Living with Colorectal Cancer:
Patient and Caregiver Experience

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GENERAL INFORMATION

Name and addresses of the clinical sites and/or other institutions involved in the study

1. Cross Cancer Institute	2001 11560 University Ave Edmonton, AB, Canada T6G 1Z2
2. Tom Baker Cancer Centre	1331 29 St NW Calgary, AB, Canada T2N 4N2
3. Holy Cross Centre	2210 2 St SW Calgary, AB, Canada T2S 3C3

Study Summary

Title	Living with Colorectal Cancer: Patient and Caregiver Experience
Short title	Living with Colorectal Cancer
Source of financial support	Canadian Institutes of Health Research (CIHR) Partnerships for Health System Improvement for Cancer Control Operating Grant "Palliative Care Early and Systematic (PaCES): Impact on Patient and Health System Outcomes"
Protocol Number	HREBA.CC-17-0429
Methodology	Interrupted Time Series (ITS)
Study Duration	January 2018 through December 2021
Study Center(s)	***1.*** Cross Cancer Institute- Edmonton, Alberta, Canada ***2.*** Tom Baker Cancer Centre- Calgary, Alberta, Canada ***3.*** Holy Cross Centre- Calgary, Alberta, Canada
Objectives	This observational study will gather outcome and experience data of patients living with advanced colorectal cancer and their caregivers. The primary objective is to measure how quality of life in this population changes over time (before, during, and after a palliative pathway becomes the new standard of care in Alberta).
Number of Subjects	Up to 1000 (patients and caregivers combined)

Diagnosis and Main Inclusion Criteria	≥18 years of age with diagnosis of advanced colorectal cancer and one or more of the following: • Failed first line of chemotherapy (disease progression on imaging) • Unable to receive first line chemotherapy • Surprise question: healthcare provider would not be surprised if patient died in the next 12 months • High symptom need (any score on ESAS-r ≥ 7) (Advanced Colorectal Cancer (aCRC) is defined as primary or metastatic cancer that is unlikely to be cured, controlled, or put into remission with treatment) Caregivers of patients who meet inclusion criteria/exclusion criteria may be invited by the patient to participate
Duration of administration	Recruitment begins January 2018. Enrollment interview to take approximately 60 minutes with follow up questionnaire completion taking 20 minutes for patient and 45-60 minutes for caregiver periodically through December 2020.

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List of Abbreviations

aCRC	Advanced Colorectal Cancer
ACP	Advance Care Planning
AHS	Alberta Health Services
CRF	Case Report Form
CRC	Colorectal Cancer
ESASr	Edmonton Symptom Assessment System-Revised
GCD	Goals of Care Designation
HREBA-CC	Health Research Ethics Board of Alberta-Cancer Committee
ITS	Interrupted Time Series
PaCES	Palliative Care Early and Systematic
PPF	Putting Patients First
PREMs	Patient Reported Experience Measures
PROMs	Patient Reported Outcome Measures

1. Background

Patients and families living with advancing cancer experience distress when transitioning from active cancer treatment to palliative care.[1] Late or no palliative care is associated with lower quality of life, higher caregiver distress, and more aggressive and costly end of life care.[2,3,4] In Calgary, typical of other Canadian centres, 60% of patients with metastatic gastrointestinal cancers have a late (< 3 months from end of life) or no palliative care referral (i.e. no contact with any palliative care service/provider).[5] This lack of timely and early palliative care is associated with aggressive cancer care in 50% of patients, as compared to 25% in those who received earlier palliative care.

A Knowledge to Action initiative called Palliative Care Early and Systematic (PaCES) has identified gaps in providing early and systematic palliative care to advanced colorectal cancer (aCRC) patients. To address these gaps, a comprehensive care pathway delivering early, systematic palliative care to aCRC patients in Alberta will be developed as a new standard of care. The pathway will be implemented first in Calgary, with Edmonton as control site, to allow for testing and refinement before dissemination to Edmonton and across Alberta. As a result of the development of this new care pathway, over the next 3 years changes are anticipated in the delivery of care for aCRC patients.

The purpose of this study is to measure outcomes and experiences of aCRC patients and their caregivers during these transformative health system changes. Patient and caregiver data collected continuously over this time will monitor how changes in cancer care delivery impact patients, and will provide periodic feedback to guide further quality improvement.

2. Study Objectives

The purpose of this current study is to better understand, guide improvements, and monitor outcomes of patients and their caregivers facing aCRC. Input on patient and caregiver reported outcome measures (PROMs) and patient and caregiver reported experiences measures (PREMs) from aCRC patients and their caregivers will be sought in order to explore how quality of life changes before, during, and after a palliative pathway becomes the new standard of care in Alberta.

3. Methods

3.1 Study Design

An observational cohort study with interrupted time series (ITS) data collection will be used to collect PROM and PREM data from aCRC patients and their caregivers over a 36 month period. ITS is a powerful method for evaluating change at a population level. The ITS method will allow us to assess secular trends, determine if there is evidence of serial dependencies in the monthly measures, and to compare measures following system changes in Calgary while observing the same measures over the same time periods in Edmonton.

3.2 Selection and Withdrawal of Subjects

3.2.1 Inclusion/exclusion

For three years, all aCRC patients at Cross Cancer Institute (Edmonton), Tom Baker Cancer Centre (Calgary) and Holy Cross Centre (Calgary) will be screened and invited by their oncology healthcare providers to join the patient outcome and experience data collection. A caregiver, identified by each enrolled patient, may be invited to participate. For the purposes of this study, caregivers are defined as family or friends who provide unpaid assistance with tasks such as transportation and personal care. Advanced Colorectal Cancer (aCRC) is defined as primary or metastatic cancer that is unlikely to be cured, controlled, or put into remission with treatment.

Inclusion criteria:

All aCRC patients ≥ 18 years with one or more of the following:

1) Failed first-line chemotherapy (disease progression on imaging);
2) Unable to receive first-line chemotherapy;
3) High symptom need (*any* score on the Edmonton Symptom Assessment System Revised (ESASr) ≥ 7);[6]
4) Surprise question: In the opinion of a healthcare provider, would not be surprised if the patient died in the next 12 months.

Caregivers of patients who meet inclusion/exclusion criteria may be invited to participate**.**

Exclusion criteria:

A participant deemed inappropriate by clinic staff to be approached for an outcomes study for any reason (for example, in crisis).

3.2.2 Subject Withdrawal

Participation in the study is voluntary. Participants will be advised that they can stop the study at any time and will not be required to give a reason for withdrawal. If a participant withdraws from the study, he/she will be offered an opportunity to withdraw both him/herself and any data gathered this far, or him/herself alone. These options will be made clear to the participant. If a participant chooses to withdraw both him/herself AND his/her data, any digital or paper files will be deleted/shredded, and excluded from the analysis. Data withdrawal can only be done up to the point of analysis.

3.3 Procedures

3.3.1. Recruitment and Informed Consent

Potential participants will be recruited from outpatient clinics at Tom Baker Cancer Centre, Holy Cross Centre, and Cross Cancer Institute. A poster/leaflet **(Appendix A)** will be posted in or near the clinics included in the study to advise potential participants about the study and provide contact information. Inclusion/exclusion criteria will be provided on a laminated card to the clinic staff **(Appendix B).** Study staff will use the EMR (electronic medical record) to prescreen for patients who may be eligible for the study based on the inclusion criteria. Patients determined by the clinic staff to meet these criteria will be approached by clinic staff who may briefly introduce the study or give them a one-page information poster/leaflet **(Appendix A).** The clinic staff will ask permission for study staff, who will be present in or near the clinic, to approach the patient and discuss their possible participation. If patients give permission for study staff to speak to them, study staff will introduce the study and give the poster/leaflet **(Appendix A)** to patients who have not received the leaflet from the clinic nurse.

If patients advise clinic staff that they would like to be contacted at a later time, they will be asked to complete a consent to provide their contact information to study staff **(Appendix C).** Clinic staff will then provide this information to study staff. Study staff will phone the patient, explain the study, give an opportunity to ask questions and then ask if he/she is interested in participating in the study. If a participant is interested, arrangements will be made to meet the participant at a future clinic appointment.

A trained member of the study team will complete the consenting process and enrollment questionnaires in a quiet place in or near the clinic. Enrollment will take place on the clinic day or shortly thereafter at a time convenient for the participant. The study staff will apply the remaining inclusion/exclusion criteria **(Appendix D).** Study staff will review the consent form **(Appendix E)** with all patient participants. If any participant refuses to give consent, he/she will not participate in the study. A consented patient participant may also name a caregiver (friend or family) to participate in the study. The informed consent form for caregivers will be reviewed and signed by the caregiver if interested **(Appendix F).** Alternatively, the consent form may be mailed, and the consenting process take place over the phone. The enrollment interview and surveys will be scheduled to take place by phone or in person once the signed consent is received.

To accommodate extenuating circumstances due to the COVID-19 pandemic, the consent process may take place exclusively over the phone. Patients will be approached by clinic staff during their appointment to determine if they are interested in participating in the study. Interested patients will complete a consent to contact form or provide verbal consent to allow study staff to contact them at a later date. Study staff will contact patients by phone and either email or mail the consent form to them. Study staff will then review each section of the consent form with the patient over the phone, answering any questions along the way. Study staff will make note of telephone consent on the consent form and initial to confirm. The patient will sign his/her copy of the consent from and mail or scan and email it back. Participants will receive a copy of the completed consent form either by email or mail, whichever they prefer. If the patient identifies a caregiver (friend or family) to participate in the study and they are interested, telephone consent will be obtained in the same manner mentioned above.

Adult patient participants without capacity will still be considered for the study. The healthcare provider screening patients for potential enrollment will indicate whether or not the patient has capacity to consent. For individuals lacking capacity, the authorized third party (e.g. substitute decision maker named on an enacted personal directive) will be approached. Assent will not be sought from the patient; however, expression of dissent will be respected. The substitute decision maker may consent to the study on behalf of the patient. See section 3.3.3 for the information/surveys that will be collected for participants without capacity. If a patient regains capacity during the study, the substitute decision maker's consent will end. The substitute decision maker will be asked to agree to contact the study team, or study doctor, if the patient regains capacity, at which time the patient will be asked to provide consent on his/her own behalf. Caregivers without capacity will not be considered for this study.

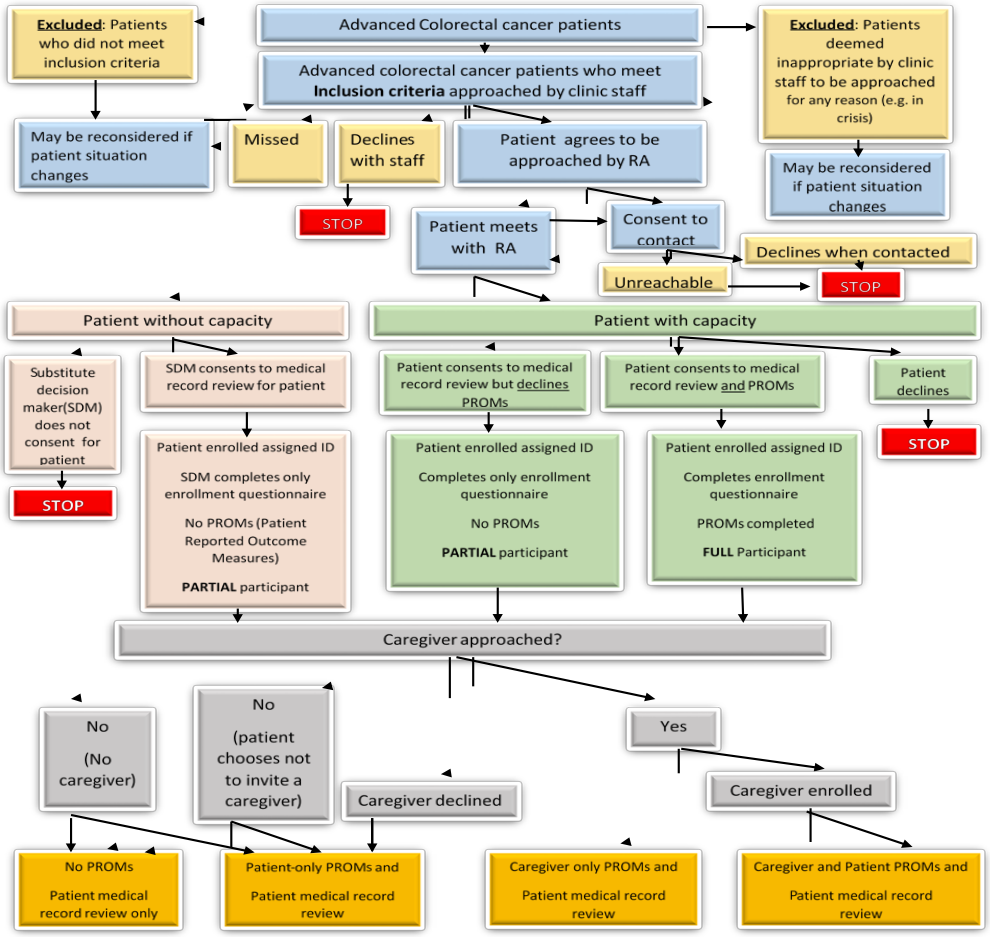
ActionDignity of Calgary* will provide study material translation to ensure that language is not a barrier to inclusion in this study. The forms translated by ActionDignity will include an attestation **(Appendix Q and R)** from a translator certifying that the translated forms accurately reflect the approved English forms. The EQ-5D-5L is available in translated versions through a licensing agreement with the Alberta PROMs and EQ-5D Research and Support Unit (APERSU). If there is a language requested for which there is not a complementary EuroQol-approved translated version of the EQ-5D-5L, RAs will not administer the EQ to the participant. EQ will not be administered in English when all other surveys for the participant are administered in their preferred/ non-English language. The ESAS-r is available in translated versions through an agreement with Cancer Care Ontario. The EQ-5D-5L and ESAS-r translated versions will not be accompanied by an attestation. The study consenting process will be completed in person with the study participant using the AHS language line and translated consent forms. The study team member who is present during the consenting conversation will sign as a witness and document the use of the interpreter, including the interpreter name, on the consent form. The actual signature of the language line interpreter will be waived. Family members or friends will not serve as the primary interpreter. Translated consent, recruitment forms, and follow up survey forms in the most commonly represented languages are available in the Appendix (**Appendices T1-T13**)**.** If the recruit requests a language that is not currently available, Action Dignity of Calgary will be contacted for translation and the newly translated forms will then be submitted as a future ethics amendment. Preferred survey follow-up for non-English speaking participants will be via post. Online follow up forms will not be available in languages other than English.

If a participant includes comments in the free-text area of the surveys written in another language, study staff who are on the ethics application and are fluent in that particular language will be contacted to assist with translation.

*ActionDignity of Calgary (formerly Ethno-Cultural Council of Calgary) is a community-based organization that facilitates the collective voice of Calgary's ethno-cultural communities towards full civic participation and integration through collaborative action.

Figure 1 (study flowchart) outlines the screening and enrollment process and participants' flow

Figure 1. Study flowchart.



3.3.2 Study Instruments

We have selected patient related outcome measures that are or will be in routine use in cancer centers in Alberta. This will be a sustainable source of quality improvement data beyond the course of this study. Currently the Advance Care Planning (ACP) Tracking Record is used to document conversations about care preferences. Putting Patients First with ESAS-r[7] is used routinely at every cancer clinic visit across Alberta and will be digitally recorded by the middle of 2018. AHS is licensed to implement EQ-5D[8,9] across all clinical sites. After the first 3 months of data collection, we will evaluate the instrument selection, frequency of data collection, and screening methods to determine if changes are required to enhance study feasibility. An ethics amendment will be requested for any changes.

Putting Patients First (PPF) with ESAS-r (Appendix G): Includes the Edmonton Symptom Assessment System (revised), and the Canadian Problem Checklist and an "at peace" question. The PPF was previously known as the "Screening for Distress tool".

EQ-5D-5L (Appendix H): Descriptive system of health-related quality of life states consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take one of five responses. The responses record five levels of severity (no problems/slight problems/moderate problems/severe problems/extreme problems) within a particular EQ-5D dimension.

The Preparedness for Caregiving Scale[10,11] (**Appendix I**)**:** A caregiver self-rated instrument that consists of eight items that asks caregivers how well-prepared they believe they are for multiple domains of caregiving.

My Conversations (Appendix K): A questionnaire exploring an individual's understanding of and satisfaction with discussions about Advance Care Planning and Goals of Care.

Enrollment ECOG-Patient Language Adaption (Appendix L): Scale to measure a patient's self-reported performance status, from which we will calculate the Eastern Cooperative Oncology Group score (ECOG) at enrollment.

CaregiverVoice (Appendix S): Survey exploring care experiences in the last 3 months of life administered to enrolled Caregiver of enrolled patient via mail 6-8 weeks after notification of death of enrolled patient.

Patient Self-Administered Financial Effects- PSAFE (Appendix U): Survey exploring patient and caregiver costs related to a diagnosis of cancer, administered to enrolled patient periodically.

3.3.3 Baseline/Enrollment

After consent is obtained, study staff will administer structured questionnaires to participants. The enrollment interview will take approximately 60 minutes to complete. Patient questionnaires include Patient Enrollment Questionnaire Case Report Form (CRF), Putting Patients First/ESAS-r, EQ-5D-5L**,** My Conversations, Enrollment ECOG, and Participant Contact Form. Caregiver questionnaires include Caregiver Enrollment Questionnaire, Preparedness for Caregiving Scale, EQ-5D-5L, and Participant Contact Form**.**

The enrollment questionnaire for patient participants **(Appendix M)** will include various demographic questions such as age, gender, marital status, education, race, religion, language, income categories and where the participant is living. The enrollment questionnaire for caregivers will include similar information and also their relationship to the patient, and if caregiver lives with the patient **(Appendix O).**

Patients will be given the option of full or partial participation in the study. Full participation will include the enrollment questionnaires, disclosure of medical records, and follow up questionnaires. Partial participation will include the enrollment questionnaires, disclosure of medical records but will not include the follow up questionnaires. A substitute decision maker signing on behalf of a patient will complete only the Patient Enrollment Questionnaire on the patient's behalf, and authorize the disclosure of medical records but will not complete the additional enrollment or follow-up questionnaires (**Appendices G,H,J,K,or L)** Caregivers will only have the option of full participation.

Participants' parking costs (if any) for the baseline/enrollment and follow up visits will be reimbursed.

It is important to note that the data from this study will not be made available to clinicians to guide individual patient care. Participants will be informed in the consent form and with follow up contacts that their responses will not be reviewed by individuals not involved in the study e.g. their healthcare provider/team. If the participant would like them to know this information, they will be advised to additionally bring it to their healthcare provider's attention.

3.3.4 Enrollment Chart Abstraction

Enrollment Chart Abstraction CRF (**Appendix P):** Information will be abstracted from the patient's Electronic Medical Record and/or paper chart by the study staff and will be completed

on day of enrollment (or as soon as possible thereafter, using information closest to enrollment date). Guidance/training for chart abstraction may be provided by study clinicians.

Information abstracted from clinic record at enrollment (**Appendix P**) will include Goals of Care Designation (GCD), ACP Tracking Record completion and diagnosis, metastasis sites, treatments and date/method of diagnosis. If a patient is unable to be contacted for a particular month, or if study team meets participant at a current clinic appointment, PPF/ESAS-r and EQ-5D-5L (if available) may be abstracted from the clinic record by the study team.

3.3.5 Follow Up

Patients will be surveyed by the study staff monthly (+/- 2 weeks, no less than 2 weeks between surveys) for 10 months and then every 3 months until death or the end of data collection (December 2020). Caregivers will be surveyed at enrollment, 1 month, then every 3 months until death of patient or end of data collection (December 2020). Following the notification of the death of a patient, the enrolled caregiver will be sent a condolence card. Study staff will receive confirmation of patient death from family members, enrolled caregivers or clinic staff. If a patient is unreachable after three attempts, study staff will check the patient's EMR for a confirmation of death. The CaregiverVoice survey **(Appendix S)** will be administered to the enrolled caregiver 6-8 weeks after notification of death of enrolled patient. This survey will be administered via post only and will be subsequently entered into the REDCap database by study staff.

The patient/caregiver will select their method of follow up as online, by phone, or in person during a regularly scheduled clinic visit. The study staff will send an email link to participants who choose to complete assessments online via secure Research Electronic Data Capture (REDCap) link. If the participant prefers none of these choices, the study team will discuss other options (e.g. via post). Follow up questionnaires should take 20 minutes for the patient and 45-60 minutes for the caregiver to complete. After 3 attempts to contact a participant via phone, a follow up letter will be sent to the unreachable participant asking that they contact the study staff. If study staff receives no response to follow up letter the participant will be categorized as "lost to follow up". If the patient is unreachable or declines a monthly follow up contact, the study staff will continue to abstract medical record information until the study staff is informed of patient withdrawal.

Preferred survey follow-up for non-English speaking participants will be via post. Online follow up forms will not be available in languages other than English.

3.4 Outcome measures

Objective	Measurement construct	Instrument
PRIMARY	Changes in EQ-5D-5L over time for patients and caregivers	**Patient:** EQ-5D-5L **(Appendix H)** monthly for 10 months then every 3 months until death or end of data collection. **Caregiver:** EQ-5D-5L at enrollment, 1 month and every 3 months until death of patient or end of data collection.
SECONDARY	Patterns of ESAS-r distress score observed over time	**Patient:** Putting Patients First (PPF) ESAS-r **(Appendix G)** monthly for 10 months then every 3 months until death or end of data collection.
	Caregiver readiness for caregiving role	**Caregiver:** Preparedness for Caregiving Scale **(Appendix I)** at enrollment, 1 month and every 3 months until death of patient or end of data collection.
	Patients knowledge of their own GCD Designation	**Patient:** "My Conversations" **(Appendix K)** at enrollment, then every month for 10 months, then annually until death or end of data collection.
	Patient's perceived engagement and satisfaction with ACP conversations	**Patient:** "My Conversations" **(Appendix K)** at enrollment, then every month for 10 months, then annually until death or end of data collection.
	# of patients with ACP Tracking Record discussions documented at enrollment	**Patient:** Enrollment Chart Abstraction CRF **(Appendix P)** at enrollment
	Measurement of care experiences across multiple settings in the last 3 months of life.	**Caregiver:** CaregiverVoice **(Appendix S)** Administered to enrolled caregiver no sooner than 8 weeks after notification of death of enrolled patient.

3.5 Duration

January 2018 through December 2021

3.6 Data Linkage

Concurrent with the Living with Colorectal Cancer outcomes study, the PaCES project will be collecting data on healthcare resource use by all aCRC patients (from diagnosis) using administrative databases from July 2011 until study end/death (separate study with separate ethics submission to be submitted). That data collection will begin at July 2011 for administrative data, January 2018 for clinical data and continue through December 2021. We are seeking consent from patients to pair their PROMS and PREMS data with that health resource utilization data.

Study staff will also check the EMR (electronic medical record) periodically, to obtain the date of death, if applicable, for all enrolled patients. In addition to this, the study team will request death date data for all enrolled patients from CMORE, every 3 months in order to obtain information that is not available in the EMR.

4. Sample population for analysis

In each centre, approximately 120 patients per year are diagnosed and die with metastatic CRC. For the primary outcome, we will have 12 months of observation measures prior to system changes in Calgary (while observing the same measures over the same time periods in Edmonton) and an additional 24 months following the system change. We anticipate a total sample size of 840 (420 in each centre). We estimate that 60% of patients will consent to participate in data collection. We will have 84% power to detect a 20% improvement in our primary outcome using logistic regression, and 77% power to detect this improvement using ITS analysis. For secondary outcomes (e.g. symptom burden), we have similar power to detect clinically meaningful changes.

4.1 Sample size

Up to 1000 (patients and caregivers combined).

4.2 Data Analysis

Descriptive statistics will be used to present the study variables. We will use means and standard deviations to summarize continuous measures that are approximately normal, and otherwise we will use medians and inter-quartile range. We will summarize binary and categorical variables as frequencies and proportions within a given period of time. Events that can occur more than once in a time period will be expressed as rates. ITS will be used to evaluate changes in service delivery that occur during the study timeframe. SAS (SAS Institute Inc., Cary, NC) version 9.3 will be used for all statistical analysis.

5. Ethical Considerations

This study will be conducted in compliance with the protocol approved by the Health Research Ethics Board of Alberta-Cancer Committee (HREBA-CC) and according to Good Clinical Practice standards. No deviation from the protocol will be implemented without the prior review and approval of the HREBA-CC except where it may be necessary to eliminate an immediate hazard to a research subject. In such case, the deviation will be reported to the HREBA-CC as soon as possible.

All subjects with capacity will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. Consent forms will be submitted with the protocol for review and approval by HREBA-CC **(Appendices E and F).** The formal consent of a subject, using the HREBA-CC approved consent form, will be obtained before that subject is submitted to any study procedure. This consent form will be signed by the subject and the investigator-designated research professional obtaining the consent. An authorized third party (e.g. substitute decision maker on an enacted personal directive) may consent to the study and sign the consent form on behalf of a patient without capacity. If the patient regains capacity during the study, the authorized third party‘s consent will end. The authorized third party will be asked to contact the study team, or study doctor, if the patient regains capacity, at which time the patient will be asked to provide consent on his/her own behalf.

Patients and caregivers will be notified that their respective data will be linked to each other.

5.1 Risk/Benefits

Risks. There are no physical risks to study participants. The risk of emotional discomfort is minimal. Due to the nature of considering end-of-life care, the study may cause mild emotional distress in some participants. However, it is anticipated that patients who are uncomfortable

with the topic will not agree to participate to begin with.

This potential risk is mitigated by two features of the study design. First, participants will be told that they may end their study participation at any time. They will also be told that they do not have to answer any questions that they do not feel comfortable with. Secondly, enrollment and administration of questionnaires will be structured; the study staff will follow a script with interview questions. The study staff will receive training about ethical conduct of studies involving human subjects, and be oriented to symptoms, treatment and potential issues in the relevant settings. Participants will be reminded that if they have concerns or are distressed to contact their health care provider.

Benefits. Potential benefits to study participants include encouragement to talk about their health care experiences and concerns. The results of the study may help improve quality of care patients receive in the future.

6. Data Handling and Record Keeping

Participants will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information, including medical records, personal data, and research data collected during the course of this study, so that the participant's identity will be kept confidential. Information that directly discloses a participant's identity will remain only with the Principal Investigator and/or designate. Participants will not be identified by name in any reports of the completed study.

A master subject identification list will be created to link study participant information with assigned study identification number. The list that matches names to the unique identifier that is used on research-related information will not be removed or released without consent unless required by law. Access to this master list will be approved only for researchers involved in the study. The master subject identification list and consent forms will be kept separate from the study data and will be kept in a locked cabinet in a locked office at the University of Calgary/ University of Alberta. Additionally, we will have a password protected electronic file of the master identification log housed in the University of Calgary's Cumming School of Medicine Information Technologies Secure Computing Data Storage service, as well as firewalled AHS servers of the Principal Investigators.

Answers for assessments will be entered into REDCap using University of Calgary/University of Alberta owned laptops. REDCap is a secure, web-based application locally hosted by the University of Calgary's Clinical Research Unit.

All electronic data (e.g. digital files) will be uploaded and stored within a secure drive on a University of Calgary/University of Alberta encrypted and password protected computer (e.g. within the University of Calgary Cumming School of Medicine's Information Technologies Secure Computing Data Storage Service), as well as firewalled AHS servers of the Principal Investigators.

Access to study data will be restricted only to study personnel, and to authorized representatives from the University of Calgary, University of Alberta, and the HREBA-CC, who may review identifiable medical/clinical study records for quality assurance purposes.

De-identified data will be shared with Canadian Partnership Against Cancer (CPAC) for the purposes of conducting the economic analysis (including analysis of PSAFE data).

Retention. Participant consent forms, case report forms, interview notes, and the master subject identification list will be kept for 5 years from the end of the project to comply with federal regulations and to accommodate data validation queries. Study data may be transported and retained for long-term storage at a secure data repository owned by the University of Calgary called the High Density Library, located at the Spy Hill Campus, for the length of time specified by the ethics board before destruction. All files will be deleted using document shredding and deletion of any electronic files from the secure drives.

Data collected from or about participants who pass away during the study will be used.

7. Supplements

Appendix	Title
A	Study Information poster-leaflet
B	Clinician's inclusion/exclusion criteria checklist card and script
C	Consent-to-contact form
D	Inclusion/Exclusion Criteria Case Report Form
E	Informed Consent Form-Patient
F	Informed Consent Form-Caregiver
G	Putting Patients First (PPF) with ESAS-r and Canadian Problem Checklist
H	EQ-5D-5L Questionnaire
I	The Preparedness for Caregiving Scale
K	My Conversations Questionnaire
L	Enrollment ECOG-Patient Language Adaption
M	Patient Enrollment Questionnaire
N	Participant Contact Form
O	Caregiver Enrollment Questionnaire
P	Enrollment Chart Abstraction Case Report Form
Q	Translation Attestation form
R	Translation Attestation signature form
S	Caregiver Voice
T	Language Translations of Appendices applicable to participants (T1- T13)
U	Patient Self-Administered Financial Effects (PSAFE)

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