Advance Care Planning Evaluation in Elderly Patients: A multicenter, prospective study

Implementation Manual

Volume 1: Conduct of the Study in Hospital or Acute Care Setting

This study is registered at ClinicalTrials.gov
Identification #: NCT01362855
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Introduction

This Implementation Manual is provided by CERU (the coordinating centre) as a guide to study conduct and expectations. It is intended to supplement the study protocol, *Advance Care Planning Evaluation in Elderly Patients: A multicenter, prospective study, The ACCEPT Study*. This manual is applicable to patients and family members in hospital and acute care settings.

**Abbreviations used in this manual:**

- **ACP**  Advance Care Planning
- **AD**  Advance Directive
- **CERU**  Clinical Evaluation Research Unit (Coordinating Centre)
- **CRF**  Case Report Form
- **CRS**  Central Randomization System (electronic system where screening & enrolment data is entered)
- **DNR**  Do not resuscitate
- **EOL**  End of Life
- **ICF**  Informed Consent Form
- **ICH GCP**  International Conference on Harmonization Good Clinical Practices
- **LST**  Life-sustaining treatment
- **REDCap**  The electronic data capture system for the study

**Coordinating Centre Contacts**

<table>
<thead>
<tr>
<th>Dr. Daren Heyland</th>
<th>Kingston General Hospital</th>
</tr>
</thead>
<tbody>
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<td>Principal Investigator</td>
<td>Angada 4, 76 Stuart Street</td>
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<td>Kingston ON K7L 2V7</td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Jennifer Korol</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Project Leader</td>
<td></td>
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<td>Email: <a href="mailto:korolj@kgh.kari.net">korolj@kgh.kari.net</a></td>
<td></td>
</tr>
</tbody>
</table>

All questions related to study procedures should be directed to the Project Leader.
Study Synopsis

Primary Research Question: In patients at high risk of dying,

1) To what extent have the components of the ACP process already been conducted with such patients and their families?
2) What are the barriers and facilitators to an ACP conversation from their (and their family’s) point of view?
3) What is their level of satisfaction with EOL communication and decision-making as measured by the CANHELP satisfaction questionnaire?

Design: This is a multicenter, prospective, design that will involve audit of current practice, followed by several audit-feedback cycles with tailored interventions designed to improve ACP practice.

Setting: Hospitals and acute care institutions in Canada and the United States.

Study Population: We will enroll patients who are at high risk of dying and/or their families (where available). We will approach consecutive, eligible patients and their family members from participating hospital units for enrollment into this study.

Study Intervention: We will time our initial approach to be after the patient has been in the hospital for at least 48 hours up until the 120th hour (i.e. between 48 – 120 hours following hospital admission) to allow for symptoms present at the time of admission to have abated enough for the patient and family to participate in an interview. Upon enrollment, the research assistant will conduct separate interviews with patients and family caregivers so they cannot influence each other’s responses.

The research assistant will administer the questionnaires in a face-to-face interview. From direct interview of either the patient and/or family and chart abstraction, we propose to capture standard baseline demographics including overall pre-admission health status (Global Rating Question from SF-36), a brief frailty scale, co-morbid illnesses using the Functional Co-morbidity Index and the Charlson Co-morbidity Index, and the Palliative Performance Status score as a measure of functional status. We will then administer a questionnaire that we will develop to evaluate whether the patient or family has engaged in ACP and to elicit their perceived barriers and facilitators to having these kinds of ACP-related conversations. Immediately following this questionnaire, the research coordinator will administer the CANHELP satisfaction questionnaire (described below). Upon completion, the research assistant will review the medical record examining for the presence of ‘Goals of Care” orders, ‘DNR’ orders and any order to withhold, limit, or withdraw life-sustaining therapies. The presence or absence of the ‘Greensleeve’, its contents, or any other chart documentation of a discussion with the patient and family will be
documented. At the conclusion of the hospital stay (following death or discharge), the research assistant will abstract data on hospital outcomes and resource utilization.

**Outcomes:** The primary outcomes of this study will be completion of ACP documentation and satisfaction with EOL care.

**Significance:** This will be the first large scale evaluation of ACP in Canada and abroad. The results will provide information on the current successes (and challenges) of ACP which will strengthen ACP implementation efforts across the country. Lessons learned can effectively be disseminated across the country with our partnership with CHPCA. By increasing the quality and quantity of ACP, we stand to make huge improvements in quality of EOL care in Canada and across the world and reduce overall health costs.
Pre-Implementation Activities

Ethics Committee Approval
All participating institutions must obtain local ethics committee approval in advance of study implementation at the local site. Local ethics committee policies should be followed when preparing the submission. Documents provided by the coordinating centre to the local sites to facilitate ethics committee submissions include:

- Protocol
- Informed Consent Form (ICF) template
- Patient & Family Member ACP Questionnaires
- Degree of System Implementation Questionnaires
- Case Report Form (chart abstraction)

If any changes are made to the protocol or tools over the duration of the study, it is the responsibility of the participating institution to ensure ethics committee approval is obtained for any amended documents.

Since the ACCEPT Study is an observational study (non-therapeutic, non-randomized), the local ethics committee may find it permissible to submit the study on an expedited basis. Local sites should communicate with their respective ethics committee to determine the appropriate method of submission.

It is the responsibility of the participating institution to ensure they complete any annual renewals for the study. The institution’s local ethics committee will have specific forms and instructions regarding completing an annual renewal.

Documentation of local ethics committee approval, including the ethics committee approved ICF, and any annual renewals must be forwarded to the Project Leader (PL) prior to the implementation of the study at the site.
**Study Duration**

The Implementation phase of the study will include distinct audit cycles conducted annually. Each Audit Cycle consists of a data collection/entry period followed by the generation of reports and development and implementation of action plans.

**Diagram 1: Audit Cycle Activities**
Setting the Stage

Finding the Correct Patient Population
In advance of commencing the audit cycle, it is advisable to determine which patient units to target for screening. The optimal ward would be where your general medical or renal patients are admitted. You may have success on oncology wards and less success on surgical wards. Focus on patients that are admitted to hospital from outside (ER, home, other hospital). Note: We are not recruiting patients or families of patients who are in the Intensive Care Unit (ICU). We are not recruiting patients or families of patients who are under the Palliative Care Service.

Staff Education and Awareness
In-servicing and education of unit staff is an important aspect to initiating the study at the participating institution. One method of disseminating information concerning the study is to distribute a Letter of Information to clinical staff. This document could be emailed, placed in communication binders or distributed as the local team sees fit. (Refer to Appendix A for a Sample Letter of Information).

Another important aspect of this process is ongoing education and promotion of the study to attending physicians, residents, nurses and other health care workers. It is helpful to begin to cultivate a relationship with health care workers on the targeted patient units by identifying the local study team (i.e. Study investigator, research coordinators, research assistants). Messages to deliver to unit staff are the study rationale and the type of patients we are recruiting.

Information posters targeted towards health care professionals on the units are being provided to sites by the coordinating centre. If you choose to use these, you must submit these to your local ethics committee for approval prior to using them.

Approaching Patients and Family Members
Once the audit cycle begins, the participating institution should initiate recruitment activities. The local team should screen for eligible patients/family members on the targeted units. Potentially eligible patients may be identified by seeking input from the attending physician, medical residents, nurses, other healthcare staff, and/or by reviewing the medical chart to determine whether the patient meets the inclusion criteria.

Before approaching the patient/family member for consent, confirm eligibility by reviewing the medical chart (if not already done) and confirm ‘suitability’ of the patient/family member by discussing the case with a member of the health care team. By suitability, we mean that the patient/family member has the physical/emotional stamina and cognitive capacity to participate in the questionnaire. We do not have a formal capacity assessment tool that we use, just the judgment of the bedside nurse or attending physician. It is important that all patients/family
members who meet the eligibility criteria are approached for consent. Regarding the patient, if they have a test scheduled or ‘is having a bad day’ (i.e., symptomatic), then perhaps return at another date.

Patients unable to communicate due to language (non-English/non-French speaking) or cognitive reasons will be excluded. However, if their family member is eligible (i.e. English/French speaking) and available, we can still approach the family member.

Study patients will be asked to identify, if applicable, a family member who knows them the best (inclusive of partners, significant others, and/or close friends) who:

1) Is greater than 18 years old;
   and
2) Has visited the patient in hospital at least once
   and
3) Who provides the most care to the patient and is not paid to do so.

Family members that are ‘out of province’ are not eligible to participate since they do not meet criteria 2 & 3 as noted above.

If there is more than one family member available, we will allow the patient to select who participates.

If the patient is too sick to identify a family member, the researcher should approach the clinical team or medical chart to see if there is a documented Power of Attorney or substitute decision maker. In the absence of such documentation, the researcher may then approach the family.

When approaching the family, the appropriate individual will often identify themselves to the researcher as the appropriate family caregiver respondent for the study. Typically the patient’s spouse or child will be the next appropriate family member respondent. Only one family member respondent can participate in the ACCEPT Study.

For the purposes of this study, the term family member refers to any caregiver that meets the definition above. A family member or caregiver does not have to be a relative, they could be a close friend or neighbour.

If there is no available family member, we will still enroll just the patient but wherever possible, we will try and enroll both patient and family members.
We will time our initial approach to be between the 48th and 120th hour, after hospital admission, to allow for symptoms present at the time of admission to have abated enough for the patient and family to participate in an interview.
**Recruitment**

## Inclusion Criteria

<table>
<thead>
<tr>
<th>#</th>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>55 years or older with one or more of the following diagnoses:</td>
</tr>
</tbody>
</table>
|    | ▪ **Chronic obstructive lung disease**  
  Defined by at least two of the four following criteria:  
  (a) Baseline PaCO2 of ≥ 45 torr,  
  (b) cor pulmonale;  
  (c) Respiratory failure episode within the preceding year  
  (d) Forced expiratory volume in 1 sec <0.5 L |
|    | ▪ **Congestive heart failure**  
  New York Heart Association class IV symptoms and left ventricular ejection fraction < 25%. |
|    | ▪ **Cirrhosis**  
  Confirmed by imaging studies or documentation of esophageal varices and one of three conditions:  
  a) hepatic coma,  
  b) Child’s class C liver disease  
  c) Child’s class B liver disease with gastrointestinal bleeding. |
|    | ▪ **Cancer**  
  Metastatic cancer or stage IV lymphoma |
|    | ▪ **End-stage dementia**  
  (inability to perform all ADLs, mutism or minimal verbal output secondary to dementia,  
  bed-bound state prior to acute illness) |
|    | ▪ **Renal Failure**  
  Defined as chronic renal failure requiring dialysis. |
| **OR** | |
| 2 | Any patient 80 years of age or older admitted to hospital from the community because of an acute medical or surgical condition. |
| **OR** | |
| 3 | Any patient 55 to 79 years of age admitted to the hospital, who does not meet the above criteria, but in the opinion of a health care team member (Doctor, resident, nurse),  
  he/she would not be surprised if the patient died in 6 months. |
Child’s Class B + C Liver Disease Classification
To determine whether a patient qualified for the study based on the Cirrhosis criteria b & c, use the following table.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Points assigned</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total Bili</strong></td>
<td></td>
</tr>
<tr>
<td>Conventional SI units</td>
<td>&lt; 2 mg/dl</td>
</tr>
<tr>
<td></td>
<td>&lt; 34 μmol/L</td>
</tr>
<tr>
<td><strong>Serum Albumin</strong></td>
<td></td>
</tr>
<tr>
<td>Conventional SI units</td>
<td>&gt; 3.5 g/dL</td>
</tr>
<tr>
<td></td>
<td>&gt; 35 g/L</td>
</tr>
<tr>
<td><strong>Prothrombin time or INR</strong></td>
<td></td>
</tr>
<tr>
<td>&gt; 4 seconds</td>
<td>4 – 6 seconds</td>
</tr>
<tr>
<td>&lt; 1.7</td>
<td>1.7 – 2.3</td>
</tr>
<tr>
<td><strong>Ascites</strong>*</td>
<td>Absent</td>
</tr>
<tr>
<td><strong>Encephalopathy</strong></td>
<td>None</td>
</tr>
</tbody>
</table>

* Refer to ultrasound results. If ascites has been drained in the past, it should be considered Moderate.

The Child-Pugh score is obtained by adding the points for all 5 criteria. Any patient having a score of 7—9 falls into Group B (significant functional compromise) and 10 – 15 falls into Group C (severe hepatic impairment). Child’s Class B (with gastrointestinal bleeding), or Class C in conjunction with documented/confirmed cirrhosis is an inclusion criteria.

Correctly Documenting the Inclusion of ≥ 80 Year Olds
For patients ≥80 years old, it is important to, whenever possible, document the specific diagnosis present.

For example: If a patient is 82 years old with COPD, they should be entered into the CRS as meeting inclusion criteria 1 “55 years or older with one or more of the following diagnoses: COPD.”

For example: If a patient is 85 years old, admitted to the hospital with a UTI, since they do not meet any of the specific diagnoses in inclusion criteria #1, they should be logged as inclusion criteria #2 “Any patient 80 years of age or older admitted to hospital from the community because of an acute medical or surgical condition.”

Clarification regarding qualifying a patient for the study using the COPD inclusion criteria: It is often difficult to find forced expiratory volume (FEV1) data in the medical chart. If the medical notes document "severe" COPD and/or air flow limitation and everything else about the condition confirms that (i.e. limited functional capacity, on home 02, frail, etc.), AND they meet one of the other formal inclusion criteria, this patient can be included in the study. Don’t exclude just because you can’t find the FEV 1 data and yet they are severe COPD.

**Exclusion Criteria**

<table>
<thead>
<tr>
<th>#</th>
<th>Patient</th>
<th>Family Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Non-English/Non-French speaking patient</td>
<td>Non-English/Non-French speaking family member</td>
</tr>
<tr>
<td>2</td>
<td>Cognitive impairment</td>
<td></td>
</tr>
</tbody>
</table>

All excluded respondents should be entered into the CRS.
Patients or Family Members who are Legally Blind
Patients and/or family members who are legally blind are eligible to participate in the study. When administering the ACP Questionnaire simply omit the REALM score (Section 1, Health Literacy) and try to get through the rest of the questionnaire.

Eligible but Not Approached for Consent
There will be instances where a respondent is eligible to be included in the study based on the entry criteria however, it is not appropriate to approach them for consent to participate. Some examples of situations where this is the case include:

- **Newly Diagnosed Patients**
  Do not enroll a newly diagnosed patient (e.g. new diagnosis of metastatic cancer). These discussions would be very sensitive in a newly diagnosed patient. The intent of the study is to speak with those that have an established diagnosis.

- **Actively Dying Patients**
  If a patient is in the process of ‘actively dying’ do not approach them or their family members for participation in the study.

If the patient/family member was not approached for consent, document the reason why using the best response from the taxonomy below.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Family Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge soon</td>
<td>Discharge soon</td>
</tr>
<tr>
<td>Can’t hear well</td>
<td>Can’t hear well</td>
</tr>
<tr>
<td>Can’t see well</td>
<td>Can’t see well</td>
</tr>
<tr>
<td>Difficulty speaking</td>
<td>Difficulty speaking</td>
</tr>
<tr>
<td>At request of health care team</td>
<td>At request of health care team</td>
</tr>
<tr>
<td>&gt;120 hours from hospital admission</td>
<td>Family member not available</td>
</tr>
<tr>
<td>Newly diagnosed</td>
<td>&gt;120 hours from hospital admission</td>
</tr>
<tr>
<td>Actively dying</td>
<td>Newly diagnosed</td>
</tr>
<tr>
<td>Other (specify): _____________</td>
<td>Actively dying</td>
</tr>
<tr>
<td></td>
<td>Other (specify): _____________</td>
</tr>
</tbody>
</table>

All eligible respondents not approached for consent should be entered into the CRS.
Obtaining Consent
Following confirmation of patient/family member eligibility, the researcher should seek consent for the patient/family member to participate in the ACCEPT Study.

“Free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.”
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Procedures for Obtaining Informed Consent
The following procedures are recommended when obtaining informed consent for a potential ACCEPT Study Patient/Family Member:

1) The study team member obtaining consent is qualified to do so, and is knowledgeable in the study procedures, and rationale for the study.
2) Assess the Patient/Family Member’s competence to consent to research, and document if you deem this individual incompetent.
3) Review the study details with the Patient/Family Member in a quiet, private location.
4) Do not coerce or unduly influence the Patient/Family Member to participate, or continue to participate in the study. If the Patient/Family Member is showing signs of stress, ask if they would like you to come back at another time.
5) Fully inform the Patient/Family Member of all pertinent aspects of research, in non-technical language that is easy to understand. If the Patient/Family Member does not speak English/French they should be excluded.
6) Provide a copy of the ICF and allow the Patient/Family Member ample time to read the ICF and ask questions.
7) Ask the Patient/Family Member questions to assess their comprehension of the material reviewed. Ensure he/she fully understands the information.
8) Ascertain the Patient/Family Member’s willingness to participate.

It is important to document the reasons why consent was refused for the patient/family member. If the patient/family member was approached for consent and refused to participate, please indicate the reason using the list below.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Family Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not interested</td>
<td>Not interested</td>
</tr>
<tr>
<td>Too upsetting</td>
<td>Too upsetting</td>
</tr>
<tr>
<td>Too tired</td>
<td>Too tired</td>
</tr>
<tr>
<td>Too sick</td>
<td>Too sick</td>
</tr>
<tr>
<td>Discharge soon</td>
<td>Can’t hear well</td>
</tr>
<tr>
<td>Can’t hear well</td>
<td>Can’t see well</td>
</tr>
<tr>
<td>Can’t see well</td>
<td>Other (specify):</td>
</tr>
<tr>
<td>Other (specify):</td>
<td>Other (specify):</td>
</tr>
</tbody>
</table>

Version: 15-Feb-2013
9) If consent is obtained, both the Patient/Family Member and the researcher will sign and date the ICF document.
10) Document the consent process (both granted consent and refusals) in the patient medical chart.
11) Place a copy of the ICF in the patient medical chart.
12) Provide the Patient/Family Member with a copy of the signed document.
13) File the originally signed ICF in the local site study files.
14) Enter the consent ‘granted’ or ‘refused’ information in the CRS.

The research site should always adhere to ethics committee procedures when obtaining informed consent. Any questions should be forwarded to the local ethics committee at the site.

Some participating institutions are required by their ethics committee to leave a letter regarding the study at the patient’s bedside before they speak to them. Refer to Appendix G for a sample letter that may be tailored to specific institutional requirements.

The Government of Canada website for the Tri Council Policy Statement Panel on Research Ethics provides a free online training course regarding research ethics. Anyone can access this training at the following link: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/
You will be provided with a Training Certificate upon completion of the course.

**Consent Scenarios**

Since the ACCEPT Study involves both patient and family member participation, it is possible that different scenarios may arise concerning granting consent and refusing consent. The table below outlines these different situations along with any special procedures or considerations.

<table>
<thead>
<tr>
<th>Patient Consent Response</th>
<th>Caregiver Consent Response</th>
<th>Procedures/Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>A separate ICF should be signed by the patient and the family member.</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Consent should be signed by the patient.</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>None.</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Consent should be signed by the family member.</td>
</tr>
</tbody>
</table>

Remember:
1) Enter all patients that meet Inclusion Criteria into the CRS, including those that are not approached for consent or those that refuse consent.
2) File the original ICF in the Patient study file.
Enrollment

A total of 60 enrollments are expected at each participating institution during each Audit Cycle. Of the 60 enrollments, at a minimum, there should be 20 patient and 20 family member respondents. For example, a site may enroll 22 patient respondents and 38 family member respondents.

The Patient/Family Member data collection package consists of the ACP questionnaire (patient and/or family member version) and the Case Report Form (medical chart data abstraction form).

Patient/Family Member data collection can begin after consent is obtained and the Patient/Family Member is formally enrolled into the study using the CRS.

The following table illustrates data collection for patients and family members given the different consent scenarios noted in Table 1.

<table>
<thead>
<tr>
<th>Patient + Family Member</th>
<th>Patient Only</th>
<th>Family Member Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACP Questionnaire</td>
<td>ACP Questionnaire</td>
<td>ACP Questionnaire</td>
</tr>
<tr>
<td>Patient Version &amp;</td>
<td>Patient Version</td>
<td>Family Member Version</td>
</tr>
<tr>
<td>Family Member Version</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case Report Form (CRF)</td>
<td>Case Report Form (CRF)</td>
<td>Case Report Form (CRF)</td>
</tr>
</tbody>
</table>

Enrolling Patients and Family Members at Different Times

It has been observed at some participating institutions that it is can be difficult to enroll family members since they often have other obligations that take them away from the hospital during regular business hours. If you are having difficulty enrolling family member respondents we suggest you make initial contact with family members by telephone to arrange for a mutually agreeable time to meet. We suggest you:

1) Identifying yourself as a member of the patient’s healthcare team.
2) Indicate the patient/family member is eligible for a study we are conducting about hospitalized elderly patients.
3) Indicate you would like to make an appointment with them to further discuss.

We are not suggesting that consent be obtained by telephone; rather we are proposing to simply make the initial contact with them in this manner. The consent process and interview would take place at an agreed upon meeting time.

**Ensure you check with your ethics committee to ensure this strategy is acceptable.

Patient/Family Member Confidentiality

By definition, and in the context of a research study, confidentiality refers to prevention of disclosure, to unauthorized individuals, of a Patient/Family Member’s identity and of records that could identify a Patient/Family Member. Care and diligence in protecting confidential Patient/Family Member information must be exercised throughout the duration of the ACCEPT
Study. It is advisable for sites to consult with their institutional procedures regarding privacy and confidentiality to ensuring they are adhering to local standards.

All Patient/Family Member’s must be identified with a unique identifying enrollment number. (Refer to pg. 24 for assignment of enrollment numbers). Remember to document the patient’s medical record number for later retrieval of the medical record for chart abstraction. Implementation Manual Volume 2 provides further details concerning chart abstraction.

**Screening/Enrollment Algorithm**

We encourage sites to adapt screening practices that are efficient and optimize their valuable time. Based on experiences at Kingston General Hospital, we are offering the following screening/enrollment algorithm as a tool for sites to identify and enroll eligible patients. (Please note adoption of this strategy is not mandatory, and local ethics committee requirements concerning screening and enrollment should be followed).

```
Determine new admissions to the ward.  
Review the medical chart.  
**Does the patient meet the study inclusion criteria?**

YES

Speak with the patient's nurse/charge nurse to get a sense of the social situation (i.e. sense of suitability).  
**Do you think that it is reasonable to approach the patient/family member for consent?**

YES

Approach the patient/caregiver for consent.  
Refer to the initial encounter script for a suggested approach to initiating discussions regarding ACCEPT.  
**Did you obtain consent from the patient/family member?**

YES

Proceed to administer the study questionnaires and collect data.

NO

Screen the ward again tomorrow

NO

Enter this respondent on the Screening & Enrollment Log

NO
```

Version: 15-Feb-2013
**Overview of Data Collection and Entry**

The following diagram illustrates the flow of data from determination of inclusion into the study through to generation of the local site benchmark report. It is important for researchers to note that there are two study databases that require data entry. The first is the Central Randomization System (CRS); this is where the research team will enter eligibility data on both included and excluded respondents. The second database called REDCap is where the ACP Questionnaire responses and chart abstraction data are entered. Together, the information entered into these databases will inform the results presented to you in your Site Report.
Documenting Screening Activities
All participating institutions screening efforts should be entered into the web-based CRS (electronic database. The CRS can be accessed at:

https://ceru.hpcvl.queensu.ca/randomize/

The CRS is an important tool to document recruitment practices at the sites. The CRS will inform sites of:

- The duration of the data collection period for each audit cycle
- Hospital units where recruitment activities are most successful
- Patient population being included
- Reasons for exclusion
- Why consent is not obtained

To Enter Screening Data and/or to Enroll a Patient

1) Log in to the CRS.

2) Select the ACCEPT Study from the list of studies.

A username and password will be granted to each user after training has been completed.
3) You will be brought to your Site Status page. This page will list all of the patient/family members you have screened and/or enrolled to date.

4) To view existing data simply click on the screening or enrollment number of interest. The Screening Form for that particular patient/family member will open.

5) To enter data on a new Patient/Family Member, click on the “Add Patient” link on the left menu bar.
6) You will next be taken to the Screening Form. Patient eligibility criteria will always be the first data entry screen.

7) Indicate which inclusion criteria the patient meets. Indicate whether the patient meets any exclusion criteria. Select SAVE.

**Inclusion**

1. Patient's Age: [66]
2. Inclusion criteria present: [55 years or older with qualified diagnosis (specify)]

Specify diagnoses (all that apply):
- ☐ Chronic obstructive lung disease.
- ☐ Congestive heart failure.
- ☐ Cirrhosis.
- ☐ Cancer.
- ☐ End-stage dementia.
- ☐ Renal failure.

**Exclusion**

1. Is the patient non-English/French speaking?: [Yes]
2. Is the patient cognitively impaired?: [Yes]

8) You will be taken to the Patient Status Page. Next you will enter data regarding the family member by selecting Family Member Screening Form.
9) Enter the data for the family member.

In this case the family member is excluded.

In this case the family member is eligible.

If the family member is approached for consent, and consent is granted, record the date consent is obtained and then SAVE the form.
If the family member is NOT approached for consent, indicate the reason why using the drop-down menu, then SAVE the form.

If the family member is approached for consent, but declines to participate, indicate the reason why using the drop-down menu, then SAVE the form.
10) When a family member or patient is enrolled you will see an enrollment confirmation form. You can print this form for your study file.

Unique Respondent Identification Numbers

All patient/family members entered into the CRS will have a screening number. The screening numbers are assigned sequentially in an 8-digit format:

'0' notes a screened patient/family member

1002-0016

Site #   Screening #

Those patient/family members that proceed to be enrolled will also be issued an enrollment number. The enrollment numbers are assigned sequentially in an 8-digit format:

'1' notes an enrolled respondent

1002-1001

Site #    Enrollment #

When you are logged into the CRS, at a glance you will be able to tell what type of respondent is associated with each enrollment number:

Site Status Page

<table>
<thead>
<tr>
<th>Screening #</th>
<th>Enrollment #</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1002-0012</td>
<td>1002-1007</td>
<td>Patient enrolled</td>
</tr>
<tr>
<td>1002-0011</td>
<td>1002-1006</td>
<td>Family member enrolled</td>
</tr>
<tr>
<td>1002-0005</td>
<td>1002-1003</td>
<td>Family member enrolled</td>
</tr>
<tr>
<td>1002-0004</td>
<td>1002-1002</td>
<td>Family member enrolled</td>
</tr>
<tr>
<td>1002-0003</td>
<td>1002-1001</td>
<td>Patient enrolled</td>
</tr>
<tr>
<td>1002-0010</td>
<td>-</td>
<td>Not Enrolled</td>
</tr>
<tr>
<td>1002-0009</td>
<td>-</td>
<td>Not Enrolled</td>
</tr>
</tbody>
</table>
Training Modules

Online self-training modules will be made available to participating institutions. It is the responsibility of participating institutions to self-administer the training modules to orient research staff to study procedures.

Site Training Modules are available to participating hospitals online at:

http://www.thecarenet.ca/index.php?option=com_content&view=article&id=155&Itemid=97

Training modules cover the following topics:

- Module 1: Background, Overview and Preparation
- Module 2: Respondent Eligibility Criteria
- Module 3: Obtaining Consent
- Module 4: CRS
- Module 5: Audit Cycle Begins
- Module 6: Data Collection
- Module 7: Data Entry (RedCap)

Any questions regarding study procedures can be directed to the Project Leader.
Audit Cycle Begins

The coordinating centre will communicate the Audit Cycle start date. Participating institutions may begin to recruit patients/family members and conduct the study before or after the target start date, as long as they have the necessary resources and training to begin.

There are 2 types of data collection to be conducted during each Audit Cycle:

1. Institution Level Data
2. Patient/Family Member Level Data

Institution Level Data
Collection of institutional data will allow for a comparison between those institutions with low and high degrees of system level implementation to determine if there is a higher prevalence of ACP and greater satisfaction of EOL communication and decision-making in institutions with higher degrees of system level implementation.

Institution Level Data: Assessment of Degree of System Implementation
At the commencement of each audit cycle, each participating institution should complete the Assessment of Degree of System Implementation – ACUTE CARE UNIT and HEALTH ADMINISTRATION LEVEL Questionnaires. Refer to Appendix C & D for each Questionnaire.

The ACUTE CARE UNIT version of the questionnaire should be completed by interview with the hospital staff member (Patient Care Coordinator, Manager) with responsibility for overall unit or specific involved program(s) from which the patients are recruited. The HEALTH CARE ADMINISTRATION LEVEL version of the questionnaire should be completed by interview with the individual (who is knowledgeable regarding ACP activities in the health region/authority/zone). This may be the palliative care team. Smaller institutions may not have an ideal respondent for this version of the questionnaire.

Following the completion of both questionnaires, the data should be entered into REDCap. Refer to the Implementation Manual Volume 2 for data entry instructions.
Patient /Family Member Data

Administering the Questionnaires

Each interviewer will develop their own style concerning the administration of the questionnaire. Some useful tips include:

- Use the respondent’s name
- Introduce yourself and your specific role
- Ensure the respondent is ready and you have a private location to conduct the interview.
- Remove barriers to communication
- Ensure comfort and put the respondent at ease

**General Instructions**

1. Determine which ACP Questionnaire should be administered to the Respondent (i.e. Patient or Family Member version).

2. The questionnaires should be administered in-person with the respondent. **Do not** give the questionnaires to the respondent to fill out at their leisure.

3. Read each question to the respondent, if the respondent does not understand, repeat the question. The researcher administering the questionnaire should not interpret the questions for the respondent.

4. When the question is open-ended, do not paraphrase or change the respondent’s answer. Record the answer verbatim.

5. If the respondent ‘declines’ to respond to a particular question, make a note in the margin. You will be able to note this when entering the data into the database (see REDCap training module).

6. Some questions have several response options. For these questions we have developed reference cards that can be handed to the respondent to aid with their responses. If applicable, the interviewer will note a statement after the question “**give CARD # to respondent.**”

7. If both the patient and family member are enrolled, conduct the interviews as close to each other as possible. They can be conducted up to 1 week apart however, every effort should be made to conduct them as close to each other as possible.

8. If the interview is started, then part way through the respondent withdraws their consent to continue do not discard the questionnaire.
a. Questionnaires that are \( \geq 50\% \) complete should be included.
b. Questionnaires that are \( < 50\% \) complete cannot be included. Another patient will need to be enrolled to replace this respondent. Contact the Project Leader for guidance on how to document this occurrence.

**ACP Questionnaire Breakdown**
The table below outlines the different sections of the ACP questionnaire, both patient and family member versions.

<table>
<thead>
<tr>
<th>Patient Version</th>
<th>Family Member Version</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 1</strong></td>
<td><strong>Section 1</strong></td>
</tr>
<tr>
<td>▪ Patient Demographics</td>
<td>▪ Family Member Demographics</td>
</tr>
<tr>
<td>▪ Frailty Index</td>
<td>▪ Patient Demographics, if applicable</td>
</tr>
<tr>
<td></td>
<td>▪ Patient Frailty Index, if applicable</td>
</tr>
<tr>
<td><strong>Section 2</strong></td>
<td><strong>Section 2</strong></td>
</tr>
<tr>
<td>▪ Determinants of Decision Making</td>
<td>▪ Determinants of Decision Making</td>
</tr>
<tr>
<td><strong>Section 3</strong></td>
<td><strong>Section 3</strong></td>
</tr>
<tr>
<td>▪ Decisions About Health care Prior to Hospitalization</td>
<td>▪ Decisions About Health care Prior to Hospitalization</td>
</tr>
<tr>
<td><strong>Section 4</strong></td>
<td><strong>Section 4</strong></td>
</tr>
<tr>
<td>▪ Goals of Care During Current Hospitalization</td>
<td>▪ Goals of Care During Current Hospitalization</td>
</tr>
<tr>
<td><strong>Section 5</strong></td>
<td><strong>Section 5</strong></td>
</tr>
<tr>
<td>▪ CANHELP Lite</td>
<td>▪ CANHELP Lite</td>
</tr>
<tr>
<td><strong>Section 6</strong></td>
<td><strong>Section 6</strong></td>
</tr>
<tr>
<td>▪ Barriers &amp; Facilitators</td>
<td>▪ Barriers &amp; Facilitators</td>
</tr>
<tr>
<td><strong>Section 7</strong></td>
<td><strong>Section 7</strong></td>
</tr>
<tr>
<td>▪ Documentation of ACP/AD in the Medical Chart at the End of the Interview</td>
<td>▪ Documentation of ACP/AD in the Medical Chart at the End of the Interview</td>
</tr>
</tbody>
</table>
Section 1: Baseline Demographics

We have developed a comprehensive list of demographics that will enable us to adequately describe the patients involved in this study. These data may help us explain if certain types of patients are or are not involved in ACP. Most of these demographic questions are self evident. A few of them warrant further explanation as to why we are collecting them or how to collect them, these details are found below.

Health Literacy (REALM)

Health Literacy is a key determinant to preferences for EOL treatment. We are using a validated short item questionnaire to measure health literacy, the REALM tool. REALM is a medical-word recognition and pronunciation test comprising of medical terms arranged in order of complexity by the number of syllables and pronunciation difficulty.

1) Provide the respondent with the reference card (CARD 1).
2) Ask the respondent to read down the list, pronouncing aloud as many words as they can.

3) As the respondent reads the list, the interviewer scores the number of words pronounced correctly. (It is not important to know which words are correct, rather it is important to capture the number of correctly pronounced words.)

Note: if a respondent is legally blind, omit this section from the administration of the questionnaire.

**Ethnicity and Language**

Recording ethnicity is quite problematic and providing long lists of various ethnic groups, like we have in past survey data, has not yielded valid results. We are trying a novel method for determining the impact of ‘ethnicity’ on access to health care resources. It turns out that disparities are most related to whether you appear as a visible minority and speak another language, other than the 2 official languages of Canada.

**Figure 1:** The multicultural population

![Multicultural Population Diagram](image)

We will categorize patients as to whether they appear to be Caucasian (this should be discerned by appearance) and by asking the patient if they are proficient in another language other than English (or French if in Quebec). In the end, we will want to be able to categorize patients (or family members) in one of the 4 quadrants below (See Figure 1).

**Frailty Estimation**

Complete the frailty estimation by considering the patient’s overall condition two (2) weeks prior to this admission to the hospital. The respondent can be provided with the applicable reference card (CARD 2).

In instances when an interview is conducted with both the patient and their family member, there may be a discrepancy between what is reported by respondent. In these cases, always use the patient’s (i.e. self-report) response.
Section 2: Determinants of Decision Making

Section 2 contains a number of questions that may relate to the respondent’s preferences for EOL care. We will want to capture these data points and analyze them afterwards to see if we can better understand what the key determinants are to preferred care at the end of life.

Lifetime Line (Question #4)

When administering question #6, read the question to the respondent, then:

4) Pass the questionnaire over to the respondent and ask them to place a mark (i.e. a line not an ‘x’) on the life line indicating where they feel they are at this point in their life.

5) After the interview, measure the distance from the ‘Birth’ anchor to the respondent’s mark.

6) Record the distance to the nearest millimeter. See below for an example.
4. The line below represents a person's total lifetime from birth on the far left to death on the far right. Please make a mark on the line where you see yourself at this point in your life.

Birth | Death

Interviewer, please measure the distance from the left anchor (birth) to this mark, in centimeters (cm) after the interview and mark here: 7.4 cm

Some interviewers have noted that this is a particularly difficult question for respondents to answer. Some respondents do not make a mark but indicate verbally their response (e.g. 3 years left to live) or they simply can not provide a response. If at the life-line is not used please note one of the following:

- Respondent could not answer (was not able to verbalize a response)
- Respondent provided a verbal response: _______

**Section 3: Decisions About Your Health Care Prior to Hospitalization**

In this section, we are trying to ascertain whether the respondent has engaged in ACP PRIOR to hospitalization.
Question #3
It is important that the respondent understand the meaning of the term ‘life sustaining treatments’ first mentioned in questions #2, 3 and in subsequent questions. Before asking question #3 give the respondent CARD 3 which explains life sustaining treatment options, so we can be sure they know to what we are referring.

Question #7
If the respondent has answered ‘yes’ they have discussed their preferences for using or not using life sustaining treatments with someone, proceed with asking the questions presented in the table. Each table row asks whether the respondent engaged in these with a specific individual (e.g. Family doctor, nurse, lawyer, etc...). If the response is ‘yes’, follow-up questions are asked regarding some of the details surrounding the discussion (e.g. how often, when they last spoke about this matter and under what circumstances).

Respondents may have had a conversation with a family member who is also their surrogate decision maker and their responses to the details of this (these) conversation(s) may be the
same. If necessary, use the space provided at the bottom of the page to note the particulars of the trigger event that precipitated the conversation.

Question 9
Part a) of this question has a blank contained within to allow for the participating institution to apply the relevant document to their province/region/institution.

This can be tailored with language that is relevant to a particular institution. e.g. Living will

Question 10
This question has a blank contained within to allow for the participating institution to note the relevant type of document for their province/region/institution.

This can be tailored with language that is relevant to a particular institution. e.g. representation agreement (BC)

Section 4: Goals of Care During Current Hospitalization
This section is trying to determine the respondent’s perspective on communication and decision making about the use of life sustaining treatments while in hospital (during current hospitalization, not prior to hospital or previous hospitalization). If respondents refer to previous conversations outside the current hospitalization, please keep directing them back to conversations and events during the current hospitalization.
Questions #1-12

Prior to starting this section, provide the respondent with CARD 4 options and explain the potential responses.

- For each question in this section (column 1), first, you are asking the respondent ‘Did this happen, yes or no?’ (response provided in column 2).
- Next, we are interested in the perspective of the respondent, “How important is the case issue to them” (response provided in column 3).
- Next, we are interested in the perspective of the respondent, “How satisfied they were…” (response provided in column 4).
  - NOTE: If the response to column 2 is “no” this question is not applicable.

Section 5: CANHELP Lite
The CANHELP questionnaire is a formal, validated satisfaction with EOL care measurement tool. This questionnaire actually has 42 questions and several subscales but to shorten the interview time, we are only using the validated subscales pertinent to ACP.

Before reading the question, show the respondent CARD 5 and explain the response options.
Literally read the instructions at the beginning of the questionnaire. Also, explain that you are asking about their rating of care over the past month, regardless as to where the care occurred (at home, hospital or other location).

Section 6: Barriers & Facilitators
Section 6 offers the respondent an opportunity to share any barriers and/or facilitators they experienced concerning discussions with health care professionals about ACP. Write their response verbatim.

Parting Words to the Respondent at the End of the Interview
You have now completed the respondent interview portion of the ACP questionnaire. (The remaining section involves you going to the patient’s medical chart to extract some information. Refer below for details concerning Section 7 of the ACP Questionnaire.)

At the conclusion of the interview please thank the respondent for their time and candor in sharing information about this important topic. If the respondent requests more information regarding ACP please refer them to the appropriate individual on the ward (e.g. Social Worker).
It is also advisable to make a Progress Note entry into the patient’s medical chart to alert any other members of the patient’s care team that an interview regarding ACP was conducted. If agreeable with the ethics committee, the site may also leave behind a pamphlet or fact sheet concerning ACP. The Speak Up campaign has several generic tools that can be used and/or adapted (www.advancecareplanning.ca).

Section 7: Documentation of ACP/AD in the Medical Record at the End of the Interview

The purpose of this section is to record any ACP/AD documents found on the medical record at the time of the interview. This data collection can occur either immediately before the interview or immediately after.

If both the patient and family member are interviewed, section 7 should be completed at the point of first contact. (i.e. after the first interview).

If blank documents are found in the medical chart (e.g. goals of care form, tracking record or My Voice workbook) they should be indicated as ‘not present’ in Section 7 of the questionnaire.

Some interviewers have noted that responses provided to them during the interview are not consistent with what is found documented in the medical chart. E.g. a patient indicates that they do not have any advance directives but a DNR form is found on the medical chart. This is an observational study, our role is to collect data and see what happens over the course of the patient’s stay. Do not intervene with the respondent and try to correct any inconsistencies.

The only reason a study team member should intervene is if the patient experiences emotional/psychological trauma, induced by our interview, and help from the clinical team is required to deal with the situation.
**Appendix**

A  Sample Letter of Information

B  Introductory Script with Patient/Family Member

C  Assessment of Degree of System Implementation – Acute Care Site

D  Assessment of Degree of System Implementation – Health Care Organization Level

E  ACP Questionnaire – Patient Version

F  ACP – Family Member Version
Appendix A – Sample Letter of Information

Research Study Notification

We wish to advise you of a new study that will recruit terminally ill patients and family caregivers from hospital units.


The goal of this study is to determine, from the patient and families’ perspectives, the prevalence of Advance Care Planning (ACP) and its various components, what barriers exist that affect the quantity and quality of ACP conversations with doctors, using a newly developed questionnaire.

We will enroll patients who are at a high risk of dying and/or their family member for an interview. We define this ‘risk’ by the following criteria:

55 years of age or older with one or more of the following diagnoses:

1. Chronic obstructive lung disease - 2 of the 4 of: baseline PaCO2 of > 45 torr, cor pulmonale; respiratory failure episode within the preceding year; forced expiratory volume in 1 sec <0.5 L.

2. Congestive heart failure - New York Heart Association class IV symptoms and left ventricular ejection fraction < 25%.

3. Cirrhosis - confirmed by imaging studies or documentation of esophageal varices and one of three conditions: a) hepatic coma, b) Child’s class C liver disease, or
c) Child’s class B liver disease with gastrointestinal bleeding.

4. Cancer - metastatic cancer or stage IV lymphoma.

5. End-stage dementia (inability to perform all ADLs, mutism or minimal verbal output secondary to dementia, bed-bound state prior to acute illness)

6. Renal failure defined as chronic renal failure requiring dialysis

OR

Any patient 80 years of age or older admitted to hospital from the community because of an acute medical or surgical condition.
OR

Any patient 55 to 79 years of age admitted to the hospital, who does not meet the above criteria but in the opinion of a health care team member (Doctor, resident, nurse), he/she would not be surprised if the patient died in 6 months.

Study patients will be asked to identify, if applicable, a family member who knows them the best (inclusive of partners, significant others, and/or close friends) who 1) is greater than 18 years old, 2) has visited the patient in hospital at least once, and 3) who provides the most care to the patient and is not paid to do so. If there is more than one family member available, we will allow them to select who participates.

For this study, the Research Coordinator will discuss eligibility with a member of the clinical team before approaching the patient for consent and will document participation in the patient’s chart. Any concerns identified during the interview will be recorded in the chart.

If you have any questions or concerns please contact the Research Coordinator <<Name here>> or Local Investigator <<Dr. Name here>>.
Appendix B – Introductory Script

Hello, my name is _____________________, and I am a research nurse (assistant) working with Dr. ______________, one of the doctors here at (Name of hospital).

We are interested in talking to patients 55 yrs and over with chronic illnesses, cancer, dementia and people over the age of 80 and or their family members about their views on advance care planning. Hospital policy now require doctors to have clear understanding of their patients and /or their powers of attorney for health wishes regarding life sustaining technologies in the event their condition deteriorates and are no longer able to communicate for themselves.

Advance care planning is a difficult topic to discuss, is often done poorly resulting in patients and family members being unsatisfied with medical management of end of life care. Patients and families have indicated there are problems related to the quantity and quality of information related to the options of aggressive medical management using life sustaining treatments compared to palliative comfort options for managing life threatening conditions that results in uninformed decision making.

The purpose of this study is to improve the communication about the use of life sustaining treatments and palliative comfort measures, between doctors, patients and their family members. Would you be interested in knowing more about this project?

If YES, proceed with informed consent discussions.
Appendix C – System Implementation (Acute Care Unit)
Bedside Letter to Patient/Family Members
Research Study Notification

We would like to invite you to participate in an ongoing study being conducted at Vancouver General Hospital that is currently recruiting patients and their family members. This study is called The ACCEPT Study, which stands for “Advance Care Planning Evaluation in Elderly Patients: A multi-center, prospective study.

Discussing plans for future medical treatments is called “advance care planning.” Advance care plans concern medical treatments a person wants or does not want in the event their physical condition declines as a result of accident, medical emergency, old age, or getting sicker from a chronic illness. Discussing advance care plans is important but this can be a difficult topic for doctors, patients and their families. The purpose of the study is to hear your views about these kinds of conversations and help us develop ways to make communication about advance care planning more open and effective.

Your relative has met the requirements for this study and we would like to obtain the views of yourself and your relative on this important subject. If you are interested in participating in this survey based study, would you please contact ____________________________ to further discuss details of the study.

Participation is voluntary and all responses will be private and confidential. This study has approval from ________ Research Ethics Board and ____________________________.

If you have any questions about this study, please contact one of the ACCEPT investigator, ______________________. If you have any concerns about rights as a research participant, please contact the ____________________________ Research Ethics Board at ____________________________.

Thank you, the ACCEPT Research Team