echo/MUGA *Bone marrow function:* absolute neutrophil count > 1.0 $x10^9$/L, absolute lymphocyte count > 0.1 $x10^9$/L**, absolute number of CD3+ T-cells > 150/mm^3, hemoglobin > 80 g/L, platelets ≥ 50 $x10^9$/L	*Pulmonary function:* pulse oxygenation > 91% on room air *Cardiac function:* LVSF ≥ 28% per echo, LVEF ≥ 45% per echo/MUGA *Bone marrow function:* absolute lymphocyte count > 0.1 $x10^9$/L**
Contraindications and Exclusion Criteria	Patient must NOT: - Have active CNS (Central Nervous System) involvement - Have had prior anti-CD19 therapy - Currently be pregnant - Have HIV, hepatitis C, or active/uncontrolled hepatitis B	NOTE: no formal contraindications Exclusion criteria may include: - Active CNS involvement (CNS-3 per NCCN guidelines) *** - Active uncontrolled hepatitis B, hepatitis C, or HIV infection - Active uncontrolled GVHD with need for ongoing immunosuppression - Prior treatment with genetically engineered T-cell product

* Patients with lab work outside of these findings may still be considered for CAR-T cell therapy
** Patients with ALC <0.1 $x10^9$/L can be considered for CAR T-cell therapy, but ALC MUST be > 0.1 for apheresis
*** Patients with history of CNS disease that has been effectively treated will still be eligible

Adapted from the HHS guidelines *Eligibility Criteria for Acute Lymphoblastic Leukemia (ALL)* and *Eligibility Criteria for Diffuse Large B-Cell Lymphoma (DLBCL),* located at https://www.hamiltonhealthsciences.ca/areas-of-care/cancer-care/cancer-services/stem-cell-bone-marrow-transplant/ ("Stem Cell and Cellular Therapy," n.d.)

Appendix B: Literature Review – Patient Experiences with CAR T-Cell Therapy



Article (Author, Year, Country)	Purpose	Participants and Data Source	Results	Critiques
Akinola et al., 2023, USA	Identifying appropriate inclusions for PRO data for patients post CAR T-cell therapy	Patients older than 18 who received CAR T-cell therapy for a hematological malignancy with a commercial product (n= 40); their caregivers (n=15); and clinical experts involved in the care of such patients (n=15) Qualitative telephone interviews, with systematic content analysis	- Experiences were varied with regards to side effects, but side effects impaired physical and mental health - Patients most frequently cited changes to social functioning - Clinicians referenced cognitive changes more often than patients did - Overall available PRO metrics found to be sufficient - One clinician remarked that available PRO measures do not incorporate social determinants of health which would be useful	Coding was performed both with open coding and pre-specified codes identified based on PRO metrics from other treatments – this may have introduced bias.

Balitsky et al., 2022, Canada	Assessing HrQoL for patients post CAR T-cell therapy	Patients older than 18 who received CAR-T cell therapy at the JHCC for a relapsed/refractor large B-cell lymphoma (n=26) PRO: FACT-Lym	-HrQoL worsened initially but improved at 6 and 12 months post CAR T-cell therapy	Abstract only. Of the 26 patients recruited only 15 completed a 12 month repeat questionnaire. However, this study occurred at the same location as the thesis data collection so was particularly relevant.
Bar et al., 2019, USA	Investigating long term neuropsychiatric outcomes of CAR T-cell therapy	Patients older than 18 with CLL, NHL, and ALL treated with CD19 targeted CAR T-cells who survived at least 1 year (n=40) PRO: PROMIS Scale v1.2-global health, PROMIS-29 Profile v2.1, 30 additional cognitive questions	- 19 reported at least 1 cognitive difficulty and/or depression and/or anxiety - 7 participants had poor global mental health - There was an association between acute neurotoxicity and long term cognitive difficulties - Almost half of participants experienced anxiety, depression, or cognitive difficulty	Study occurred as part of a clinical trial which is a different experience than an approved treatment.
Barata et al., 2021, USA	Investigating patient's perceived cognition at baseline vs after CAR T-cell therapy	Patients post CAR T-cell therapy (n=118) PRO: ECog (Everyday Cognition Questionnaire)	- at 90 days post CAR T-cell therapy 17% reported worsened global cognition, and at at 360 days post 28% reported worsened global cognition - No correlation to disease status	There was significant drop out throughout the study (115 participants performed baseline assessment, 86 performed 90 day assessment, and 70 performed 360 day assessment) which could be altering the results.
Bixby et al., 2023, USA	Investigating patient's perceptions of CAR T-cell therapy, experiences with inpatient administration, and perceptions on potential outpatient treatment	Patients above the age of 18 who had either received CAR T-cell therapy or discussed CAR T-cell therapy as an option with their clinician (n=18) Qualitative interviews analyzed with thematic analysis.	- Patients had high expectations for their treatment, and often described reinfusion as anticlimactic - Of participants who received treatment, only 1 began with outpatient treatment and was admitted with a fever on day +4 - All had positive experiences with their admission and expressed that while home is more comfortable hospital felt safer	Only one researcher was responsible for analyzing transcripts. Results were not stratified based on whether or not participants had actually gone on to receive CAR T-cell therapy.
Buitrago et al., 2019	Review of survivorship in adults post CAR T-cell therapy	N/A Literature review including clinical trials data	- Late effects include: cytopenias, infection, B-cell aplasia, hypogammaglobulinemia, secondary malignancies, neurologic toxicities, fatigue, infertility - Psychosocial sequelae also noted: elevated fear of recurrence, QoL changed with changes in physical functioning - CAR T-cell therapy described as a lifeline	Limited information was available on search strategy and methodology so difficult to critically appraise.

			- Noted that nursing role is critical to support transitions to survivorship care	
Cheng et al., 2021, USA	Explore patient descriptions HRQoL	Patients older than 18 with DLBCL post CAR T-cell therapy (n=18) Fous group interviews	- Patients reported impact on HRQoL across: social functioning, emotional functioning, fatigue, physical functioning, cognitive functioning, role functioning, sleep, and pain/discomfort - They reported an ongoing fear of recurrence - conditioning chemotherapy and chemotherapy in general impacted functioning - After treatment, participants reported difficulty resuming work and regular activities and often reported ongoing pain - Important to note that HRQoL was often impaired prior to CAR T-cell therapy as well	Authors provided both a definition of PRO: "any report of the status of the patient's health condition that comes directly form the patient, without interpretation of the patient' response by a clinician or anyone else" and rationale for the development of their interview guide (literature review). There was an excellent sample size, however all participants were members of the patient advisory committee which could skew results.
Dhawale et al., 2023, USA	Investigating prognostic awareness prior to treatment, and quality of life/distress during treatment with CAR T-cell therapy	Patients older than 18 receiving CAR T-cell therapy for hematological malignancies (n=100) PRO: FACT-G, HADS, PAIS, PCL	- Participants who had strong emotional coping/adaptive skills at baseline experienced better QoL and less anxiety, depression, and PTSD. - Prognostic awareness was not tied to emotional coping.	Information about prognostic understanding was very limited as it used a quantitative tool to measure understanding; and limited rationale was provided for the use of this tool.
Efficace et al., 2022, Italy	Scoping review investigating available information on PRO data for patients with hematological malignancies receiving CAR T-cell therapy	N/A Scoping review including clinical trials data.	- Overall, PRO data demonstrates improvements in symptom burden over time - Noted that there is minimal data from patients who did not respond to treatment	A detailed description of search strategy and appraisal methods was available. Findings were stratified depending on whether PRO data was collected in a clinical trial or an approved standard care.
Elsawy et al., 2021, USA	Comparison in PROs between patients with relapsed/refractory large b cell lymphoma treated with CAR T-cell vs standard of care	Participants within ZUMA-7 study; relapsed/refractory large b cell lymphoma (n=296; 165 CAR-T cell, 131 standard care) PRO: EORTC QLQ-C30, EQ-5D-5L	- QoL improves more with CAR T-cell therapy than standard care at 100 days following CAR-T cell therapy	Participants were all participating in a clinical trial, which is different than the experience of those receiving standard care.
Ernst et al., 2021, USA	Literature review on CAR T-cell therapy	N/A Literature Review	- 2/13 included studies reported data on QoL which overall suggested an improvement - comparison made between 259 baseline participants at	Limited information was available on QoL, which is less a weakness of the review than the body of literature as a whole.

			59 participants at 12/18 months	
Foster et al., 2020, Canada	iKT study focused on engaging patient partners in developing clinical trial for CAR T-cell therapy	Two patient partners with a blood cancer (n=2) Patient partners engaging in systematic review, identification of barriers/enablers to participating in clinical trial, provided insight on potential economic costs, attended team meeting to discuss results, attended information session for CAR-T cell to provide feedback, shared information on their own experience	- identified quality of life and health utility measures as important – no studies identified in systematic review included this - potential costs identified included travel, parking fees, lodging expenses, and loss of income	Patient partners had not received CAR T-cell therapy and this is a very unique therapy so their experiences may be quite different. They were also involved in the development of a clinical trial protocol rather than a standard care protocol which is quite different.
Hoogland et al., 2021, USA	Investigation of PROs in first 90 days after CAR-T cell therapy	Patients over the age of 18 treated with Yescarta for a hematological malignancy either as standard care or via a clinical trial (n=103) PRO: Medical Outcomes Study Short Form-36 version (SF-36) and PROMIS-29	- Physical functioning, pain, fatigue, and depression all seen to improve - Anxiety worsened - not associated with disease response or neurologic toxicity - most common/severe symptoms: dry mouth, decreased appetite, nausea, cough, hair loss, hand-foot syndrome, impaired concentration, impaired memory, headache, fatigue, aching muscles, diarrhea	Only 2/3 of participants completed both the baseline and 90 day assessment.
Jenei et al., 2021, Canada	To gain information on patient experiences and perspectives on CAR T-cell therapy	Patients posting on Reddit to r/cancer, r/lymphoma, r/leukemia (87 threads) Qualitative content analysis to identify key themes	- Four main themes were identified: navigating uncertainty, finding a cure, managing treatment related uncertainties, and overcoming uncertainties about access - overall very positive view of the therapy	Information was collected online with no way to verify identity of participants, and the subject pool was limited to those using Reddit which is likely not representative. There was no ability to clarify meaning or intent behind statements given nature of study. However the subject pool could have been diverse in terms of location and other demographic factors.
Jim et al., 2018, USA	To examine PROs and neurocognitive functioning in first 90 days after CAR T-cell therapy	Adult patients treated with Yescarta for DLBCL, FL, MLBCL, or other (n=29) PRO-CTCAE, SF-36 QOL measure, RBANS	- symptoms generally peaked at day 14 and returned to baseline by day 90 - most common at day 14: decreased appetite, fatigue, dry mouth - most common at day 90: fatigue, insomnia, joint pain	Abstract only. This was a very small sample of patients, and only 11 patients completed one of the assessments (RBANS).

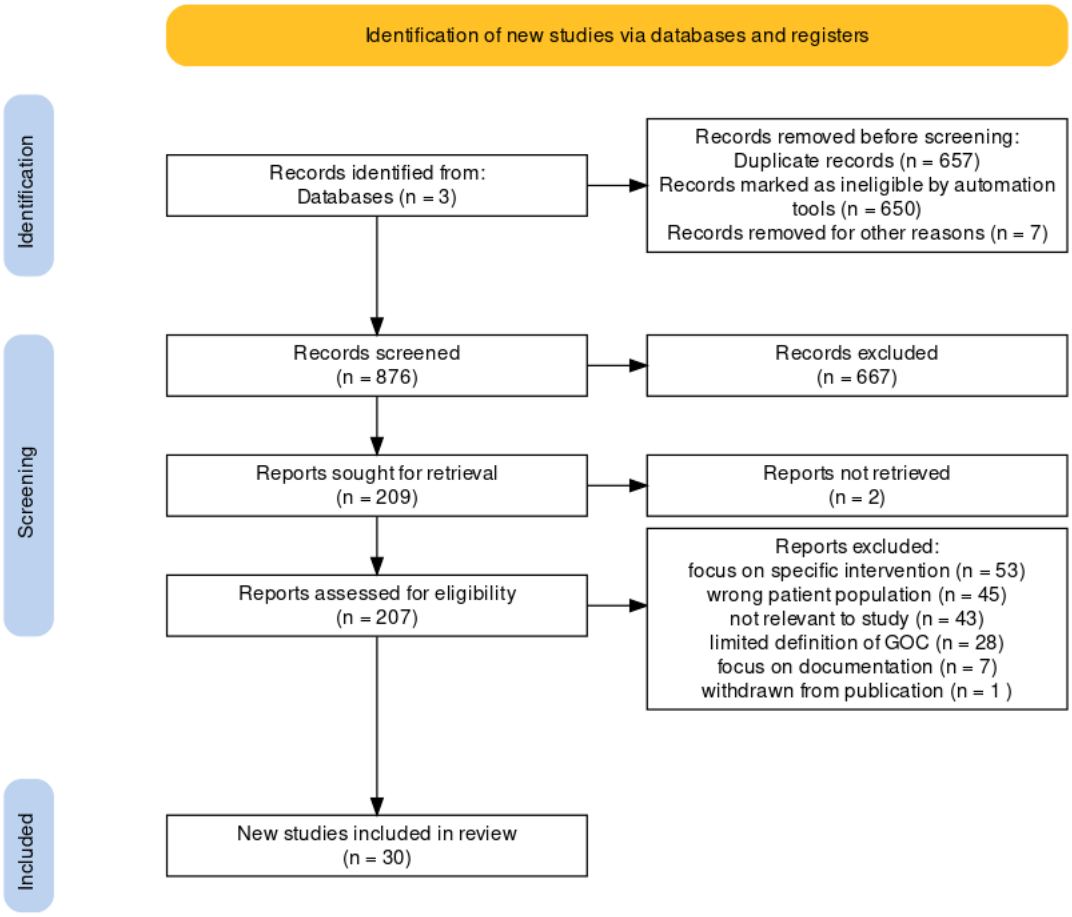
Johnson et al., 2023, USA	To examine QOL, psychological distress, and physical symptoms using PROs post CAR T-cell therapy	Adult patients treated with CAR T-cell therapy for a relapsed/refractor hematological malignancy (n=103) PRO: FACT-G, HADS, PHQ-9, PCL, modified ESAS	- QOL and depressive symptoms worsened from baseline after 1 week, but improved from baseline at 1, 3, and 6 months - Anxiety/PTSD symptoms improved from baseline at one month post treatment, but remained clinically significant at 1, 3, and 6 months -	Physical symptoms were not stratified into the specific symptoms, but only as mild, moderate, or severe. This data was difficult to interpret as a result.
Kamal et al., 2021, USA	To understand the use and utility of PROs in patients receiving CAR T-cell therapy	N/A Systematic review; 3 articles included in total covering 206 patients; also included clinical trial data	- main areas investigated were cognitive impairment, emotional wellbeing, QoL, and symptom burden - did not report on overall findings as PROs not yet validated - Remarks on frequent issues with compliance completing PRO assessments after therapy	Search strategy and critical appraisal methods were clearly described.
Kersten et al., 2019, Netherlands	Understanding the development of neurologic toxicities post CAR T-cell therapy	Two patients: a 71 yr old male and a 49 year old male who both received CAR T-cell therapy Case studies	- Participants reported this to be a frustrating and frightening experience - Family reported noticing things the participant did not	Formal interviews were not performed so only minimal patient experience data was collected.
Knight et al., 2022, USA	To investigate PROs and neurotoxicity in patients receiving CAR T-cell as part of a clinical trial	Patients over the age of 18 receiving CAR T-cell therapy as part of a clinical trial for relapsed/refractor B-cell non-Hodgkin's lymphoma, chronic lymphocytic leukemia, or small lymphocytic lymphoma (n=15) PRO: IDAS, FSI-fatigue, PSQI-sleep, BPI-pain	- There was a statistically significant rise in depressive symptoms at day 14 post treatment compared to baseline, and a statistically significant decrease in depressive symptoms at day 90 post treatment compared to baseline - There were no statistically significant changes in pain, sleep, or fatigue	This was a very small sample size, and took place as part of a clinical trial which is a different experience than standard care treatments.
Maillet et al., 2021, France	To investigate neurological and cognitive toxicities 6-12 months after treatment with CAR T-cell therapy	Patients older than the age of 18 treated with Yescarta or Kymriah for relapsed lymphoma; patients must not have had worsening tumour size at 6-12 months (n=27) PRO: HADS, QMRP; also had clinician-graded assessments	- 48% of patients had clinically significant anxiety at baseline, with only 30% reporting this at the time of follow up - Self-reported depressive symptoms decreased from 11% to 7% - Self-reported memory improved from baseline overall following treatment.	There was a small sample size for this study, and it only assessed surviving patients without tumor progression which could have skewed results. Limited information was provided on PRO data, and there was a long interval between baseline and follow-up assessments which missed the acute post-reinfusion period.
Mao et al., 2023, China	To gather information on patient experiences with CAR T-cell therapy for treatment of relapsed or refractory DLBCL	Patients older than the age of 18 with relapsed/refractor DLBCL within 2 years of receiving CAR T-cell therapy (n=21)	- Four themes were identified: physiological distress, functional impacts, psychological impact, and need for support	Interview guide was open-ended and asked appropriate questions. This study was originally performed in

		Qualitative interviews, analyzed with content analysis	- a number of symptoms were identified, but most common were fatigue, anorexia, diaphoresis, pain, vomiting, dizziness, and dry mouth; most prolonged were fatigue, rash, and cognitive changes - functional impacts included changes to daily life and social life - referenced viewing CAR T-cell as a last hope, with either very negative or very positive expectations - participants referenced needing social support, adequate information about treatment, and having their spiritual needs met	Mandarin and translated, so some meaning may have been lost.
Matthews et al., 2019, USA	Understand patient and caregiver needs over the process of receiving CAR T-cell therapy	Patient and caregiver pairs receiving CAR T-cell therapy at study site (n dyads = 21) Qualitative interviewing, patient observation, and "low fidelity experimentation"	- Participants were unprepared for multiple aspects of treatment (clinical encounters, emotions, toxicities) - The volume of information provided was - "consumer like expectations" were remarked upon - Patients were already exhausted from prior treatments - Reported it was difficult not being able to connect with others who had gone through same treatment	This was an abstract only and no information was provided on how the themes were developed.
Maziarz et al.	To evaluate HRQoL at a median follow-up length of 19 months after infusion	Patients over the age of 18 with relapsed/refractor DLBCL involved in JULIET clinical trial (n=108) PRO: FACT-Lym, SF-36	- QoL improved in those who responded to treatment - limited response from those with disease progression	This was one of the formative clinical trials for CAR T-cell therapy and is heavily referenced in other studies. However, of 108 participants who completed baseline assessments, only 30 completed the 12 month follow-up, and 21 completed the 18 month follow-up.
Patrick et al., 2021, USA	To evaluate the effect of CAR T-cell therapy on HRQoL	Patients involved in the TRANSCEND clinical trial of CAR T-cell for large B cell lymphoma (n=181 for EORTC QLQ-C30) (n=86 for EQ-5D-5L) PRO: EORTC QLQ-C30, EQ-5D-5L	- global health status improved from 1-18 months - physical functioning significantly improved although initial deterioration at 1 month and subsequent improvements NOT clinically meaningful - fatigue improved from baseline - pain scores initially increased, worsened, and then improved again	This took place as part of a clinical trial which is different than the experience of standard care.

			- also saw improvements in role and emotional functioning	
Ruark et al., 2020, USA	To investigate long-term neuropsychiatric adverse effects of CAR T-cell therapy	Patients with CLL, NHL, and ALL 1-5 years after treatment with CAR T-cell therapy (n=40) PRO: PROMIS Scale v1.2 Global Health, PROMIS-29 Profile v2.1 as well as 30 questions on cognitive functioning	- 37.5% reported one or more cognitive difficulty - overall not many clinically meaningful differences - subset of patients (30%) with clinically meaningful anxiety/depression	The time point for data collection post treatment varied between 1-5 years, making it difficult to interpret.
Sidana et al., 2019, USA	To compare HrQoL and symptom burden of CAR T-cell therapy to autologous and allogeneic stem cell transplantation	Patients with hematological malignancies treated with CAR T-cell (n=20), auto SCT (n=37) and allo SCT (n=36) FACT-G, PRO-CTCAE, NeuroQOLv2	- baseline scores similar across groups - overall HrQoL did not worsen as signficiantly with CAR T-cell therapy - most common PRO-AEs for CAR T-cell were decreased appetitie, diarrhea, and fatigue	This was an abstract only.
Stenson et al., 2021, England	To investigate patient and caregiver experience with CAR T-cell therapy to identify areas for improvement	Patients receiving CAR-T cell therapy at study location (n=10) and their caregivers (n=4) Qualitative interviews	- CAR T-cell nurse specialist role helpful as patient navigator - Acute side effects included: fatigue, poor appetite/weight loss, problems with memory/cognition - patients and caregivers felt fairly prepared for acute side effects but not long term - uncertainty caused a lot of disruption to personal lives - found it difficult to plan for future	This was an abstract only.
Wang et al., 2021, USA	To quantify patients' perspectives of symptom burden and functional status in first year after CAR T-cell therapy after experiencing grade 2-4 toxicities	Patients receiving CAR T-cell therapy as standard of care at MD Anderson in 2019; within 12 months of receiving therapy (n=60) PRO: MDASI, PROMIS-29, EQ5D, HRQoL scale, additional 22 symptom items related to CAR T-cell therapy	- most severe symptoms within first year were fatigue related - symptom severity for all cases was highest within first 90 days - higher grade CRS and ICANS associated with higher symptom burden even past day 30	There was no comparison to baseline metrics for this study.
Whisenant et al., 2019, USA	To identify symptoms experienced by patients receiving CAR T-cell therapy and to determine content domain for a PRO to measure symptom burden of CAR T-cell therapy	Patients receiving CAR T-cell therapy for a B cell lymphoma at MDACC (n=21) Qualitative interviews, analyzed via content analysis	- symptoms experienced by greater than 20% included pain, fatigue, lack of appetite, headache, chills, and confusion - described symptoms bad enough to impact ADLs and require assistance - symptoms interfered with daily activities, walking, relationship with others, mood, work, and enjoyment of life	This was a methodologically strong study, with a large sample size. It was also one of the only studies to focus heavily on the role of nursing.

			- notes that oncology nurses should have knowledge of symptoms expected - interviewed at varied time points within 12 months of therapy - mentions role of oncology nurse in symptom related communication and management	

Appendix C – Literature Review – GOC



Article (Author, Year, Country)	Purpose	Participants and Data Source	Results	Critiques
Apostol et al., 2015, USA	Pilot cohort study investigating the use of GOC meetings in patients with advanced/refractory cancer at risk for critical care interventions, and association of GOC meetings with patient outcomes	Patients with metastatic solid tumours or relapsed/refractory hematological malignancies admitted to hospital and requiring supplemental oxygen and/or cardiac monitoring (n=86) Survey for patient/surrogate regarding meeting, medical record review	-34/86 participants had a reported GOC meeting - most important goal rated by patients and discussed at meeting was maximizing survival time - patients thought meetings met their needs moderately well - focused primarily on medical management and use of all available cancer treatments	The marker of being at risk for critical care interventions is a stronger indicator for end of life than treatment status.2024-10-07 10:29:00 AM
Bernacki et al., 2015, USA	To identify life priorities important to	Patients with advanced cancer at risk of death within a year	- 97.5% of participants rates these as important: being at home, physically	This article was an abstract only, and no information

	patients with advanced cancer	(n=174) Life priorities survey	comfortable, mentally aware, spiritually/emotionally at peace, independent, having medical decisions respected, not being a burden, loving family - most frequently ranked in top 3 were: mental awareness, comfort, and being at home - living as long as possible only in top 3 in 23% of patients	was available on what the life priorities survey asked
Boucher, 2021, USA	To provide recommendations for improving the ability of oncology nurses to assist in ACP and creation of GOC	N/A	- GOC should include cancer diagnosis, prognosis, treatments, and identification of patient goals and wishes for care - Nurses are essential to GOC conversations	Article was providing recommendations only, not a study.
Brazee et al., 2021, USA	To explore prevalence, pattern, and likelihood of having a GOC discussion in women with metastatic breast cancer across different characteristics	Female patients with MBC who died between November 2016-November 2019 treated at study centre in Pennsylvania (n=167) Chart review looking at documented GOC discussions	- Majority of patients did have a GOC discussion - in 45% of participants these conversations occurred 3 months or less prior to death - differences in race – black women had their first GOC conversations closer to death than white women	This study used documentation to count GOC conversations, but conversations may have occurred without documentation and therefore missed. There was no mention of quality or breadth of discussions.
Chen et al., 2022, USA	To explore patient understanding and what they prefer for GOC communication around palliative radiotherapy	Patients over the age of 18 receiving palliative radiotherapy for lung or bone mets who were able to speak in English (n=31) Semi-structured interviews	- Patients often misunderstood treatment intent - Patients were facing a lot of uncertainty around their prognosis - Conceptualized GOC as to restore or to cure	The interview guide was available for review and was comprehensive. There was a thorough description of the coding process.
Dillon et al., 2021, USA	To investigate how patients with cancer and their clinicians (oncology and palliative care) discuss GOC	Patients with advanced cancer (n=25) and care team members (n=25) In depth interviews, demographic questionnaires; grounded theory approach to analysis	- Major themes of GOC conversations: conversations about treatment goals, prognosis, stopping/opting out of treatment, advance care planning, transitioning to hospice, end-of-life planning - barriers to GOC conversations were timing, training, and receptivity of patients and families - Goal-concordant care requires shared decision making	This was a well conducted study, with an appropriate sample size and strong methodologically.
Douglas et al., 2019, USA	To describe and identify predictors for patient-physician discordance surrounding GOC	Patients with metastatic lung, GI or pancreatic cancer (n=378) and oncologists (n=11) who cared for these same patients 100-point VAS with 0 = quality of life, 100 = survival	- about ¼ dyads had a discordance - oncologists tended more towards survival than their patients	Using the VAS quantified GOC which does not give an accurate picture.
Dulaney et al., 2017, USA	Review of definitions of health across cancer trajectory; intended to help facilitate effective communication	Review focused on all aspects of cancer trajectory; information extracted from section on advanced cancer patients	- patients often more optimistic than providers - clear communication of prognosis important to allow for patients to set goals	This was a review and not a study, and unclear how strong the findings are.

	between HCP and patients		- overall well-being requires realistic prognosis to guide care - fear of causing a loss of hope/distress can prevent open discussions around prognosis and GOC	
Elias and Odejide, 2019, USA	Overview of treatment of the older adult patient with immunotherapy, provides overview of recommendations for discussing GOC	Patients eligible for immunotherapy in the setting of advanced cancer; focus on older adults	- GOC discussions improve care; and are not associated with increased depression, anxiety, or worry - difficult to predict prognosis with immunotherapy	This was not an actual study, so unclear if generalizable.
Emiloju et al., 2020, USA	Examination of association of timing of GOC, length of time to readmission to hospital	Patients with stage IV solid tumours per ICD-10, admitted to study centre between August 2017 and July 2018; excluded newly diagnosed metastases (n=241) Retrospective chart review	- less than 50% of patients had GOC addressed during their admission	Study used documentation as a marker for GOC conversation, and did not provide information about the content of the discussion.
Frey et al., 2014, USA	Survey based study to investigate whether ovarian cancer survivors' acceptance of treatment side effects changed with GOC changes	Women with ovarian cancer (n=328) Online survey of 30 questions asking patients about acceptability of side effects based on goal of treatment (cure vs stable disease vs remission)	- women listed most important goal of treatment as overall survival - when asked what was most meaningful, common responses were amount of time alive, ability to engage in ADLs and having tolerable side effects - When goal of treatment is cure, women report being more able to tolerate side effects than when the goal is stable disease - generally patients hope for cure early in diagnosis but later goals shift to maintaining QoL	This is a very specific patient population, and use of an online survey prevented any clarifying questions regarding responses.
Frey et al., 2017, USA	Qualitative study to explore differences between patients and providers in terms of treatment expectations and GOC	Women with ovarian cancer from specified support organization (n=22) Focus group	- while 100% of participants felt GOC should be addressed in treatment decisions, only 68% reported being able to bring this up with their physician, and only 14% said these occurred prior to initial treatment regime - felt GOC discussions should occur frequently, that they were often rushed, and that they were not communicated well between providers	Very specific patient population, and the use of a focus group could have made some uncomfortable. It also would have allowed collaboration however.
George et al, 2020, USA	Survey study to investigate how well patients with advanced cancer understand their prognosis and the intent of any treatments being received	Patients with advanced cancers refractory to at least one line of chemotherapy (n=334) Previously completed survey	- high percentage had inaccurate understanding of treatment intent - people receiving treatment were more likely to have decreased prognostic awareness - people not getting any treatment better understood their prognosis	Not enough information was provided on whether or not patients were receiving potentially curative treatments.

Gruß and McMullan, 2019, USA	Qualitative examination of SDM process in a multidisciplinary breast cancer clinic to understand how sharing information is balanced with eliciting patient goals and values	Patients with breast cancer who are considered choice between mastectomy and lumpectomy (n=11) and providers (n=6) Semi-structured interviews and ethnographic observation of clinic visits	- clinicians place heavy emphasis on sharing biomedical information such as risk of recurrence and statistical information and given 30 minute time slot, observed to be difficult to both share all needed information and elicit patient goals and values - patients must be able to process lots in info, embrace swift decision making, to formulate their values, and to prioritize surgical choice over other goals for meeting	The use of observation strengthened results.
Hong et al., 2021, USA	Survey study based at understanding barriers and dynamics of GOC discussions by medical vs radiation oncologists	Medical (n=153) and radiation oncologists (n=76) Online survey	- common reasons for not initiating GOC discussion: has already been done by another clinician, patient has good/uncertain prognosis, limited comfort or training	Most of the results were focused on practice differences between medical and radiation oncologists, so not all relevant.
Kim et al., 2015, USA	Survey study investigating patient perceptions of the chance of cure following surgical resection for lung or colorectal cancer	Adult patients who underwent cancer-directed surgery for lung or colorectal cancer (n=3954) Online survey	- even with stage IV disease, 57-80% of patients believed that their cancer might be cured after surgery - only 13-40% of patients reported that their decision making was patient centred as opposed to physician centred	The use of an online survey does not allow for clarifying questions.
Kuhne et al., 2021, USA	Scoping review intended to better understand prognostic awareness.	24 articles focused on prognostic awareness, analyzed via content analysis	- Conceptualized prognostic awareness as an awareness of disease status and associated chance of cure and predicted lifespan - Reports mental health is negatively correlated to prognostic awareness	There was good description of search strategy and available for review was information on appraisal. It is unclear why they have drawn a conclusion about mental health being negatively impacted by prognostic awareness, as multiple studies have found the opposite to be true.
Lennes et al., 2013, USA	Survey study to investigate concordance in patient and provider understanding of GOC at time of starting chemotherapy	Adult patients newly diagnosed with a solid malignancy receiving their first IV chemotherapy at Massachusetts General Hospital (n=125) Survey and medical chart review data (intent of treatment entered in chemotherapy orders as adjuvant, neoadjuvant, curative intent OR as palliative, metastatic intent	- 24% of patients understood the intent of their chemotherapy differently than their physicians - in patients who misunderstood the treatment intent, 66% were more optimistic than their physicians	Using the treatment intent as entered for the chemotherapy orders may not have captured the true intent, and as it was a survey it is hard to know whether intent was discussed.
Littell et al., 2019, USA	Literature review providing overview of why and how to discuss GOC with patients with gynecological malignancies	N/A	- five barriers exist to discussing GoC: inadequate preparation, inadequate time, fear of destroying patient's hope, emotional discomfort of provider, uncertainty in prognostication	There was no description of the search strategy used.
Myers et al., 2018, USA	Systematic review outlining different tools for performing	N/A	- more tools exist for ACP than GOC	This was not a study, and was not clear regarding

	and documenting ACP and GOC discussions		- GOC is a relatively new term in healthcare	exactly what patient population was referenced.
Naik et al., 2016, USA	Qualitative study investigating GOC of older, multimorbid adults recently diagnosed with cancer	Veteran adults with multiple comorbidities diagnosed with a head and neck, colorectal, gastric, or esophageal cancer and completed treatment within last 12 months (n=146) Interviews with two major questions asking what current values were important after treatment, and what GOC would be if cancer were to recur	- goals noted as important were: self-sufficiency, life-enjoyment, connectedness and legacy, balancing quality and length of life, and engagement in care	The results of this study may be less generalizable as it was limited to veterans. However, it was a large sample size with open ended interview questions allowing for in-depth responses.
Pintova et al., 2020, USA	To describe the length of time it takes to perform a GOC discussion	Solid-tumour oncologists who see at least 2 new patients/month with advanced cancer and a prognosis of less than or equal to 2 years (n=22) Videotaped interviews of GOC discussions – focused on length of time	- commonly cited GOC: to be cured, to live longer, to improve or maintain QOL, to be comfortable, to accomplish a particular life goal, to provide support for family and caregivers - overall median length of time was 15 minutes, typically an extra 5 minutes to discuss evidence of progression on imaging	Given that interviews were recorded, there was no question of whether length of time was recalled accurately.
Pompa et al., 2016, USA	Questionnaire study investigating patients' comprehension of their disease, treatment options, and goals of therapy with advanced cancer	Patients diagnosed with metastatic cancer with the option of palliative or life-extending chemotherapy (n=52) 34 item questionnaire about understanding of cancer, etc.	- 30% felt they knew not enough about their diagnosis and 33% felt they knew very little about their prognosis	This study was published as an abstract only.
Roldan et al., 2020, USA	Qualitative study investigating experiences and perceptions of patients with advanced metastatic cancer receiving palliative radiation	Patients with advanced metastatic cancer receiving their first cycle of palliative radiation (n=17) Semi structured interviews, content analysis	- 53% linked palliative rads with improving QOL - 35% thought RT would completely cure them - only 53% reported having discussed prognosis with their clinician	This study was published as an abstract only.
Schulman-Green et al., 2018a *Facilitators and Barriers to Oncologists' Conduct of GOC Conversations*, USA	Qualitative interpretive descriptive study looking at barriers to GOC conversations as reported by oncologists	Oncologists seeing at least 2 new patients with advanced solid tumour malignancies per month (n=21) Individual semi-structured interviews	- Facilitators to GOC conversations = poor functional status, high health literacy, family understanding and acceptance, high degree of practice experience, supportive practice environment - Barriers: patient demographic and clinical characteristics, patient religion and culture, patient denial, lack of time	This was a methodologically strong study.
Schulman-Green et al., 2018b *Oncologists' and Patients' Perceptions of Initial,*	Interpretive descriptive study looking at perceptions of timing and content of GOC conversations across both patients and providers	Oncologists seeing at least 2 new patients with advanced solid tumour malignancies per month (n=21) and patients with advanced chancer having	- both patients and oncologists identified three distinct time frames – initial, intermediate, and final - initial good to ensure on same page, set shared expectations; both patients	This was a methodologically strong study.

Intermediate, and Final GOC Conversations, USA		received one or more lines of therapy (n=39) Individual interviews, covering experiences with/preferences for GOC conversations, topics whey felt should be a part of the conversations, and topics which should be discussed	and physicians think this should occur early on but there are different perceptions on how much information - intermediate seen as occurring when there is progression or change; focuses on changes and side effects as well as prognosis - final conversation occurs near end of care trajectory, often patients wanted to delay this until unavoidable or when "they had enough"	
Secunda et al., 2019, USA	Systematic review and QDA to characterize use and meaning of GOC within healthcare literature	All publications with "GOC" in title/abstract	- often term not used to convey specific patient values - first used in 1987 and has rapidly increased over time - GOC often taken for granted – the default/implicit GOC seems to be cure/survival	This was a very broad search, covering numerous articles.
Tulsky et al., 2021, USA	Survey study investigating agreement about advanced cancer treatment decisions among patients, clinicians, and caregivers	Triads of patients with metastatic GI cancer, metastatic thoracic cancer, or relapsed/refractory hematological malignancies and their clinicians/caregivers, who had recently made a treatment decision (n triads = 70) Survey questions assessing understanding of primary treatment goal (cure, live longer, improve QOL), impact of caregiver on decision, as well as decisional conflict scale, satisfaction with decision scale, and decision regret scale	- 28/70 triads had full agreement on goal of treatment - in triads that did not agree patient more likely to be more optimistic than clinician - caregivers influence is underestimated by clinicians	Using a survey would not have allowed for clarifying questions.
Winner et al., 2017, USA	Literature review investigating patient-surgeon communication prior to cancer surgeries	Articles with terms of "surgery", "preoperative", "discussion, "treatment goals", "patient perceptions", and "cure"	- discussions pre-operatively rarely discuss GOC or possibility of cure - tend to lean towards offering surgery or treatment (both patients and clinicians) - use of word treat does not mean cure, but some believe it does - clinicians may try and avoid impacting hope - range of options including no treatment are rarely discussed	There was not information provided on the appraisal process for included articles.
Wittenberg et al, 2016, USA	Survey study investigating how nurses feel their role is involved in GOC conversations	Nurses attending an end-of-life education consortium (n=193) Survey developed by nurses with open responses; use of case studies	- nurses see a need for earlier GOC conversations - nurses often left in the room after a physician shares a poor prognosis - patients often ask nurses about their treatment decisions once physicians have left	Survey structure was unclear.

Appendix D: HiREB Approval

Hamilton Integrated Research Ethics Board

Sep-30-2022

Project Number: 14451

Project Title: Understanding Goals of Care for Patients Undergoing Chimeric Antigen Receptor T-Cell Therapy: A Qualitative Descriptive Study

Student Principal Investigator:

Local Principal Investigator: Dr. Denise Bryant-Lukosius

We have completed our review of your study and are pleased to issue our final approval. You may now begin your study.

The following documents have been approved on both ethical and scientific grounds:

Document Name	Document Date	Document Version
14451 CAR-GOC Demographics & Clinical Information V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Master File V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Budget V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Consent Form V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Interview Guide Review Package V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Participant Tracking V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Resources for Emotional Distress V1 August 15	Aug-15-2022	1
14451 CAR-GOC Clinician Referral Instructions V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Research Protocol V2 September 27 CLEAN	Sep-27-2022	2
14451 CAR-GOC Recruitment Poster V2 September 27 CLEAN	Sep-27-2022	2
14451 CAR-GOC Script for Contact, Consent, and Scheduling an Interview V2 September 27 CLEAN	Sep-27-2022	2
14451 CAR-GOC Interview Guide V2 September 27 CLEAN	Sep-27-2022	2
14451 CAR-GOC Letter of Information V2 September 27 CLEAN	Sep-27-2022	2

The following documents have been acknowledged:

Document Name	Document Date	Document Version
Denise Bryant-Lukosius TCPS Cert	Jul-29-2021	1
14451 CAR-GOC Response to Provisional Approval V1 Sept 27	Sep-27-2022	1
14451 CAR-GOC CCO Eligibility V1 Aug 15	Aug-15-2022	1
14451 CAR-GOC Confidentiality Agreement V1 Aug 15	Aug-15-2022	1

In light of the current COVID-19 pandemic, while HiREB has reviewed and approved this application, the research must be conducted in accordance with institutional and/or public health requirements.

Any changes to this study must be submitted with an Amendment Request Form before they can be implemented.

This approval is effective for 12 months from the date of this letter. Upon completion of your study please submit a **Study Completion Form**.

If you require more time to complete your study, you must request an extension in writing before this approval expires. Please submit an **Annual Review Form** with your request.

PLEASE QUOTE THE ABOVE REFERENCED PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Good luck with your research,

Kristina Trim, PhD, RSW
Chair, HiREB Student Research Committee
McMaster University

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare Hamilton, Research St. Joseph's-Hamilton, the Faculty of Health Sciences at McMaster University, and Niagara Health and operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practice Guideline (ICH GCP); Part C Division 5 of the Food and Drug Regulations of Health Canada, Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. For studies conducted at St. Joseph's Healthcare Hamilton, HiREB complies with the Health Ethics Guide of the Catholic Alliance of Canada.

Appendix E: Clinician Referral Instructions

CLINICIAN REFERRAL INSTRUCTIONS (MD, RN, NP, SW)

There will be three primary steps involved for clinicians assisting in this process:

(1) Identify potential participants
(2) Inform potential participants about the research study
(3) Provide the student researcher with the potential participant's contact information

Detailed instructions are provided below with clear guidelines and scripts for each step involved. We have tried to minimize how much we are asking you to do, as we know you are already extremely busy. We thank you in advance for your assistance with this project.

(1) IDENTIFYING POTENTIAL PARTICIPANTS

We plan to recruit between 8-10 patients to participate in this study. They will participate in a scheduled 1-hour interview by Zoom or telephone, between day 30-100 post reinfusion.

Eligible patients must meet the following criteria:

i. They meet CCO (Cancer Care Ontario) criteria for CAR T-cell therapy.
ii. They are less than 100 days out from their reinfusion.
iii. They can communicate verbally in English.
iv. They are cognitively able to consent to participation.
v. They have the mental and physical capacity to participate in a one-hour interview.

Patients may be recruited any time during their treatment up to and including day 100 post reinfusion. We ask that if you identify eligible patients, let them know about the study and ask if they would be willing to be contacted by the student researcher to learn more.

(2) INFORMING POTENTIAL PARTICIPANTS ABOUT THE STUDY

To minimize your time, a brief script to guide your conversation with patients is found below. You will be provided with copies of the information letter about the study to give to patients. Extra copies are at the reception and main desks in ODS/Clinic F.

(3) PROVIDING STUDENT RESEARCHER WITH CONTACT INFORMATION

If patients have agreed to sharing their contact information, please email to Danielle Jones at jonesdani@hhsc.ca.

SCRIPT FOR INFORMING PATIENT ABOUT RESEARCH STUDY

NOTE: Opportune times to discuss this study with patients could be following an initial family meeting, at a routine follow-up appointment within 100 days of reinfusion, or during their leukapheresis.

I wanted to let you know about a research study which will be starting shortly that is looking for patients who have received CAR T-cell therapy to share some information about their experience, is this something you might be interested in?

[NO] Do not discuss further.

[MAYBE/NEEDS MORE INFO] We have a letter of information I can give to you with more information about the study. The letter of information has contact information for the student researcher if you would like to think about it further. If you are comfortable, would you agree to me passing on your contact information to the student researcher? You may also contact them directly by phone or email.

[YES] Great! We have been asked to provide the student researcher with your first name and either your phone or email so that she can contact you to discuss further – would phone or email be preferred for you? *Collect phone number or email.* You can expect a phone call or email within the next 2-3 days to talk more about the study – if you have a chance, please look over the letter of information before then.

Appendix F: Letter of Information

LETTER OF INFORMATION

Understanding GOC for Patients Undergoing Chimeric Antigen Receptor T-Cell Therapy: A Qualitative Descriptive Study

Investigators:

Local Principal Investigator:
Dr. Denise Bryant-Lukosius, RN, PhD

School of Nursing
McMaster University
Hamilton, ON, Canada
(905) 525-9140 ext. 22408
Email: bryantl@mcmaster.ca

Student Investigator:
Danielle Jones, RN, CON(C), MScN 2023

School of Nursing
McMaster University
Hamilton, ON, Canada
(905) 387-9495 ext. 64127
Email: jonesdani@hhsc.ca

Purpose of the Study

You are being invited to participate in a study looking at the experiences of patients who have received Chimeric Antigen Receptor (CAR) T-cell therapy at the Juravinski Hospital and Cancer Centre (JHCC).

We are completing this study to gain a better understanding of the patient expectations and experiences in receiving CAR T-cell therapy. This study is being completed as part of a master's thesis within the School of Nursing at McMaster University.

Procedures Involved in the Research

We expect that around 8-10 patients will participate in this study. If you decide to participate in this study, you will be asked to complete a one-on-one interview with the student researcher. During the interview you will be asked questions about your decision to receive CAR T-cell therapy and what it was like for you to receive this treatment at the JHCC. The interview will take approximately 45 to 60 minutes to complete and will be done online via Zoom or by telephone.

Zoom is an externally hosted cloud-based service. A link to their privacy policy is available https://explore.zoom.us/en/privacy/. While the Hamilton Integrated Research Ethics Board has approved using the platform to collect data for this study, there is a small risk of a privacy breach

for data collected on external servers. Please note that if you would prefer to have a Zoom interview, you would not need to have your camera on unless you choose to do so.

With your permission, the interview will be audio-recorded (at no point will there be any video recordings, even for Zoom interviews where you may or may not have your camera turned on) and then transcribed into a written document that can be analyzed by the researcher. During the interview we will also collect some personal information about you, such as your gender, education, marital status, and other aspects of your social situation. To better understand the care you received, information about your diagnosis and treatment will be collected from your medical record. We will only review the portion of your medical records relating to your CAR T-cell therapy treatment.

Potential Harms, Risks or Discomforts:

The risks involved in participating in this study are minimal. You may feel uncomfortable with the interview process or find it stressful to recall your experiences in having CAR T-cell therapy.

You do not need to answer questions that you do not want to answer or that make you feel uncomfortable, and we can take a break at any point during the interviews. You can withdraw (stop taking part) at any time.

Potential Benefits

The research will not benefit you directly. We hope to learn more about how people are feeling about their CAR T-cell therapy, why they chose this treatment, and if their experiences in receiving this treatment met their expectations. The results could also help to identify new or improved ways to provide care during CAR T-cell therapy.

Payment or Reimbursement

In appreciation of the time you have invested in our study, at the end of the interview you will be given a $25 electronic gift card to Tim Hortons.

Confidentiality

Your participation in this study is confidential. The only people who will be aware of your participation in this study are the student researcher and her research supervisor. We will not share your name or any information that would allow you to be identified. However, we are often identifiable through the stories we tell. Since the group of patients who receive CAR T-cell therapy at the JHCC is small, others may be able to identify you based on references you make. Please keep this in mind in deciding what to tell us.

The results of this study may be published in a journal or presented at professional conferences. Direct quotations may be included in publications of this study and in the student researcher's thesis, but any potentially identifying information within these quotations will be removed.

Your name and contact information will be the only identifying information collected by the student researcher and will be stored in a password-protected master file located on a secure server. You will be assigned a unique participant ID and all other information will be linked

directly to this ID rather than to any of your identifying information. Identifiable data will be deleted at study completion, and de-identified data will be retained for 10 years.

Information kept on a computer will be protected by a password and stored on a secure server. Audio recordings stored on the digital recorder will be kept in a locked cabinet in a secure location (the research supervisor's office at the JCC), to which only the student researcher has a key. Prior to discussing any study information or findings with the research committee, we will ensure that any information that could identify you or other individuals has been removed.

The interviews will take place in a private location using headphones to ensure that no one can overhear your responses. Audio recordings will be converted into written documents by a member of the team who has signed a confidentiality agreement. The student researcher will delete audio recordings once transcription is complete.

Participation and Withdrawal

Your participation in this study is voluntary. By participating in this study you do not waive any rights to which you may be entitled under the law. It is your choice to be part of the study or not. If you decide to be part of the study, you can decide to stop (withdraw) at any time, even after verbally consenting to participate or part-way through the study. To withdraw from the study, simply call or email the student researcher.

If you decide to withdraw, there will be no consequences to you. Information provided up to the point where you withdraw will be kept unless you request that it be removed. If you do not want to answer some of the questions you do not have to, but you can still be in the study. Your decision whether or not to be part of the study will not affect your continuing access to services at the JHCC.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board, affiliated sites, or other regulatory authorities may consult your research data. By consenting to participate in this study, you authorize such access.

Information about the Study Results

We expect to have this study completed by approximately March 2023. If you would like a summary of the results, please let me know how you would like it sent to you.

Questions about the Study

If you have questions or need more information about the study itself, please contact me at jonesdani@hhsc.ca. I am happy to answer any questions you may have about the study. You may also contact my research supervisor, Dr. Denise Bryant-Lukosius, at bryantl@mcmaster.ca.

Appendix G: Recruitment Poster

HAVE YOU RECEIVED OR ARE YOU PREPARING TO RECEIVE CAR T-CELL THERAPY AT THE JURAVINSKI HOSPITAL AND CANCER CENTRE?

We are currently recruiting participants for a research study looking at patient's experiences with receiving Chimeric Antigen Receptor (CAR) T-Cell therapy at the Juravinski Hospital and Cancer Centre (JHCC).

Who is eligible?
All patients who will receive CAR T-cell therapy or who have received CAR T-cell therapy within the last 100 days

What does it involve?
The study involves a one-on-one interview with a researcher to ask about your experiences in receiving CAR T-cell therapy. It will take about 45-60 minutes and will occur by telephone or online via Zoom.

Participation in the study is **completely voluntary and confidential.**

Why should I participate?
By participating in this study, you will help us to better understand patient experiences and ways to improve care for future patients who receive CAR T-cell therapy at the JHCC. Eligible participants will receive a $25 electronic giftcard to Tim Hortons.

If you are interested in participating, please take a letter of information and contact us at:

PHONE: (905) 387-9495 ext. 64127

or

EMAIL: jonesdani@hhsc.ca

This study has been reviewed by the Hamilton Integrated Research Ethics Board under Project 14451, Version 2, September 18, 2022.

PHONE: (905) 387-9495 ext. 64127 EMAIL: jonesdani@hhsc.ca

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PHONE: (905) 387-9495 ext. 64127 EMAIL: jonesdani@hhsc.ca

Appendix H: Patient Tracking Excel File

Participant ID :
Verbal Consent Obtained (Y/N) :
Verbal Consent – Researcher :
Verbal Consent – Date :
Interview Scheduled (Y/N) :
Interview Date :
Interview Modality :
Chart Review Complete (Y/N)
Interview Transcribed (Y/N)
Gift Card Sent (Y/N)

Appendix I : Consent Documentation Form

CONSENT STATEMENT

The participant has read the consent form, had an opportunity to ask question and those questions have been answered. The participant verbally agreed to participation in the study. The participant's verbal consent to participate in the study has been recorded.

Printed name of participant provided		Date consent was
Signature of person conducting the consent discussion	Printed name and role	Date consent was documented

Appendix J: Script for Contact, Consent, and Scheduling an Interview

SECTION 1: INTIAL CONTACT EMAIL/TELEPHONE SCRIPT

SECTION 1A: EMAIL SCRIPT

[USE IF PROVIDED WITH EMAIL BY CLINICIAN OR IF PARTICIPANT HAS EMAILED DIRECTLY TO SELF-REFER]

Dear _____,

Thank you so much for taking an interest in our research study about the experiences of patients receiving Chimeric Antigen Receptor (CAR) T-Cell therapy at the Juravinski Hospital and Cancer Centre (JHCC). This research study is being performed as part of a master's thesis within the School of Nursing at McMaster University. I was provided with your email by _____ [*if referred by clinician]* **OR** Thank you for contacting us regarding your interest in participating in our research study regarding the experiences of patients receiving CAR T-Cell therapy at the Juravinski Hospital and Cancer Centre (JHCC) [*if self-referred*] This research study is being performed as part of a master's thesis within the School of Nursing at McMaster University. I would like to schedule a 10-minute telephone conversation with you to confirm you are eligible for the research study, review the details of the research study, obtain consent, and to schedule a time for us to conduct the interview.

You may have already reviewed our letter of information, but I have attached it to this email for you to review prior to our phone conversation. I can answer any questions you may have at that time, or you can email me with any questions or concerns at your convenience.

If you are still interested in participating, can you provide a date and time for when we can schedule a telephone call? Also, what would be the best number to reach you?

Thank you so much for reaching out about our research study, it is greatly appreciated!

Sincerely,

Danielle Jones, RN, BScN, CON(C), MSc 2023

McMaster University, School of Nursing

EMAIL: jonesdani@hhsc.ca

PHONE: (905) 387-9495 ext. 64127

[ONCE COMPLETE, PROCEED TO SECTION 2: SECOND CONTACT PHONE SCRIPT]

SECTION 1B: TELEPHONE SCRIPT

[USE IF PROVIDED WITH PHONE NUMBER BY CLINICAN OR IF PARTICIPANT HAS LEFT MESSAGE]

"Hi, may I speak with _____?

My name is Danielle Jones, and I am calling regarding your interest in participating in a research study about the experiences of patients receiving CAR T-cell therapy at the Juravinski Hospital and Cancer Centre. This research study is being performed as part of a master's thesis within the School of Nursing at McMaster University. I was provided your contact information by _____ [*if referred by clinician*] **OR** I received your message about potentially participating in our research study investigating the experiences of patients receiving CAR T-cell therapy at the Juravinski Hospital and Cancer Centre [*if self-referred].* This research study is being performed as part of a master's thesis within the School of Nursing at McMaster University.

Is now a good time to talk?

[NO]: What would a better time to reach you? _____

Great, I will contact you then – thank you so much for your time.

[IF YOU CONTACT PATIENT AT A LATER TIME, RESUME AT SECTION 1B: TELEPHONE SCRIPT]

[YES] Great, thank you so much! This phone conversation is to confirm you are eligible for the research study, review study information, obtain verbal consent, and schedule a time for our interview. I am now going to ask you a few questions to confirm your eligibility to participate in this research study.

1) Are you going to receive CAR T-cell therapy at the JHCC or have you received CAR T-cell therapy at the JHCC within the last 80 days?
2) Are you comfortable communicating verbally in English?
3) Are you able to participate in a one hour interview?

[*If yes to all of above*] Great, thank you so much! You are eligible to participate in this research study. We will now move on to reviewing study information and obtaining verbal consent.

[*If no to any of above questions*] Thank you so much for your interest in our research study. Unfortunately, you do not meet our eligibility criteria to participate in this study. Thank you for reaching out and taking the time to speak with me. Have a great day!

Thank you so much for your interest in participating in our research study! Before we start, do you have a copy of our Letter of Information?

[*If yes*]: Great! Did you have any questions about anything discussed? [*If not, proceed to Section 3: Letter of Information. If yes, answer questions then proceed to Section 3: Letter of Information]*

[*If no*]: I would like to send you a copy for your reference – what is the best email address to send this to? [*Collect information here].* Perfect! I will give you some time to review this now, and then we will resume with our conversation [*Give participant 5-10 minutes to review information and then proceed to Section 3: Letter of Information]*

SECTION 2: SECOND CONTACT PHONE SCRIPT

[USE WHEN CONTACTING PATIENTS AFTER INITIAL EMAIL CONVERSATION]

Hello, may I speak with _____?

Hello, my name is Danielle and I am calling in regards to a research study you had expressed interest in about the experience of patients receiving CAR T-cell therapy at the Juravinski Hospital and Cancer Centre. Is now a good time to talk?

[YES] Great, thank you so much! I had sent you a copy of our letter of information previously, have you had a chance to review it?

[*If yes*] Do you have any questions about anything? [*If yes, answer these questions then proceed to Section 3: Letter of Information]*

[*If no*] If you don't mind, I would like to go over this information with you now verbally; it should take about 10 minutes and then you can have some more information to help you decide if you would be interested or not. [*Proceed to Section 3: Letter of Information]*

[NO]: What would a better time to reach you? _____

Great, I will contact you then – thank you so much for your time.

[IF YOU CONTACT PATIENT AT A LATER TIME, RESUME AT SECTION 2: SECOND CONTACT PHONE SCRIPT]

SECTION 3: LETTER OF INFORMATION

I am now going to review some more information about our research study – this information is also available in the letter of information to review at your convenience or to have on hand for any questions that may come up later. Do you have any questions before I begin?

[YES] Answer questions then proceed to Section 3A: Study Purpose.

[NO] Proceed to Section 3B: Study Purpose.

SECTION 3A: STUDY PURPOSE

This purpose of this research study is to look at the experiences of patients who have received Chimeric Antigen Receptor (CAR) T-cell therapy at the Juravinski Hospital and Cancer Centre (JHCC).

We are completing this research study to gain a better understanding of the patient's expectations and experiences in receiving CAR T-cell therapy. This research study is being completed as part of a master's thesis within the School of Nursing at McMaster University.

Do you have any questions about the purpose of our research study?

[YES] Answer questions then proceed to Section 3B: Study Procedures.

[NO] Proceed to Section 3B: Study Procedures.

SECTION 3B: STUDY PROCEDURES

We expect that around 10-12 patients will participate in this research study. If you decide to participate in this study, you will be asked to complete a one-on-one interview with the student researcher. During the interview you will be asked questions about your decision to receive CAR T-cell therapy and what it was like for you to receive this treatment at the JHCC. The interview will take approximately 45 to 60 minutes to complete and will be done online via Zoom or by telephone.

Zoom is an externally hosted cloud-based service. A link to their privacy policy is available in the letter of information. While the Hamilton Integrated Research Ethics Board has approved using the platform to collect data for this study, there is a small risk of a privacy breach for data collected on external servers. Please note that if you would prefer to have a Zoom interview, you would not need to have your camera on unless you choose to do so.

With your permission, the interview will be audio-recorded (at no point will there be any video recordings, even for Zoom interviews where you may or may not have your camera turned on) and then transcribed into a written document that can be analyzed by the researcher. We ask that participants do not make any unauthorized recordings of these sessions.

During the interview we will also collect some personal information about you, such as your gender, education, marital status, and other aspects of your social situation. To better understand the care you received, information about your diagnosis and treatment will be collected from your medical record. We will only review the portion of your medical records relating to your CAR T-cell therapy treatment.

Do you have any questions about what participating in this research study would involve?

[YES] Answer questions then proceed to Section 3C: Potential Risks.

[NO] Proceed to Section 3C: Potential Risks.

SECTION 3C: POTENTIAL RISKS

The risks involved in participating in this research study are minimal. You may feel uncomfortable with the interview process or find it stressful to recall your experiences in having CAR T-cell therapy.

You do not need to answer questions that you do not want to answer or that make you feel uncomfortable, and we can take a break at any point during the interviews. You can withdraw (stop taking part) at any time.

Do you have any question about potential risks involved in this research study?

[YES] Answer questions then proceed to Section 3D: Potential Benefits.

[NO] Proceed to Section 3D: Potential Benefits.

SECTION 3D: POTENTIAL BENEFITS

The research will not benefit you directly. We hope to learn more about how people are feeling about their CAR T-cell therapy, why they chose this treatment, and if their experiences in receiving this treatment met their expectations. The results could also help to identify new or improved ways to provide care during CAR T-cell therapy.

Do you have any questions about the potential benefits of participating in this research study?

[YES] Answer questions then proceed to Section 3E: Confidentiality & Privacy.

[NO] Proceed to Section 3E: Confidentiality & Privacy.

SECTION 3E: CONFIDENTIALITY & PRIVACY

Your participation in this research study is confidential. Only me and my research supervisor (Dr. Bryant-Lukosius) will know whether you participated, unless you choose to tell them. We will not share your name or any information that would allow you to be identified. However, we are often identifiable through the stories we tell. Since the group of patients who receive CAR T-cell therapy at the JHCC is small, others may be able to identify you based on references you make. Please keep this in mind in deciding what to tell us.

The results of this research study may be published in a journal or presented at professional conferences. Direct quotations may be included in publications of this research study and in the student researcher's thesis, but any potentially identifying information within these quotations will be removed.

Your name and contact information will be the only identifying information collected by the student researcher and will be stored in a password-protected master file located on a secure server. You will be assigned a unique participant ID and all other information will be linked directly to this ID rather than to any of your identifying information. Identifiable data will be deleted at study completion, and de-identified data will be retained for 10 years.

Information kept on a computer will be protected by a password and stored on a secure server. Audio recordings stored on the digital recorder will be kept in a locked cabinet in a secure location (the research supervisor's office at the JCC), to which only the student researcher has a

key. Prior to discussing any study information or findings with my research committee, I will ensure that any information that could identify you or other individuals has been removed.

The interviews will take place in a private location using headphones to ensure that no one can overhear your responses. Audio recordings will be converted into written documents by a member of the team who has signed a confidentiality agreement. The student researcher will delete audio recordings once transcription is complete.

Do you have any questions about the steps we are taking to protect your privacy?

[YES] Answer questions then proceed to Section 3F: Participation and Withdrawal.

[NO] Proceed to Section 3F: Participation and Withdrawal.

SECTION 3F: PARTICIPATION AND WITHDRAWAL

Your participation in this study is completely voluntary and you can decide to stop (withdraw), at any time, even after providing verbal consent or part-way through the study. By participating in this study you do not waive any rights to which you may be entitled under the law. If you decide to withdraw, there will be no consequences to you, and you have the option of removing your data from the study at your request. If you do not want to answer some of the questions you do not have to, but you can still be in the study.

Your decision of whether to participate in this study will not impact the care you receive at the JHCC in any way. You are not giving up any rights to which you may be entitled under the law by consenting to participate in this study. If you would like to withdraw from the study at any point, simply email or call the student researcher.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board, affiliated sites, or other regulatory authorities may consult your research data. By consenting to participate in this study, you authorize such access.

Do you have any questions about consenting to participate or withdrawing from this study?

[YES] Answer questions then proceed to Section 3G: Wrap-Up.

[NO] Proceed to Section 3B: Wrap-Up.

SECTION 3G: WRAP-UP

I expect to have this study completed by approximately March 2023. If you would like a summary of the results, please let me know how you would like it sent to you.

As a compensation for the time you have invested in our study, at the end of the interview you will be given a $25 e-gift card for Tim Hortons.

If you have questions or need more information about the study itself, you can contact myself or my research supervisor. For questions about your rights as a research participant, you can contact the Office of the Chair, HiREB, at (905) 521-2100 at extension 42013.

Before we move on to reviewing verbal consent, do you have any further questions or concerns about any of the information we have just discussed?

[YES] Answer questions then proceed to Section 4: Script for Verbal Consent.

[NO] Proceed to Section 4: Script for Verbal Consent

SECTION 4: SCRIPT FOR VERBAL CONSENT

I will now ask you for your verbal consent to participate in the study. If you feel that we have covered all of the necessary information you need to make a decision about participating in this study, I will ask you to repeat a short statement. This affirms your consent to participate in the study, but does not mean you are obligated to complete our interview – if you change your mind at any point you can simply contact me to let me know.

Would you like to proceed with verbal consent?

[YES] I am going to ask you to repeat the following statement after me. [*Begin recording. Pause after each sentence to allow participant to repeat]*.

> *"I understand what participating in this study involves. All my questions have been answered. I consent to being contacted by the student researcher to perform an interview. I also consent to having my medical chart reviewed for data collection*."

Thank you so much for your consent to participate. We will now move on to scheduling an interview [*Stop recording after consent has been repeated]*.

[NO] Thank you so much for your time. Please feel free to reach out if you would like to participate at a later time.

[*DOCUMENT VERBAL CONSENT IN PATIENT TRACKING DOCUMENT INCLUDING DATE AND OBTAINED BY WHOM]*

[PROCEED TO SECTION 5: SCRIPT FOR SCHEDULING AN INTERVIEW]

SECTION 5: SCRIPT FOR SCHEDULING AN INTERVIEW

Do you have a preference for having the interview by telephone or virtually via Zoom?

[IF ZOOM] Can I have your email address so that I can send you an email containing a link to the secure interview?

[IF PHONE] I will call you from this phone number for the purposes of our interview. If you are not able to answer that is okay – I will try again 5 minutes later and if you need to reschedule we can do that to a time more convenient for you.

Is there a specific date and time you had in mind?

Great – I will speak with you then. Please contact me if you need to reschedule or if you have any questions or concerns before we speak next.

[IF PATIENT HAS NOT YET RECEIVED THEIR CAR T-CELL REINFUSION]

I know you will be having your CAR T-cell reinfusion within the next few weeks and our interview will be about a month or so after that – would you be okay if I called or emailed you again one week before our interview to confirm you are still interested and feeling up to participating

[YES] Perfect! I will reach out to you then.

[NO] Okay, that is not a problem. I will reach out to you on our interview date. Like I said, you can always call or email me before then if you have any questions or concerns.

[ENTER ALL INFORMATION INTO PATIENT TRACKING SHEET: NAME, CONTACT INFORMATION, PREFERRED DATE OF INTERVIEW, PREFERRED MODE OF COMMUNICATION]

[IF PATIENT HAS NOT YET RECIEVED THEIR CAR T-CELL REINFUSION, PHONE BACK ONE WEEK PRIOR TO SCHEDULED INTERVIEW TO REAFFIRM CONSENT TO PARTICIPATE; PROCEED TO SECTION 6: SCRIPT FOR RECONFIRMING CONSENT]

SECTION 6: SCRIPT FOR RECONFIRMING CONSENT

SECTION 6A: EMAIL SCRIPT

Dear _____,

I know our interview is coming up shortly and that you have most likely just recently started fully recovering from your CAR T-cell therapy. I just wanted to check in and see how you are doing, and to confirm you are still interested in participating in our study!

I know we had originally scheduled our interview for _____, does this still work for you? If not, I am happy to reschedule it to a time that is better for you.

Let me know if you have any questions, concerns, or if you would no longer like to participate in an interview. If I do not hear back from you, I will call or speak with you via Zoom at our previously arranged interview date and time,

Thank you,

Danielle Jones, RN, BScN, CON(C), MSc 2023

McMaster University, School of Nursing

EMAIL: jonesdani@hhsc.ca

PHONE: (905) 387-9495 ext. 64127

SECTION 6B: PHONE SCRIPT

“Hi, may I speak with _____?

My name is Danielle Jones, and I am calling regarding your interest in participating in a study about the experiences of patients receiving CAR T-cell therapy at the Juravinski

Hospital and Cancer Centre. I know our interview is coming up shortly and I just wanted to check in – are you still interested in participating in our study?

[NO] Okay – not a problem. I will remove you from our study list at this time – if you change your mind and would like to participate at a later time please feel free to reach out.

[YES] Perfect! Does ___ still work for you, or would you like to adjust the date or time?

[*READJUST OR CONFIRM DATE AS NEEDED]*

Okay great – I will be speaking with you on _____. Please reach out if you have any questions or concerns before then. Thank you!

Appendix K: Demographic and Clinical Information Excel File

Variable Name	Data Type	Description	Codes
			Demographics
D1_Gender	Numeric	Gender	1=Male, 2=Female, 3=Non-Binary 4=Other, 999= Prefer not to answer
D2_Distance	Numeric	Kilometres from home to JHCC	1= 0-40, 2= 40-60, 3 = 60-80, 4= 80+, 999= Prefer not to answer
D3_Education	Numeric	Highest level of education obtained	1= Elementary school, 2= High school, 3= College diploma, 4= Bachelor's degree, 5= Master's degree, 6= PhD, 999= Prefer not to answer
D4_Income	Numeric	Total household income in $/year	1= less than 30,000, 2= 30,000 - 59,999, 3= 60,000 - 89,99, 4= greater than 90,000, 999= Prefer not to answer
D5_MaritalStatus	Numeric	Marital status	1= Married/Common Law, 2= Divorced/Separated, 3= Single, 4= Widowed 999= Prefer not to answer
D6_Employment	Numeric	Is the participant currently employed?	1 = Yes, working full or part time, 2 = No, on leave/disability 3= No/Retired, 999= Prefer not to answer
			Clinical Information
CI1_Age	Numeric	Age at time of interview	
CI2_Dx	Numeric	Underlying cancer type	1= B-ALL, 2= DLBCL, 3= High grade B-cell lymphoma, 4= FL transformed to DLBCL, 5= Primary mediastinal B-cell lymphoma
CI3_DxDate	Numeric	Date of initial cancer diagnosis	
CI4_CAR-Tdate	Numeric	Date of CAR-T cell infusion	
CI5_PrevTher	Numeric	Number of previous lines of treatment	
CI6_PrevTherDescription	Free text	What previous therapies has the patient received?	
CI7_SCT	Numeric	Previous stem cell transplant (Yes/No)	1= Yes, 2= No
CI8_Hospitalization	Numeric	Was patient hospitalized during CAR T (Y	1= Yes, 2= No
CI9_LengthAdmission	Numeric	Number of days admitted to hospital	
CI10_ICU	Numeric	Was patient admitted to ICU during CAR T	1= Yes, 2= No
CI11_Toci	Numeric	Did patient receive tociluzumab (Y/N)	1= Yes, 2= No
CI12_TociDoses	Numeric	Total number of doses of tociluzumab	
CI13_Corticosteroids	Numeric	Did patient receive corticosteroids (Y/N)	1= Yes, 2= No

Appendix L: Interview Guide Review Package

Interview Guide Review Package

To begin, our research team would like to express our appreciation for your time in reviewing our interview guide. We value your opinions and are eager to hear what you think about the questions we have developed. We have not yet begun our study and would like to seek some feedback on how these questions might be perceived by patients before we roll out this interview guide within our study.

We will provide you with a brief description of our study, some suggestions for how to go about reviewing our interview guide and will provide an evaluation form with space for you to leave comments and feedback at the end. If you have any further questions or would like to provide additional feedback, please feel free to contact the student researcher at jonesdani@hhsc.ca or (905) 387-9495 ext. 64127.

STUDY OVERVIEW: We will be conducting a study to investigate the experiences of patients who have received CAR T-cell therapy at the Juravinski Hospital and Cancer Centre. Briefly, CAR T-cell therapy is a form of immunotherapy intended to treat some forms of leukemia and lymphoma. We are interested in learning about what goals or values are important to patients when they are deciding to pursue this treatment, as well as to understand how we might be able to better prepare patients for what they may experience throughout their care.

INSTRUCTIONS: Please review the interview questions we have prepared below. As you go through them, think about your own experiences with treatment – would these have been questions you would have been able to answer yourself? Would any of these questions have been distressing to you, offensive, or difficult to understand? I have included some questions to guide your evaluation of the questions below, but please feel free to add any additional feedback you think would be helpful. You can also add comments directly on each of these questions – feel free to make notes or suggestions as you make your way through the guide.

INTERVIEW GUIDE

QUESTION 1: If you can, think back to when you first heard about CAR T-cell therapy. Tell me a little bit about what was going through your head when you learned about this therapy.

QUESTION 2: What information did you receive from your healthcare team before deciding to receive CAR T-cell therapy?

QUESTION 3: Have you ever heard of the phrase "GOC"? When did you first hear about this term? What does the term "GOC" mean to you?

QUESTION 4: In general, what goals or values stood out for you as being the most important when making a decision about receiving CAR T-cell therapy?

QUESTION 5: What has it been like to discuss your GOC with your healthcare team?

QUESTION 6: Before starting CAR T-cell therapy, did you feel like you had a good handle on what to expect?

*QUESTION 7***:** To what extent did your experiences with receiving CAR T-cell therapy match your expectations?

*QUESTION 8***:** Is there anything you wish that you knew before receiving CAR T-Cell therapy?

*QUESTION 9***:** Knowing what you know now, would this change your initial decision to receive CAR T-Cell therapy?

*QUESTION 10***:** Reflecting on your GOC of _____, do you feel your experience with receiving CAR T-cell therapy was consistent with these goals?

QUESTION 11: What were your experiences with nursing care throughout the process of receiving CAR T-cell therapy?

EVALUATION QUESTIONS

1) How easy were these interview questions easy to understand? *Please circle your choice.*

Not at all easy Somewhat easy Easy Very Easy Extremely Easy

If NOT AT ALL EASY or SOMEWHAT EASY, please identify the questions which were difficult to understand below:

What about these questions were difficult to understand?

2) Were there any questions you think we should remove? *Please indicate your response.*

YES: □ NO: □

If YES, please identify the question numbers below:

3) Are there any questions you think we should add? *Please indicate your response.*

YES: □ NO: □

If YES, please describe below:

4) Would you feel comfortable answering these questions in an interview? *Please circle your choice.*

Not at all comfortable	Somewhat comfortable	Comfortable	Very Comfortable	Extremely Comfortable

If not, please identify the questions you would not feel uncomfortable answering by listing them here:

5) Is this an appropriate number of questions to ask? *Please indicate your response.*

YES: □ NO: □

If NO, what would be a more appropriate number and why?

6) Is there anything else you think we should know about your thoughts on these interview questions?

Appendix M: Interview Guide

INTERVIEW GUIDE

Hello ___, thank you so much for taking the time to speak with me today. As a reminder, the purpose of our interview today is to gather information related to your experience with receiving CAR T-cell therapy at the Juravinski Hospital and Cancer Centre.

I am a registered nurse at the Juravinski Cancer Centre and a student researcher at McMaster University. Today I will be speaking to you only in my role as a student researcher, and I will not be sharing any of this information with your cancer care team. I would like to remind you that this interview and your participation in this study is confidential. We welcome you to provide honest answers about your experiences in order to help us understand the best ways to improve care. You will not be identified in any presentation or publication that may result from this study.

I would also like to remind you that this interview will be audio recorded. We ask that participants do not make any unauthorized recordings of these sessions. We can stop the interview at any point, and you do not have to answer all the questions I ask you. Do you have any questions or concerns?

Do I have your consent to begin recording and start our interview?

Great! To begin, I am going to ask a few questions about things such as your gender that may help us better understand the population of patients who receive CAR T-cell therapy. You do not have to answer these questions if you do not feel comfortable doing so.

Demographic Question 1: What is your current age in years?
Demographic Question 2: What gender do you identify as?
Demographic Question 3: Approximately how many kilometers do you have to travel from your home to reach the JHCC?
Demographic Question 4: What is the highest level of education you have received?
Demographic Question 5: This next question is about your estimated total household income. I will list a few different categories for total household income and will ask which one you fall into. The categories are as follows: less than $30,000 per year, between $30,000 to $59,999 per year, between $60,000 to $89,999 per year, or greater than $90,000 per year?
Demographic Question 6: How would you describe your current marital status?
Demographic Question 7: Are you currently employed?

RESEARCH QUESTION 1: What are patient's perceptions of GOC related to CAR T-cell therapy?

I will start with our interview now. We are going to start with some questions about how you first learned about CAR T-cell therapy, and what your reactions were. It may be hard to remember this far back, but you can take as long as you need to answer these questions. Again, if there are any questions you are not comfortable answering, please let me know. If you do not understand what I am asking with any of these questions, please let me know and I can rephrase them.

QUESTION 1: If you can, think back to when you first heard about CAR T-cell therapy. Tell me a little bit about your first reaction when you learned about this therapy.
PROMPT: How did you first learn about the treatment?
PROMPT: Had you ever heard about this treatment before?
PROMPT: Did you know immediately this was a treatment you wanted to pursue?

QUESTION 2: What information did you receive from your healthcare team before deciding to receive CAR T-cell therapy?
PROMPT: Who provided you with this information?
PROMPT: Did you have any discussions or the chance to ask questions about the information?
PROMPT: Did the information you received help you decide whether to receive CAR T-cell therapy?
PROMPT: In your own words, can you describe how CAR T-cell therapy works to treat your cancer?

QUESTION 3: Have you ever heard of the phrase "GOC"?
PROMPT: When did you first hear about this term?
PROMPT: What does the term "GOC" mean to you?
PROMPT: GOC can be defined as goals for your health or healthcare, including what you are hoping to achieve from a specific treatment or therapy.

QUESTION 4: In general, what goals or values stood out for you as being the most important when making a decision about receiving CAR T-cell therapy?
PROMPT: Some goals that people cite as important are to be cured, to live longer, to maintain quality of life, to be comfortable, or to achieve specific life goals. Do any of these goals resonate with you?
PROMPT: When considering CAR T-cell therapy, what was the most important goal you were hoping to achieve?
PROMPT: Was this a goal you had set by yourself, or did you come up with this goal in discussions with your healthcare team?

QUESTION 5: What has it been like to discuss your GOC with your healthcare team?
PROMPT: To what extent do you feel like your healthcare team is aware of your GOC?
PROMPT: How did conversations about your GOC get started?
PROMPT: Which members of your healthcare team have you discussed this with? Do you remember discussing this with any nurses or nurse practitioners?

Is there anything we have not talked about regarding your decision to pursue CAR T-cell therapy that you would like to go over or that really stood out?

SUMMARIZE*:* So far, what we have talked about is _____. It seems like what was important to you was _____, and you mentioned that your goals for this treatment were ___. Did I understand you correctly?

RESEARCH QUESTION 2: What are patient's experiences in receiving CAR T-cell therapy and how do these experiences align with their GOC?

Great, thank you so much for answering those questions! We will now talk a little bit more about your experience with receiving CAR T-Cell therapy and how this experience fit with what you were expecting. Again, you can take as long as you would like to answer these questions and you do not have to answer all of them.

QUESTION 6: Before starting CAR T-cell therapy, did you feel like you had a good handle on what to expect?

PROMPT: What information were you provided beforehand?
PROMPT: Did you have an idea of how you would feel during the recovery period?

QUESTION 7: To what extent did your experiences with receiving CAR T-cell therapy match your expectations?
PROMPT: What aspects of the experience were the most surprising?
PROMPT: Was anything easier or more difficult than you expected?

QUESTION 8: Is there anything you wish that you knew before receiving CAR T-Cell therapy?
PROMPT: What information could we have given you to make the experience more consistent with your expectations?

QUESTION 9: Knowing what you know now, would this change your initial decision to receive CAR T-Cell therapy?
PROMPT: If you would not receive it again, why is that?

QUESTION 10: Reflecting on your GOC of _____, do you feel your experience with receiving CAR T-cell therapy was consistent with these goals?
PROMPT: If you cannot determine yet if it met these goals, was your experience of receiving CAR T-cell therapy something you feel was in line with your general expectations for your healthcare?

Great, thank you so much! I will now ask you a few questions about how registered nurses were involved in your experience, as we are hoping to better understand the role of nursing staff in caring for patients receiving CAR T-cell therapy.

RESEARCH QUESTION 3: What are patients' perceptions of the role of registered nurses in discussing GOC and contributing to overall healthcare experiences when receiving CAR T-cell therapy?

QUESTION 11: What were your experiences with nursing care throughout the process of receiving CAR T-cell therapy?
PROMPT: In what ways could registered nurses improve the care they provide to patients undergoing CAR T-cell therapy
PROMPT: Did you discuss some of your GOC with registered nurses throughout this experience?

Is there anything we have not covered yet that would be important for me to know about your nursing care or experiences in receiving CAR T-Cell therapy?

Thank you so much for your time today. I will now conclude our interview and end the recording. I will transcribe a copy of this interview for my records and will remove any comments/information that could be used to identify you.

Do you have any other questions or concerns?

Thank you so much – this was incredibly helpful, and I really appreciate your time and contribution. Please reach out to me if you have any further questions.

Appendix N: Script for Supporting Participants After Noting Emotional Distress

SCRIPT FOR DEBRIEFING POST INTERVIEW IF NEEDED

[*TO BE USED WHEN INTERVIEWER NOTES EMOTIONAL DISTRESS THROUGHOUT INTERVIEW]*

Now that our interview is complete and we are no longer recording, I wanted to offer some space for you to debrief if needed. I know we covered a lot of heavy topics, and I wanted to let you know that if you are feeling distressed or if this brought up a lot of negative memories, that there are several resources available for help working through those feelings.

How are you feeling now that the interview is over?

[*Allow space for participant to express their thoughts. Provide support and validation]*

At this point, do you feel you might benefit from talking to someone objective about how you are feeling?

[NO] In the future if you feel like this is something you might benefit from, please reach out to either your cancer care team or your family doctor – there are many resources available to you if you need them.

[YES] If you are local to Hamilton or still being followed closely by the team at the JHCC, there is a program available called the Psychosocial Oncology program – if you speak with the clinical team, they can connect you to this resource. If you would rather reach out for support directly, you call Wellwood at (905) 667-8870. Wellwood is a local organization affiliated with HHS which offers free programs including peer support and mindfulness groups.

Your family doctor may also be able to refer you to resources available in your community.

If you are not local to Hamilton, your family doctor may be able to refer you to available resources. If you have any difficulty with this, our Psychosocial Oncology team may also be able to facilitate a referral to a local organization.

Please reach out if you feel you need extra support. I know this may have been a very difficult interview, as some people find their experiences with treatments such as these quite traumatic.

Do you have any further questions or concerns before we end our call?

[YES] *Answer questions and then move to concluding call.*

[NO] Thank you so much for your time today. If you have any further questions or concerns about your participation in our research study, please feel free to reach out.