Improving Communication about Serious Illness (ICSI) Protocol

University of Washington, School of Medicine
Cambia Palliative Care Center of Excellence

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I. Personnel

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Intervention Team: The Intervention Team, led by Dr. Curtis, is responsible for all aspects of the intervention, including refinement of the intervention tools, clinician training, and implementation of the intervention.

Evaluation Team: The Evaluation Team, led by Dr. Engelberg with support from Dr. Lober and Ms. Downey, is responsible for data collection, outcome measurement, and data analysis.

II. Administration

Study Sponsor / Funding Agency: Patient Centered Outcomes Research Institute (PCORI)
Contract # IH-12-11-4956; Health System Intervention to Improve Communication about End-of-Life Care for Vulnerable Patients
August 1, 2013 – January 31, 2017

Human Subjects: UW IRB #44023, Committee G
Initial approval date: 13 December 2012
Annual renewal [1]: 6 December 2013
Annual renewal[2]: 4 December 2014
Annual renewal[3]: 6 November 2015 [12/6/15 through 12/5/18]
*Northwest ROC approval: 16 August 2013
*Valley ROC approval: 19 July 2013

DSMB: The Data Safety Monitoring Board was convened on December 17, 2013. At this initial meeting the charter was reviewed and approved. The voting membership of the DSMB at the initiation of the study is as follows.

Chair:
- Jean S. Kutner, MD, MSPH, University of Colorado School of Medicine

Members:
- Patrick Judson Blatchford, PhD, University of Colorado Denver
- Rebecca Sudore, MD, University of California, San Francisco
- Karen E. Steinhauser, PhD, Duke University

ClinicalTrials.gov: The study has been registered with ClinicalTrials.gov registry and results database: http://clinicaltrials.gov/show/NCT01933789.

III. Community Advisory Board

This research study is utilizing the resources of the Cambia Palliative Care Center of Excellence (PCCE). The Cambia PCCE has a Community Advisory Board (CAB) made up of patients, family members and other stakeholders (e.g., clinicians, patient advocates, community representatives). The Board has provided feedback on the specific aims and proposed methods. The study teams meet with Board on a quarterly basis to review progress, assess plans for the coming quarter, and discuss any potential changes in the intervention or evaluation plans. The agendas for these meetings are developed jointly by Drs. Curtis and Engelberg and the chair of the CAB. Members of the Board are provided an honorarium in accordance with the rules and regulations of the University of Washington.

IV. Objectives and Aims

The goal of this research is to ensure that patients receive the end-of-life care they desire through improved patient-centered communication with the clinicians and interdisciplinary teams caring for these patients. The specific aims include evaluating the effect of a health system intervention (a "Jumpstart" feedback form) designed to improve: the occurrence and quality of patient-centered communication about end-of-life care for patients with chronic life-limiting illness and their families; 2) agreement between patients' preferences for care and care received; and 3) symptoms of anxiety and depression experienced by patients and families.

- Aim 1: Evaluate the effect of the intervention on facilitating and improving patient-clinician communication about end-of-life care for patients with chronic life-limiting illness. The primary outcome is the occurrence of patient-clinician communication about end-of-life care for patients who desire such communication. We will also assess the intervention's effect on all patients' ratings of the quality of this communication.
- Aim 2: Assess the effect of the intervention on ensuring that patients with life-limiting illness receive desired care as measured by: a) concordance between care patients want and care they receive; b) use of palliative care services for patients with unmet palliative care needs; and c) use of intensive life sustaining treatments at the end of life for patients reporting they don't want such treatments.
- Aim 3: Evaluate the effect of the intervention on patients' and families' symptoms of anxiety and depression in the context of receiving care for a life-limiting illness.

V. Subjects, Inclusion and Exclusion Criteria

The study recruits from UW Medicine --including University of Washington Medical Center (UWMC), Harborview Medical Center (HMC), Northwest Hospital & Medical Center (NW), and Valley Medical Center (VMC). UWMC includes the main medical center, the clinics at Roosevelt Medical Center, and the Neighborhood Clinics under the UW Physicians network. Affiliate clinics at NW and VMC are also included, e.g. Western Washington Cardiology (NW) and the Southlake Clinics (VMC).

The study also recruits from Swedish Medical Center via the Primary Care Clinics with assistance from the Clinical Trials Unit.

The main study subjects are "Primary Clinicians" (physicians, nurse practitioners, physician assistants) and "Patients". We also recruited "Family Members" and "Team Members / Interprofessional Clinicians" (nurses, social workers, medical assistants.

Primary clinicians (n=120). Eligible primary clinicians include all clinicians who provide ongoing primary or specialty care to eligible patient populations. This includes physicians (e.g. family medicine, internal medicine, oncologists, pulmonologists, cardiologists, gastroenterologists, nephrologists, and geriatricians), nurse practitioners, and physician assistants. A primary role denotes any clinician for whom having a discussion about end-of-life care with eligible patients would be indicated.

Patients (n=500). We enroll up to 6 patients per primary clinician. Eligible patients will be those under the care of the participating primary clinician and who are 18 years of age or older, have had 2 or more visits with the primary clinician in the last 18 months, have an upcoming appointment on record (or a reasonable expectation of an upcoming appointment – e.g. "RTC 3 months"), and meet one of the diagnostic criteria. The diagnostic criteria include the following, with the goal of identifying patients with a median survival of about 2 years:

- Metastatic cancer **or** inoperable lung cancer;
    - Cancer that has spread from primary site to another organ or system; most common sites of cancer metastasis are bone, liver, and lung; can be indicated by Stage IV cancer; can be indicated by M1 in the TNM system [Primary Tumor (T)/Regional Lymph Nodes (N)/Distant Metastasis (M)]; does NOT include mets to nodes or mets to same system (e.g. uterine and fallopian = removal is curative)
    - Includes Stage III non-small cell lung cancer (NSCLC)
    - Note about Cancer screening: Due to some uncertainties and concerns with these cancer patients at UW/SCCA, before entering new patients into the database, the research nurse will review and confirm eligibility. If a diagnosis of Cancer mets is the ONLY reason that the patient is eligible, and that cancer is well controlled, cured/curative, etc. then that patient is probably NOT appropriate for enrollment under the oncologist. HOWEVER, if the patient is eligible by any of the other eligibility criteria, then that patient is eligible for the study, even for enrollment under the oncologist.
- Chronic obstructive pulmonary disease (COPD) with FEV1 values < 35% predicted (Forced Expiratory Volume represents the amount of air that leaves the lung after the first second of a full exhalation) **or** oxygen dependence;
    - Use the most recent pulmonary function measurement; FEV1 unlikely to improve over time so there is no cut-off to when the 'most recent' must be
    - Oxygen dependence is indicated by daily, day-time use of supplemental oxygen (ICD9 V46.2, ICD-10 Z99.81); O2 use that is limited to overnight or sleeping only is not applicable

- Restrictive lung disease with a TLC < 50% predicted (Total Lung Capacity is the total volume of gas contained in the lungs.);
- New York Heart Association Class III **or** Class IV heart failure;
- LVAD (Left Ventricular Assist Device) **or** ICD (Implantable Cardioverter Defibrillator) with age over 65 years;
- Child's Class C cirrhosis or Model for End-Stage Liver Disease (MELD) score of >17;
    - Also known as the Child-Pugh score or the Child-Turcotte-Pugh score. Note: although Child-Pugh calculators are available online using lab values and clinical indicators, we are using available scores in the EHR and not scoring this ourselves
    - MELD calculators are available online using lab values, bilirubin, INR, and creatinine: http://www.hepatitisc.uw.edu/go/management-cirrhosis-related-complications/liver-transplantation-referral/calculate-meld-score
    - For MELD scores between 10-19, 3 month mortality is 6 %
- Dialysis-dependent renal failure **and** either diabetes **or** a serum albumin of < 2.5;
    - Terminology to consider includes CKD (chronic kidney disease), kidney failure, end-stage renal disease (ESRD), diabetic nephropathy, diabetic kidney disease (DKD)
    - Record most recent lab values
- Pulmonary arterial hypertension with 6MWD (6-minute walking distances) <250;
- Restrictive lung disease (idiopathic pulmonary fibrosis, interstitial lung disease) w/ TLC (total lung capacity) <50%;
    - Includes idiopathic pulmonary fibrosis, interstitial lung disease; look for documentation and use the most recent pulmonary function measurement
- Cystic fibrosis with FEV1 < 30%;
    - use the most recent pulmonary function measurement
- Age 75 years or older with at least one life-limiting chronic illness;
    - Consider any of the classifications/diagnoses above (cancer, COPD, heart failure, PAH, cirrhosis, ESLD, renal failure, IPF, ILD, CF) that are not severe enough to be eligible outright but will be for this age group.

        Example: 80 year old patient with NYHA2; document diagnosis on the screening form
- Age 90 years or older;
- Hospitalization from any cause within the last 18 months with diagnosis of lesser severity;
    - Consider any of the classifications/diagnoses above (as noted) that are not severe enough to be eligible outright but will be in combination with a hospitalization in the last 18 months
    - Hospitalization may be unrelated to primary diagnosis; document date and reason for hospitalization on the screening form

        Example: a 70 year old patient with COPD who was hospitalized 6 months ago for a fall;
    - For diagnoses that may have frequent (e.g. CF) or curative (cancer) hospitalizations, this criterion alone will not be sufficient for eligibility
    - All patients who would be eligible by this criterion must be reviewed by the research nurse before being accepted
- Total comorbidity, Charlson index score >=6.
    - Scores are identified from standard review of the 'Problem List' and office visit documentation at the time of screening
    - Information on the Charlson Index can be obtained at: http://www.rtog.org/LinkClick.aspx?fileticket=8o6FpyC8s9w%3D&tabid=290
    - Modifications to scoring were made in the following areas:
        - AIDS (HIV C3) – Charlson index assigned a value of 6 points; because it is now similar to a chronic disease, we assigned it 1 point
        - Cerebrovascular disease and Hemiplegia -- Charlson index noted that if hemiplegia was due to stroke, then CVA was not counted separately, but we **are** counting twice

- Diabetes and Diabetes with organ damage -- Charlson index noted that if there was end organ damage due to diabetes, DM was not counted separately, but we **are** counting twice
- Any tumor in the last 5 years and metastatic solid tumor – For the Charlson index, if there were mets, cancer was not counted separately, but we **are** counting twice
- Myocardial Infarction -- We are including CAD here
- COPD – Charlson index inclusive of asthma, but not for this study
- Diabetes – Charlson index limited to treatment with insulin or oral hypoglycemic, but not for this study (e.g. controlled via diet alone assigned 1 point)
- Points for age – We **are** including these in the total

Exclusion criteria include:

- Non-English speaking
- Significant dementia or cognitive impairment that would limit the patient's ability to complete questionnaires.
- Other reason (e.g. recent transplant, on curative course of treatment) -- document on screening form

Families (n=100). We enroll any family members identified by the patient. Eligible family members are identified by the patient, with the criteria that the patient would want the family member involved in medical decision-making for the patient if the patient was not able OR that the patient identifies the family member as someone involved in his/her medical care. For the purpose of this study, "family member" is not confined to legal next-of-kin or immediate family member. Any family member, friend, or caregiver is eligible who speaks English and has no dementia or delirium limiting ability to complete questionnaires.

Interprofessional (IP) team members (n=5). We enroll any team members identified by the clinician. Most primary clinicians do not have an IP team member working with eligible patients and this information is noted. Eligible IP team members will include nurses, social workers and other clinicians who are part of an enrolled primary clinician's clinic and who deliver care to eligible patients. Primary clinicians assist with the identification of these team members

Reasons for exclusion for all subject groups include: legal or risk management concerns; and physical or mental limitations preventing ability to complete research activities. For patients and family members, participation in the pilot phase is also an exclusion criterion in the full study.

VI. Pilot Study & Debriefing

Phase one of this research will be a pilot test of the full study design described in detail below. The only differences between the pilot and the full study are:

- smaller sample size,
- recruitment from HMC/UWMC only,
- fewer instruments administered,
- no chart abstraction, and
- abbreviated follow-up procedures.

At the end of the pilot activities, there is a short (15-minute) cognitive debriefing interview with subjects to get their thoughts and feelings on the activity and the feedback form itself.

VII. Methods and Procedures, Full Study

Screening

Primary Clinicians. Primary Clinicians are identified at each site via publicly available lists of providers in each practice or by screening the clinic's electronic health records (EHR) to identify those clinicians with eligible patients in their clinic panels. This requires a waiver of consent and waiver of HIPAA authorization. Where possible, potential Primary Clinicians are identified as those having 10 or more eligible patients and are screened until enrollment targets are achieved. When it is not possible for study staff to screen clinicians for eligibility (e.g., no data from the EHR repository), we directly contact potential clinician subjects and allow them to review our minimal criteria (i.e. ten eligible patients – with the goal of enrolling six – seen over 12 month period) and self-select whether they meet this criteria. Clinicians are also asked to confirm their eligibility at recruitment. At this point, no protected health information or patient identifying information is collected or recorded. The screening is only to assess the clinicians' eligibility, i.e., to confirm that they see a sufficient number of the types of patients that will be eligible for this study.

Patients. Using the medical records/EHR, study staff identify consecutive patients who are cared for by a participating Primary Clinician using the eligibility criteria. Information collected at this point includes: diagnoses, dates of clinic appointments, demographics (sex, ethnicity, race), birth date, medical record number, name, and contact information. This screening requires a waiver of consent and waiver of HIPAA authorization. In the event that a patient sees more than one Primary Clinician who is enrolled in this study, the patient will participate in the study with only a single clinician. At Swedish Medical Center, screening of patient records is conducted by Swedish Medical Center research study staff.

Notes on procedures:

- Look up patients in medical records/EHR.
  - Confirm that patient has had enough visits with provider to be eligible.
  - Check for valid and eligible (~ 40 miles) address and contact information.
  - Review most recent chart notes for eligibility criteria.
  - Review problem list for eligibility via comorbidities.
  - Review for hospitalization within 18 months.
  - Remember to check for English speaking, cognitive impairment, or other exclusion factors.
- Complete screening forms for each eligible patient until six patients are found.
  - If there are not six patients at this time, take whoever is identified.
  - If there are more than six eligible patients, the database will only permit six open slots at a time, so choose the six best by criteria such as proximity to target date.
- Record determination of all patients that were screened (e.g. eligible, not eligible, check later, etc.) on the screening sheets for future reference.
- Record date and MRNs for HIPAA disclosure report; send to RC/ Program Manager.

Recruitment

Primary Clinicians.

Initial recruitment contact procedures:

1) Study staff initiate initial contact. A one-page study summary, invitation and response form are mailed to eligible clinicians, asking them to indicate if they are willing to hear more about the study, provide some demographic data to describe the sample, and collect information about reasons for refusing (as applicable). Reminders were made to non-responders to the initial letter, and included 4

additional attempted contacts. Respondents indicating an interest in participating in the study were then contacted directly by study staff and an in-person enrollment visit is arranged.

2) Study PI initiates initial contact. The study PI makes the initial contact (e.g., phone, email) to practices and clinics with likely eligible clinicians with the goal of introducing the study and assessing acceptability and interest for the clinic as a whole. Study staff continue to approach practice clinicians individually via the recruitment protocols.

Follow-up efforts: Potential clinician subjects who responded to the initial mailing with interest received a second contact from the study (i.e., mail, email, phone, in-person, or via a practice manager or lead clinician). This contact includes additional information about the study and notice that study staff will arrange an enrollment visit. Reminders were made to non-responders to the second letter, and included 4 additional contacts to reach those clinicians who had expressed interest in participating in the study.

Final recruitment: Once contact was made with an interested Primary Clinician and s/he has been made aware of the study purpose and procedures and the parameters for eligibility have been discussed (e.g. panel includes enough seriously ill patients to meet study goals), an enrollment appointment would be set and entered into the database.

Patients. After initial screening, study staff contact the patient by mail for recruitment. Eligible patients receive an introductory letter from the enrolled Primary Clinician with an introductory letter from the study PI. The letters provide a summary of the study and instructions on how to participate or reply to the study mailing. Study staff then contacts the patient by telephone or in person. Study staff summarizes the study, asks if the patient is interested in participating and, if so, arranges to meet for completion of informed consent and baseline survey administration. At Swedish Medical Center, the contact protocol is modified so that the first contact to patients will be will be made by letter from the Swedish research study staff. They will ascertain whether the patient is willing to be contacted by the UW research team. If so, the patient's contact information will be released to the UW team.

Families. Family members are identified by participating patients. If an eligible family member is available at the time of the patient's enrollment, s/he is approached by study staff about participating in the study. If an eligible family member is not present, s/he is approached by mail and by telephone. These family members receive an introductory letter from the study, copies of the consent form, and survey materials with a return envelope. Study staff follow-ups the mailing with a phone call to ensure delivery, answer questions and ascertain the family member's interest in participation.

Interprofessional Team Members. Interprofessional team members identified by Primary Clinicians are initially approached by mail, email, or in person. When necessary, follow-up consists of a phone call or email by study staff to ensure receipt of the introductory packet, answer questions and ascertain the team member's interest in participation. This check-in may also occur in person at the office or clinic of the Primary Clinician.

Enrollment and Informed Consent

All study subjects are approached for consent by UW research study staff. All study staff are trained in the protection of human subjects through the University of Washington or its affiliates (e.g. CITI).

Primary Clinicians. Primary Clinicians meet in person with study staff to compete enrollment. At these enrollment meetings, Primary Clinicians review study materials and complete written informed consent. Signatures are collected at this time to use on the cover letters for patient recruitment.

Notes on procedures: Enrollment appointment for the Primary Clinician (PC) is done in person, importantly to complete informed consent and to collect the PC's signature used for patient

recruitment letters. These appointments usually take no longer than 15 minutes, including collection of baseline data. Study staff brings all materials needed. If possible, the study staff calls the study office during the appointment to find out which study arm the PC has been randomized to. If not possible, study staff assesses assignment after return to the office and emails the participant to let him/her know their randomization status. The video explaining the Jumpstart intervention may be seen at this time or delayed until after randomization assignment.

Subjects who were randomized to the intervention must have a 'training session' logged into the database before being able to proceed. The date for this training session would be the date of the enrollment visit if the PC was shown the video. If the video was not shown, the date for the training session would be the date the randomization result was emailed to the PC; this email contained a link to the video and instructions for viewing.

Before letters to Patients are generated, the Primary Clinician's signature must be logged into the database.

Patients. Patients meet in person with study staff to compete enrollment. At these enrollment meetings, potential patient subjects review study materials, complete written informed consent and HIPAA authorization. For Patients who are assigned to the intervention, they have an opportunity to view the video that explains the Jumpstart form and how it may be used. These appointments can take anywhere from 30 minutes to 2 hours depending on the patient, the conditions surrounding the visit, and numerous other factors. The enrollment appointment should include the collection of baseline data. Study staff bring all materials. Subjects have not completed enrollment until baseline data have been entered in the Access database.

Families. The enrolled Patients will identify the potential family member subjects. Usually if a family member is going to be a participant, s/he is present at the Patient's enrollment appointment and can be recruited and enrolled at the same time. (The Patient's enrollment packet will contain materials for this situation.)

If the family member is identified but not present at the enrollment appointment, his/her name and contact information are entered in the Access database and initial mailings are generated. These include: introductory letter, copies of consent form (a waiver of documentation of consent is in place), baseline survey, and return envelope. Cash payments are sent upon receipt of materials. Follow-up and reminders are made according to protocol – see below. On occasion subjects return questionnaires but neglect to include a copy of the signed consent form. In order to accept the data that these subjects have contributed, we have a Waiver of Written Documentation of Consent. If recruited and enrolled in person, written consent will be obtained.

Interprofessional Team Members. Interprofessional team members receive an introductory mailing that contains copies of the consent form, and survey materials with a return envelope. On occasion subjects return questionnaires but neglect to include a copy of the signed consent form. In order to accept the data that these subjects have contributed, we have a Waiver of Written Documentation of Consent. If recruited and enrolled in person, written consent will be obtained.

Randomization

Primary Clinician participants are assigned to intervention or control. The unit of randomization is the Primary Clinician with Patients, Family Members, and Interprofessional Clinicians clustered under the Primary Clinicians. The study database randomly assigns block sizes of 4, 6, or 8 to each recruitment site. Within randomization blocks, it randomly assigns Primary Clinicians in equal numbers to the intervention and control

conditions, and when a site-specific block is full, it randomly assigns a new block size to the site for the ensuing block. Study staff are blinded to the randomization blocks created in the database. Randomization assignments are made within the database and stored on a network server.

Baseline Data Collection

Primary Clinicians. Baseline data for Primary Clinicians are collected at the time of enrollment. Questionnaires are self-administered, and may be completed on paper or online. Clinicians receive a coffee card ($5) with their baseline survey, or they are mailed this receipt. The baseline questionnaire includes the following:

- Competence in Communication about End-of-Life Care: 17 item self-assessment of perceived competency,
- Demographics.

Patients. Baseline data for Patients are collected at the time of enrollment. Questionnaires are usually self-administered, and may be completed on paper or online. Questionnaires may be administered by study staff in person or by phone, but the format remains the same. Patients receive $5.00 with their baseline survey. The baseline questionnaire includes the following:

- Preference for Care Intensity Preferences: 2 items about preference for intensity of care at end of life from the SUPPORT study, and 2 items about preferences for CPR;
- Communication Barriers & Facilitators: 16 items assess patient-specific barriers and facilitators to end-of-life communication;
- Quality of Communication (QOC_eol): 6 items assess the quality of communication about end-of-life care among patients and family members;
- Trust: 5 items assess respondent's perceived trust of clinician;
- Patient Health Questionnaire (PHQ-8): assesses symptoms of depression among patients and family members;
- Generalized Anxiety Disorder (GAD-7): assesses symptoms of anxiety among patients and family members;
- Religion and Spirituality: 4 items assess respondent's experience and thoughts; and
- Demographics.

Families. Baseline data for Family Members are collected at the time of enrollment. Questionnaires are usually self-administered, and may be completed on paper or online. Questionnaires may be administered by study staff in person or by phone, but the format remains the same. Family Members receive $5.00 with their baseline survey. The baseline questionnaire includes the following:

- Preference for Intensity of Care at End of Life: items addressing the patient's care preferences;
- Trust: 5 items assess respondent's perceived trust of clinician;
- Patient Health Questionnaire (PHQ-8): assesses symptoms of depression among patients and family members;
- Generalized Anxiety Disorder (GAD-7): assesses symptoms of anxiety among patients and family members; and
- Demographics.

Interprofessional Team Members. Baseline data for team members are collected at the time of enrollment. Questionnaires are self-administered, and may be completed on paper or online. Team members receive a coffee card ($5) with their baseline survey. The baseline questionnaire includes the following:

- Skills and Behavior in Practice: 14 item self-assessment of demonstrated skills; and
- Demographics

Engagement

At the time of the patient's enrollment the "target clinic visit" is identified as the next scheduled visit with the enrolled Primary Clinician. This visit, for both intervention and control patients, is the trigger point for the intervention and for scheduling the administration of the follow-up surveys. Tracking target visits consists of daily monitoring for pre-visit mailings (to intervention patients) or phone calls (control patients). Prior to the pre-visit contact, the study staff should confirm the status of the target visit via the patient's EHR.

--- Intervention

The intervention, based on self-efficacy theory, consists of a communication feedback ("Jumpstart") form based on a patient's preferences for communication and training in the use of the form for the clinicians who will be using it. The intervention "feeds back" patient-specific preferences for communication about end-of-life care, patient-specific barriers and facilitators to this communication as identified by patient self-report, and patient preferences for CPR. The Jumpstart form is a short document provided to clinicians, patients, and family members. Jumpstart forms are specific to each patient based on his/her responses to the baseline questionnaire. The Jumpstart forms are tailored to each recipient to support the communication tasks which that recipient will be positioned to address. For example, the form for the clinician includes cues to initiate discussion as well as suggestions for addressing issues with patients who report not wanting to talk about end-of-life care; and the patient and family forms include tips for ways to bring up topics of concern with clinicians as well as between the patient and family.

Upon receipt of the baseline questionnaire, the Jumpstart forms may be created. Patients' baseline questionnaire items included in the intervention feedback are: whether the patient have/ would like to talk to the Primary Clinician about end-of-life care; the patient's care preferences; and primary barrier (or facilitator) they endorsed. Study staff generates the Jumpstart forms based on these responses and then tailors them for each recipient (clinician, patient, family).

Jumpstart forms for the Primary Clinician are provided via secure email or fax ~2 days prior to the patient's target clinic visit and again the morning of the visit. Forms may also be delivered in person to the clinic. As noted above, clinicians in the intervention receive a short training video in the use of the forms at enrollment, and again (via hyperlink) with receipt of the Jumpstart forms. Clinicians in the intervention have the option of delaying discussion about end-of-life care to a subsequent visit if the timing is not appropriate at the target visit. The timing of data collection will not change to ensure comparability between study arms.

In addition to information about patient-specific barriers and facilitators to discussing end-of-life care, clinicians may also receive suggestions about referral to Palliative Care for potentially unmet palliative care communication needs related to end-of-life care. Patients are identified as having potentially unmet palliative care communication needs if they endorse the following items: a) they would like to talk about end-of-life care; b) they have not discussed end-of-life care; and, c) they report an orientation toward ensuring comfort rather than extending life. This triggers a recommendation on the Jumpstart form for the clinician to consider referral to Palliative Care.

The Interprofessional Team Member receives the feedback forms at the same times and using the same methods as the Primary Clinician. The goal of incorporation of the interprofessional team is to use the interprofessional team to reinforce discussions between the clinician and patient and provide support for patients and family.

Jumpstart forms are sent by mail to Patients and to participating Family Members prior to the target clinic visit. In this mailing (forms may also be provided in person at clinic visits) these subjects also receive: cover letter,

link to view Jumpstart video online and/or video summary handout (transcript of video), and study steps checklist (a list of time points for contact i.e. "what you will do in our study… Step 1, complete baseline → Step 5, compete 3-month survey").

--- Control

The control arm constitutes usual care. All participants randomized to the control arm complete the same surveys at all data collection points outlined below, but patient-specific information is not provided to patients, family members, or clinicians. Control subjects receive a call to remind them about the upcoming target visit and that surveys from the study will follow.

Post Data Collection

After the target clinic visit, the follow-up survey schedule begins (post-visit/2 weeks; 3 months; 6 months). This is the same for subjects in the intervention arm and subjects in the control arm.

Clinicians. Primary Clinicians and Interprofessional Team Members complete one post-visit survey for each patient via mail or email/online; they receive a coffee card "thank you" with each survey within 1-2 days of the target visit.

> *Notes on procedures*: All enrolled clinicians are periodically emailed (~ three months) by the RC/Program Manager. These emails consist of study status, status of patient recruitment, and continued thanks for participation.
>
> 1. Intervention -- Clinicians receive copies of the Jumpstart forms via email attachment two days prior to the target visits and on the morning of the target visit. Ideally, these emails come from the ICSI email account. Intervention clinicians should receive after-visit surveys within 1-2 working days of the target visit. The target visit should be confirmed via the EHR or other screening system prior to sending by US mail or email. At Swedish, the emails with be reminders only and the Jumpstart forms will be faxed.
> 2. Control -- Clinicians should receive after-visit surveys within 1-2 working days of the target visit. The target visit should be confirmed via the EHR or other screening system prior to sending by US mail or email.
>
> MAILINGS for Primary Clinicians and Interprofessional Team Members include: personalized letters from database, coffee card ($5.00), questionnaire and return envelope.

Patients and Family Members. Patients have follow-up surveys sent to them for completion at 2-weeks (2W) post target visit. Both patients and family members have follow-up surveys sent to them at 3-months (3M) and 6-months (6M) post target visit. The schedule for all mailings at each of the time points includes: pre-mailing notification phone-call, initial mailing, and follow-up phone call and/or mailing to non-responders. These mailings contain: cover letter, subject payment ($5.00), survey booklet, study steps checklist, return envelope. Surveys may also be completed by phone or online.

> *Notes on procedures*: Before being able to print out follow-up letters, the database will prompt you to make anticipatory calls for 2-weeks, 3-month and 6-month. Voicemail has been approved with careful consideration to confidentiality. Pre-target visit contact will be made via call and/or sending of Jumpstart forms. This call will also serve as reminder for 2-week survey. The 3-month and 6-month calls are straightforward: remind subject of involvement with study and Primary Clinician by name and that survey is coming. These may be completed by phone at the time of the anticipatory call (and then mail subject payment afterwards).

MAILINGS for patient (2W, 3M, 6M) and family (3M, 6M) include: personalized letters from database, updated study steps checklist (intervention or control version), subject payment $5, questionnaire, return envelope.

Questionnaire entry occurs as soon as possible after survey completion or receipt.

Chart abstraction of the patient's medical record (EHR) occurs at the end of the follow-up period. Data elements include: disease characteristics including type and severity; occurrence and documentation of advance care planning; occurrence and timing of hospitalizations including acute care and ICU stays; receipt of life-support measures including CPR and mechanical ventilation; and specialty referrals, consults and visits including palliative care, social work, spiritual care and ethics. [See Appendix for ABSTRACTION MANUAL.]

VIII. Data Elements and Sources

Primary Outcome Variable. Occurrence of communication for patients who indicate a desire to talk with their clinician about end-of-life care is the primary outcome and is evaluated by patient report using a validated dichotomous item. The primary time-point is at 2-weeks; 3-months and 6-months after target visit are additional time-points.

Secondary Outcome Variables. The secondary outcome variables are:

- Quality of Communication about End-of-Life Scale (QOC_eol);
- Care Concordance -- Concordance between the care patients report they want at baseline and the care they report having received at the 3 month assessment is measured with the two questions from SUPPORT. The first question defines patient preferences for either extending life or ensuring comfort. The second question assesses patients' perceptions of current treatment. The outcome is a dichotomous variable measuring whether the preference matches the patient's report of the care received;
- Referral to Palliative Care Services -- Referral to palliative care services for patients who potentially have unmet palliative care communication needs (as determined from the baseline patient questionnaire) is assessed using the electronic health record (EHR). The outcome measure is a binary variable which indicates whether the patient received a referral for palliative care consultation services;
- Provision of Life-Sustaining Therapies -- Review of the EHR assesses use of three indicators of life-sustaining therapies: admission to an ICU, receipt of CPR, and receipt of mechanical ventilation. These analyses include a consideration of patients' preferences for care;
- Generalized Anxiety Disorder (GAD-7); and,
- Patient Health Questionnaire (PHQ-8).

Table 1: Main study measures and data collection protocol

Main Outcome Measures	Concept	Data Collection
I. Aim 1		
Communication items: 1) preference for conversations; 2) occurrence of desired conversations	End-of-life care communication: concordance with preferences and occurrence	**Patients**: enrollment, 2-week, 3-month, 6-month
Quality of Communication: QOC	End-of-life care communication: quality	**Patients**: enrollment, 2-week, 3-month, 6-month
II. Aim 2		
Preference for intensity of care at end of life	Concordance: care preferences matching care received	**Patients**: enrollment, 2-week, 3-month, 6-month
Palliative care referral	Concordance: palliative care referral in those with unmet palliative care needs	**EHR**: end of study period/after-death
ICU admit, receipt of CPR, mechanical ventilation	Concordance: use of life-sustaining treatments matches preferences	**EHR**: end of study period/after-death
III. Aim 3		
Generalized Anxiety Disorder: GAD-7	Symptoms of anxiety	**Patients**, **Family**: enrollment, 3-month, 6-month
Patient Health Questionnaire: PHQ-8	Symptoms of depression	**Patients**, **Family**: enrollment, 3-month, 6-month

Intervention, Covariate Measures	Concept	Data Collection *
Barriers and Facilitators Questionnaire	Patient-specific barriers, facilitators; unmet need for palliative care	**Patients**: enrollment
Competence In Communication And End-of-Life Care	Self-assessment of competency delivering end-of-life care	**Clinicians**: enrollment
Clinician Communication and Visit Checklist	Communication occurrence	**Clinicians**: post-target visit

IX. Data Management and Quality Control

It is necessary to record direct subject identifiers for the purpose of tracking subjects through the enrollment and evaluation phases of the study. This information consists of the names of subjects, contact information (e.g. address, email, telephone), and institutional identification numbers (e.g. medical record numbers for patients). To protect against disclosure, all subjects are assigned a unique study identification number at the time of data entry. It is this number that accompanies study materials and data. The information that would allow for a link between this study ID number and the direct identifiers is kept securely and separately from this data. The links for subject identifiers are to be destroyed no later than three years after the study end-date or by November 30, 2020.

This project requires the creation, maintenance, and analysis of a multivariate, longitudinal and clustered database that includes a variety of measures from multiple sources and sites. Systematic data collection, quality control, and data-management procedures are: 1) specification and use of concise protocols for data entry; 2) rigorous training, certification, and periodic re-training of study staff, with ongoing monitoring of adherence to data collection protocols; 3) regular review of questionnaire response rates and missing items to identify and correct problem areas; 4) verification of all data collected through use of custom-designed data entry systems; and 5) twice-monthly study-team meetings and progress reports to provide specific feedback to project staff concerning potential difficulties as well as follow-up to ensure that problems are resolved quickly.

To guarantee reliability and validity of EHR data, study staff uses current program methods for training and quality control. Abstractors undergo 40 hours of training including instruction on the protocol, guided practice review, and independent review followed by reconciliation with a trainer. A 5% random sample of all records is re-abstracted.

Data Entry.

A. Missing Values
- 555 = “unintelligible or irreconcilable”; endorsed incompatible items, or respondent writes in own text to change a question
- 666 = “not asked”; info not collected by survey (seen with different versions, or if pages are missing)
- 777 = “refused”; no answer and was not following defined skip pattern
- 888 = “n/a”; not answered because of defined skip pattern or allowable ‘not applicable’
- 999 = “don’t know”; respondent writes “not sure” or “I don’t remember” or “?”, etc.

B. General Coding Conventions
- For Yes/No items, if respondent writes “possibly” or any other positive response, treat this as a “Yes” response.
- If a respondent circles the words “Almost Perfect” on the scale, it is coded as a 10. If a respondent circles the words “Terrible” it is coded as a “0”.
- If “none” is a response option, but the respondent does not circle anything, code as refused “777”; do not assume “none” if nothing is selected.
- If a respondent endorses a value on a scale, but also selects a missing option, use the endorsed value.
- If two consecutive numbers are circled or written in, use a random numbers list or coin-flip to determine the response: 1 or ‘tails’= Use lower of the two responses; 2 or ‘heads’= Use higher of the two responses.

C. Back-coding

1. Family relationship – Some relationships are categorized different by different family members. In the past we have tried to standardize these in the following ways:

- "Steps" (e.g. step-brother) – code as ANOTHER RELATIVE
- "Adopted" – code as CHILD, or PARENT
- "Exes" (e.g. ex-wife) – code as ANOTHER RELATIVE
- "In-laws" – code as ANOTHER RELATIVE
- "Caregiver" – code as OTHER
- "Fiancée" – code as SPOUSE/PARTNER

2. Ethnicity & Race – We use the categories and definitions from the Census for NIH reporting standards. Ethnicity is collected for everyone, so that gets coded no, yes, or refuse including people who endorse any of the other racial categories. Hispanic/Latino respondents who don't want to endorse a race will be coded as "no" for the racial categories, but then enter "Hispanic/Latino" in the text box for "Other" race.

- "Hispanic or Latino" A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race; the term, "Spanish origin" can be used in addition to "Hispanic" and "Latino"
- "American Indian or Alaska Native" A person having origins in any of the original peoples of North and South America (including Central America) who maintains cultural identification through tribal affiliation or community attachment
- "Asian" A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian Subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- "Black or African American" A person having origins in any of the black racial groups of Africa
- "Native Hawaiian or Other Pacific Islander" A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands
- "White" A person having origins in any of the original peoples of Europe, the Middle East, or North Africa; includes Caucasian, Persian
- "Race/ethnicity unknown" The category used to report those whose race and ethnicity are not known; also used for "Human" and refusals and skips

X. Data Analysis

Because all outcomes are specific to clinician-patient pairs, with each clinician serving multiple patient participants, analyses are based on clustered regression models, with patients and families clustered under clinician. The predictor of interest for all models is the clinician's randomization allocation (intervention vs. control), and all models include adjustment for confounders, with confounders defined as variables that alter the size of the coefficient for the intervention by more than 10% when added as a second predictor of the outcome of interest. The link function to be used in each regression model is determined by the distribution of the outcome variable, with the estimator for model coefficients following best practices for the selected link function: linear and logistic regression models estimated with restricted maximum likelihood; probit and tobit models with either restricted maximum likelihood or weighted mean- and variance-adjusted least squares. Analysis defines continuous (or pseudo-continuous) outcomes as censored, and uses a tobit link for regression models, if more than 25% of responses are at the minimum or maximum values on the response scale. Analyses are based on intention to treat. The final regression model for each outcome includes the predictor of interest (the control/intervention indicator) and any covariates that act as true confounders of the association between that predictor and the outcome. A $p<0.05$ was selected as signifying statistical significance for the primary outcome. In addition to constructing the regression models detailed below, testing the intervention's effect on each outcome at that outcome's primary follow-up point, the analysis also compares the control and intervention groups' values on outcomes at other time points with the goal of providing insights into the intervention's durability of effect and generating hypotheses for future studies. Analysis also explores differences in perspective between clinicians and patient/family participants regarding whether end-of-life discussions occurred, and we will do exploratory analyses of heterogeneity of treatment effects.

<u>Analyses for Specific Aims</u>

Analysis for Aim 1: assessing the intervention's effect on occurrence of communication about end-of-life care for patients who want this communication and on the quality of communication about end-of-life care.

The intervention's effect on the occurrence of communication about end-of-life care for patients who desire it is assessed with a clustered regression model (logistic or probit) appropriate for a Bernoulli outcome collected at the assessment 2 weeks after the target visit, and with adjustment for confounders. The primary analyses will examine this outcome among the denominator of all patients who indicate at enrollment a desire for discussion about end-of-life care or who indicate "I don't know" to this question and who indicate at 2-week follow-up whether such a discussion occurred after enrollment. The sample includes patients who report having already had discussions with their clinician, as well as those for whom no such discussion had occurred prior to enrollment, because these discussions should not be a one-time event. The primary outcome examines the proportion of these patients who report on the after-visit survey (at 2 weeks post-target vist) that a discussion occurred. In addition, we will also compare the proportion who reported that a discussion occurred for all patients completing the after-visit survey.

The intervention's effect on the quality of communication about end-of-life care is assessed with the composite QOC_eol outcome, also collected 2 weeks after the target visit. The QOC_eol composite score will be tested for unidimensionality and between-group measurement invariance to ensure that the most appropriate composite score is used as an outcome. We will use a clustered linear regression model, estimating the coefficient for the outcome regressed on the control/intervention predictor, after adjustment for the baseline QOC_eol score and any other variables that act as confounders. The sample includes all patients for whom the QOC_eol score can be computed at both baseline and the 2-week follow-up assessment. In addition to these analyses, we will also examine each QOC_eol item as individual outcomes.

Analysis for Aim 2: assessing the intervention's effect on several outcomes measuring the match between the treatment patients receive and their treatment wishes.

The intervention's effect on concordance between care desired and care received is tested with a clustered logistic/ probit regression model, using a dichotomous outcome based on patient responses at baseline and the 3-month follow-up. Analyses will include the following approaches: 1) the sample will include all patients who completed the 3-month survey and whose stated treatment preference is the same at baseline and 3 months. Care is deemed concordant if the preference at baseline and 3 months is quality of life and the patient reports at 3 months that current medical care is focused on relieving discomfort, or if the preference at baseline and 3 months is on extension of life and the patient reports at 3 months that current medical care has that focus; and 2) the sample will include all patients who completed the 3-month survey; care will be deemed concordant if the preference for care and the assessment of current care are concordant at the 3-month assessment. The regression model includes adjustment for the patient's orientation toward quality of life/comfort care vs. life-sustaining therapies, plus any confirmed confounders of the association between randomization assignment and concordance. Analysis also examines the intervention effect on the subgroups that desire care focused on comfort as compared with those that desire care focused on sustaining life.

The intervention's effect on referrals to palliative care services for patients with unmet needs is tested with a clustered logistic/probit regression model, adjusted for confounders, and using a dichotomous outcome based on EHR review. The outcome indicates whether the patient was referred to palliative care services during the 3-month period following the target visit. The sample includes all patients who, at baseline, indicate that they have never discussed end-of-life care with their clinician, that they would like such a discussion, and that their preference is for care focused on comfort, rather than on extending life. We will also examine referrals to palliative care services for all patients who, at any assessment point, indicated that they preferred treatment focused on comfort and that (additional) discussion was desired. Finally, we will examine referrals to palliative care services for all patients in the intervention group compared to the control group.

The intervention's effect on reducing unwanted life-sustaining therapies will be tested over the 6 month follow-up period with clustered logistic/probit regression models, adjusted for confounders, and using a dichotomous outcome based on the EHR. The outcome indicates whether patients received any of the three targeted life-sustaining therapies (i.e., admission to the ICU, receipt of CPR, receipt of mechanical ventilation).The sample includes patients whose preferences indicate that they want care focused on comfort, and these preferences will be ascertained from the time period closest to the hospitalization during which life-sustaining therapies were received. In addition, secondary analyses will compare utilization of any of the three targeted life-sustaining therapies by all patients randomized to intervention vs. control across the full 6-month follow-up.

Analysis for Aim 3: assessing the intervention's effect on patients' and family members' anxiety and depression 3 months after the target visit.

Anxiety is assessed with the GAD-7 anxiety score (a continuous scale with 0-21 range); depression is assessed with the PHQ-8 depression score (a continuous scale with 0-27 range). These scores will be tested for unidimensionality and between-group measurement invariance to ensure that the most appropriate composite score is used as an outcome. The test is based on clustered regressions, with outcomes (i.e., patient anxiety, patient depression, family anxiety, family depression) regressed on the randomization predictor, after adjustment for the baseline score of the outcome measure and for other confounders.

Subgroup Analyses

In addition to the regression models specified for the full sample, analysis tests the same regression models outlined above, but within subgroups. In particular, this looks at groups defined by patient race/ethnicity and the presence of the following chronic illnesses, including cancer, lung disease, liver disease, kidney disease, and heart disease.

Handling of missing data

The primary approach to missing data (either missing measures or missing responses within a measure) is to minimize it by reducing respondent burden, offering multiple methods for survey completion, and having trained staff in frequent contact with participants. Indirect tests of the mechanism of missingness are explored by examining: 1) baseline characteristics of those who ever and never missed, by treatment group allocation; and 2) the difference between mean outcome scores of patients with missing vs. non-missing data. To address missing data, the study will use two approaches: 1) a FIML approach that allows for the use of all available data for each regression model; and 2) propensity scoring. Although multiple imputation models are available, some of the assumptions of MI models (e.g., continuous outcomes, assignment of imputed values that are outside the range of permissible values) make it less attractive than these other methods. Sensitivity analyses will be used to explore the effect of differing assumptions and methods on the results, and we will report these results.

Avoidance of bias

Bias is minimized by the RCT design in which clinicians are randomly assigned to control or intervention. Other potential sources of bias that are important to address include:

- Potential respondent bias in an unblinded study -- The intervention precludes blinding clinicians, patients, or family. This could introduce bias if patients or family in the intervention arm give different ratings for reasons other than the intervention (i.e. they want to please researchers). However, intervention and control participants receive the same contact with study staff, which mitigates this potential source of bias.
- Non-participation and loss-to-follow-up -- Patients, families, and clinicians who agree to participate may be different from those who decline. Many patients or families who refuse may also refuse to participate in this intervention in clinical practice. This mitigates the effect that non-response bias has on the generalizability of the findings. Nonetheless, data on response rates and basic data on non-respondents is collected to allow for estimates on the magnitude of this potential bias.
- Contamination -- Because enrolled Primary Clinicians may work in clinics and within teams that are shared by other enrolled clinicians, it is theoretically possible that contamination through the teams could result in improved care delivered to the patients of control clinicians. This is unlikely to have a major effect because the primary hypothesis and preliminary data suggest care is unlikely to improve without the patient-specific feedback provided by the intervention for which the “phase II” study showed efficacy. While the study cannot control for potential contamination, analyses can look for improved outcomes in the control group over time as a way to identify a potential contamination effect. Since contamination would bias results toward the null hypothesis, the results will provide a conservative estimate of an intervention effect.

XI. Publications about Study Procedures

Information about the study is published on the web at:

- Patient-Centered Outcomes Research Institute, http://www.pcori.org/assets/PCORI-PFA-Cycle-II-Awardees-050613.pdf
- UW End-of-Life Care Research Program, http://depts.washington.edu/eolcare/current-research/pcori-icsi/
- ClinicalTrials.gov, http://clinicaltrials.gov/show/NCT01933789

ICSI Patient Screening Form [HIPAA disclosure done ☐]

CID: _____ Screened by: _____ Date: _____

Inclusion Criteria

☐ **Age ≥ 18** age at screening: _____; date of birth: _____

☐ **≥2 visits with 1° Clinician in last 18 mos.** [_____] [_____] and next visit: [_____]

☐ **Diagnosis**

☐ metastatic cancer	☐ inoperable lung cancer
☐ COPD w. FEV1 < 35% predicted	☐ COPD w. oxygen dependence
☐ NYHA Class III or IV heart failure	☐ LVAD, or ICD with age over 65 years
☐ PAH w. 6MWD <250m	☐ PAH w. NYHA III or IV HF
☐ Child's Class C cirrhosis	☐ End-stage Liver Disease MELD score > 17
☐ dialysis-dep. renal failure w. diabetes	☐ dialysis-dep. renal failure w. albumin <2.5
☐ restrictive lung disease (IPF, ILD) w/ TLC <50%	
☐ cystic fibrosis with FEV1 < 30%	
☐ age > 75 years with at least 1 life-limiting chronic illness: _____; ≥90	

or

☐ **Hospitalization within the last 18 months** [_____]: diagnosis of above with lesser severity, or not enough info, even if hospitalization is unrelated to primary diagnosis; reason: _____

or

☐ **Comorbidity, Charlson Index Score ≥ 6** [_____]: standard review of 'Problem List'

___	AIDS (HIV C3)	[1 point]**
___	Myocardial Infarction	[1 point] MI, NSTEMI, STEMI, myocardial infarction, CAD
___	Congestive heart failure	[1 point] CHF, all HF (e.g. diastolic, etc.)
___	Peripheral vascular disease	[1 point] PVD, PAD
___	Cerebrovascular disease*	[1 point] TIA, CVD, CVA, stroke
___	Dementia	[1 point]
___	COPD	[1 point] emphysema, chronic bronchitis
___	Connective tissue disease	[1 point] lupus, scleroderma, RA, polymyositis, dermatomyositis)
___	Peptic ulcer disease	[1 point] PUD, duodenal ulcer, gastric ulcer
___	Mild liver disease	[1 point] any liver disease that is not noted above, e.g. fatty liver
___	Diabetes*	[1 point] DM, DM1, DM2
___	Hemiplegia*	[2 points]
___	Mod to severe renal disease	[2 points] baseline creatinine ≥3, on hemodialysis (HD), ESRD, chronic renal insufficiency (CRI), chronic kidney disease (CKD) but has to have baseline creatinine ≥3 or be on hemodialysis
___	Diabetes w/ organ damage*	[2 points] DM with kidney disease, e.g. renal insufficiency
___	Any tumor in the last 5 yrs*	[2 points] any tumor or cancer stage I-IIIb
___	Lymphoma	[2 points] Hodgkin's disease, Non-Hodgkin lymphoma
___	Leukemia	[2 points] acute lymphocytic leukemia (ALL), acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), myelofibrosis
___	Mod to severe liver disease	[3 points] cirrhosis w portal hypertension, ascites, chronic jaundice, hx liver txplant
___	Metastatic solid tumor*	[6 points] stage IV cancer, mets; meets diagnosis criteria above
___	Points for age:	50+ [1pt]; 60+[2pts]; 70+[3pts]; 80+[4pts]; 90+[5pts]; 100+[6pts]

*indicates double scoring in contrast to Charlson standard scoring

**assigned 1 point instead of Charlson standard score, 6 points

Exclusion Criteria

☐ non-English speaking
☐ significant dementia or cognitive impairment
☐ other reason: _____

Contact Information

Patient name: _____ PID: _____

MRN: _____

☐ male ☐ female | ☐ Hispanic ☐ non-Hispanic | race: _____

Phone1: _____ Phone2: _____

Address: _____ [limit 40 miles? ☐]

_____

city _____ state ___WA___ zip _____

email _____

LNOK: _____

Relationship: _____

___ involved in decision-making / named by patient

PCORI: Improving Communication about Serious Illness (ICSI) Study

Training on the Jumpstart Form for Clinicians

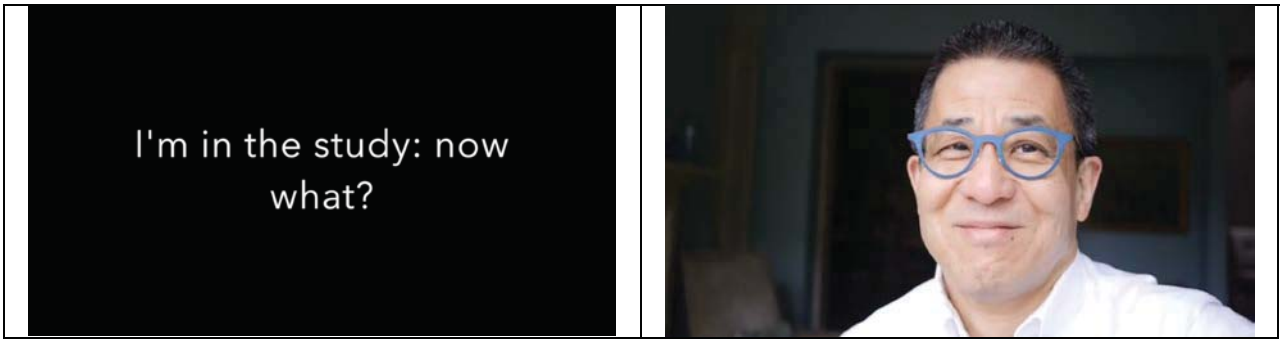
Hi, I'm Tony Back and I'm one of the investigators on this study. I'm here to give you a heads-up about what to expect with your participation in the study. First, thank you for participating. We know that clinical work is busier than ever and yet what you are doing is incredibly important in helping patients think about the future.

The idea of our study is to use patient preferences to guide discussions about advance care planning. We're trying to remind patients and providers both to discuss advance care plans by having the patients fill out a questionnaire. Then, right before the visit, we have both the patient and the providers get a form that summarizes what the patient said on the questionnaire. We're calling the form a 'Jumpstart' form because we're hoping it will jump-start the conversations to make them, for you, both easier and more efficient. So before you go into the clinic room with your patient you should have received an email or hard copy of the Jumpstart form. Take a second to glance over it. It does have a couple of things that you could say that will summarize important points from the patient's questionnaire. When you go in, one way you could start is to say, "You know I have a couple of things on my agenda for today, and I'd like to save a couple of minutes for that Jumpstart form. But what's at the top of your list?" Then, when you're done with the visit, document the discussion in the chart. A sentence or two is fine. If the patient isn't ready to decide, just note that you discussed it, because starting that process of thinking is what's really important. Thank you.

https://vimeo.com/user20181740/review/116890241/2796f889bb

PCORI: Improving Communication about Serious Illness (ICSI) Study

Using the Jumpstart Form – for Patients



Hi, I'm Dr. Tony Back. You're seeing this video because you've agreed to be in our study. Thank you. We know that you want to get the best possible medical care for yourself. We want to make it easier for you to get the medical care that's best for you by improving the conversation that you have with your doctor or nurse practitioner.

Right after you agreed to be part of our study, you might remember that we asked you to fill out a questionnaire – and you might have just finished it, or you might have done it a while ago. Either way, before your next visit to your doctor or nurse practitioner, we'll send you a form that reminds you about what you said on the questionnaire. The form is called a 'Jumpstart' form because we're hoping that it will jump-start your conversation with your doctor or nurse.

We've learned from our research that if you tell your doctor or nurse about the kind of medical care you want if you got sicker, that you're more likely to get that care. But we know it's also hard to do. They're tough conversations to have, so here's what to do. . .

Take the Jumpstart form with you when you go to see your doctor or nurse. The form will give you some tips about what to say. Your doctor or nurse will also get a reminder from us, so they'll probably be expecting you to bring it up. They might even bring it up first. You might find that after the visit that you have new questions or different thoughts, and that is normal. Lots of people think about things over time, sometimes they even change their minds about what's important. So don't worry about it, just tell your doctor or nurse the next time you see them. It will help you get the medical care that is best for you. Thank you.

https://vimeo.com/116908500

PCORI: Improving Communication about Serious Illness (ICSI) Study

Using the Jumpstart Form – for Family Members

Hi, I'm Dr. Tony Back. You're seeing this because you're a family member who's participating in our study. Thank you. By "family member" we mean anyone who is important enough to be at a doctor's visit. You might be a friend; you might be family. For our purposes, you're there, and that's what's most important. Thank you for everything you do. We know you're there because you want your family member to get the best possible medical care. That's why we're doing this study. We want to see if we can help doctors have better conversations with people about the kind of care they would want if they got sicker.

Here's what you can do. Before the visit, take a look at the Jumpstart form that you'll get from us. And say to your family member, "Hey, did you get that form? What did you think about it?" Then during the visit, when you're with your family member, at some point you might be able to say, "Hey, what about that Jumpstart form?" What we're trying to do is get a conversation started. I have seen family members be so helpful when they say things like, "You once told me that if you got sicker (this) was what was most important for you. Is that still true?" Or you can just say, "You know, I didn't understand what you were saying, Doctor. Could you repeat that?"

Your family member and you don't have to make any final decisions today. This is just about getting the conversation started, because we know from experience that it takes everybody a while to sort of figure this issue out. It's often not something people will know right off the tops of their heads. Your help and support are so important; it's terrific that you are taking the time to do this. Thank you.

http://vimeo.com/user20181740/review/85045368/375a483d56

I improving
C communication about
S serious
I illness

"Jumpstart" Form: Your Patient's Perceptions of Communication and Care

Here's a summary of what your patient, [patient name], endorsed on our questionnaire about goals of care. Your appointment with this patient is coming up on [appointment date]. We're providing this information to help facilitate a discussion about his/her goals of care, both currently and in the event he/she was unable to speak for him/herself in the future. Feel free to use or adapt these suggestions to your style and your patient.

Is your patient ready to discuss goals of care or end of life wishes/preferences?

Ever discussed preferences if/when too sick to speak for self? ..... YES
Ever discussed preferences if/when too sick to speak for self? ..... NO
Ever discussed preferences if/when too sick to speak for self? ..... DON'T KNOW
Ever discussed preferences if/when too sick to speak for self? ..... [other comment]
Want to discuss / discuss more? ..... YES
Want to discuss / discuss more? ..... NO
Want to discuss / discuss more? ..... DON'T KNOW
Want to discuss / discuss more? ..... [other comment]

STUDY SUGGESTION: [matrix]

What is your patient's perception of care currently? [quality of life (relieving pain/discomfort); extending life]

Prefers to focus on ..... EXTENDING LIFE
Prefers to focus on ..... QUALITY OF LIFE
Prefers to focus on ..... NOT SURE
Perception that care now is focusing on ..... EXTENDING LIFE
Perception that care now is focusing on ..... QUALITY OF LIFE
Perception that care now is focusing on ..... NOT SURE

STUDY SUGGESTION: [matrix]

What makes it harder for your patient to talk about this? [barriers]

- "I don't know what kind of care I would want if I were to get very sick."
- "I'm not ready to talk about the care I would want if I were to get very sick."
- "I don't like to talk about getting very sick."
- "My doctor never seems to have the time to talk about issues like end-of-life care."
- "I would rather concentrate on staying alive than talk about death."
- "I feel that talking about death can bring death closer."
- "I have a living will, and that means I don't need to talk with my doctor about the care I would want if I were too sick to speak for myself."
- "My ideas about the kind of medical care I want change at different times."
- "I have not felt sick enough to talk with my doctor about end-of-life care."
- "I'm not sure which doctor would be taking care of me if I were to get very sick."

What makes it easier for your patient to talk about this? [facilitators]

- "I have been very sick so it is easier to talk about."
- "I have had family or friends who have died so it is easier to talk about."
- "I worry about the quality of my life in the future."
- "I worry that I could be a burden on my friends and family if I were to become very sick."

What makes it harder or easier for your patient to talk about this? [barriers/facilitators]

- (Your patient did not endorse any of the barriers or facilitators that were presented.)

STUDY SUGGESTION: [matrix]

In the future: [CPR]

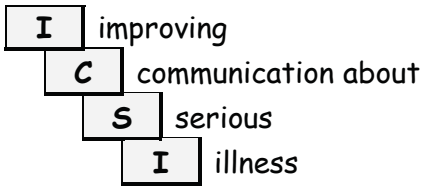
In current state of health ..... DEFINITELY DOES NOT WANT CPR
In current state of health ..... PROBABLY DOES NOT WANT CPR
In current state of health ..... PROBABLY WANTS CPR
In current state of health ..... DEFINITELY WANTS CPR

In state of dependent on others for ADLs ..... DEFINITELY DOES NOT WANT CPR
In state of dependent on others for ADLs ..... PROBABLY DOES NOT WANT CPR
In state of dependent on others for ADLs ..... PROBABLY WANTS CPR
In state of dependent on others for ADLs ..... DEFINITELY WANTS CPR

STUDY SUGGESTION: [matrix]

Wrap-up & Thank you

Thank you for your participation and please remember to document any discussions you have with the patient in the medical record.



Getting a "jumpstart" on your appointment with your doctor.

Thank you for being in our study. You filled out a questionnaire for us a little while ago. This is a friendly reminder that you will have an appointment with your doctor soon. We want to help you make the most of your appointment.

Talking to your doctor about your medical care: It's easier than you think.

Your doctor is interested in hearing your thoughts and worries about your medical care. The doctor and nurse will be grateful that you are willing to talk. You don't have to go into lots of detail. Just get the conversation started.

Here are 2 important questions: [Take this sheet of paper in to your appointment!]

1. Could we talk about what I want if something serious were to happen *now* in my current health?
2. I am hoping for the best, but I also want to plan if something serious were to happen *in the future*. Could we talk about that?

If you feel a little nervous…

It's ok! Many people think that the doctor might not have time, or might know best – but remember that you are the expert on what is important in your life. So just give these questions a try!

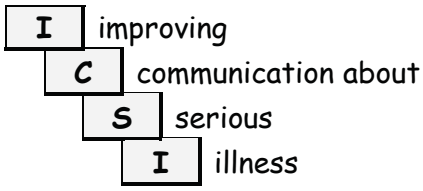
Here is some information from your questionnaire. These are just reminders for you. You can change your mind at any time.

We asked:	*Have you talked to your doctor about medical care you want if you got too sick to speak for yourself?*
	You answered: Yes \ No \ I don't know
We asked:	*Would you like to talk about what is important in your medical care if you got too sick to speak for yourself?*
	You answered: Yes \ No \ I don't know
We asked:	*Do you prefer that your medical care is more focused on extending life, or on quality of life?*
	You answered: My priority is on EXTENDING LIFE
	You answered: My priority is on QUALITY OF LIFE (relieving pain and discomfort)
	You answered: I am NOT SURE
We asked:	*Is your current medical care more focused on extending life, or on quality of life?*
	You answered: Seems focused on EXTENDING LIFE
	You answered: Seems focused on QUALITY OF LIFE (relieving pain and discomfort)
	You answered: I am NOT SURE
We asked:	*Have you thought about whether you would want CPR?*
	You answered: If my health is like it is today, I would DEFINITELY NOT WANT CPR

PID

You answered: If my health is like it is today, I would PROBABLY NOT WANT CPR
You answered: If my health is like it is today, I would PROBABLY WANT CPR
You answered: If my health is like it is today, I would DEFINITELY WANT CPR
You answered: If I was confined to bed & dependent on others, I'd DEFINITELY NOT WANT CPR
You answered: If I was confined to bed & dependent on others, I'd PROBABLY NOT WANT CPR
You answered: If I was confined to bed & dependent on others, I'd PROBABLY WANT CPR
You answered: If I was confined to bed & dependent on others, I'd DEFINITELY WANT CPR

We hope this information is useful. Feel free to take this to your appointment – pull it out when you are talking to your doctor or nurse.



Getting a "jumpstart" on your family member's doctor appointment.

Thank you for being in our study. This is a friendly reminder that your family member will have an appointment with your doctor soon. (To us, 'family' means anyone important enough to be at the doctor's visit—you might be a relative or a friend.)

You can help by talking to your family member before the appointment.

Say: "I want to make sure you get the best care possible. Tell me what you are thinking about your medical care if things got serious. I will just listen so I can remember."

When you are at the appointment:

DO let your family member talk first.
YOU CAN SAY, "I remember that you told me about what you wanted…"
IT'S OK to say: "Doctor, I would like to understand this better. Could you say more?"

If you feel a little nervous…

It's ok! Many people think that the doctor might not have time, or might know best—but actually doctors feel it's very important to talk about this stuff.

Thank you! Your help is really important!

Feel free to take this in to the appointment.

We asked:	*Would you like to talk about what is important in your medical care if you got too sick to speak for yourself?*
	Your family member answered: Yes \ No \ I don't know
We asked:	*Do you prefer that your medical care is more focused on extending life, or on quality of life?*
	Your family member answered: My priority is on EXTENDING LIFE
	Your family member answered: My priority is on QUALITY OF LIFE (relieving pain & discomfort)
	Your family member answered: I am NOT SURE
We asked:	*Is your current medical care more focused on extending life, or on quality of life?*
	Your family member answered: Seems focused on EXTENDING LIFE
	Your family member answered: Seems focused on QUALITY OF LIFE (relieving pain & discomfort)
	Your family member answered: I am NOT SURE
We asked:	*Have you thought about whether you would want CPR?*
	Your family member answered: If my health is like it is today, I'd DEFINITELY NOT WANT CPR
	Your family member answered: If my health is like it is today, I'd PROBABLY NOT WANT CPR
	Your family member answered: If my health is like it is today, I would PROBABLY WANT CPR
	Your family member answered: If my health is like it is today, I would DEFINITELY WANT CPR

	Your family member answered: If I was confined to bed and dependent on others, I would DEFINITELY NOT WANT CPR
	Your family member answered: If I was confined to bed and dependent on others, I would PROBABLY NOT WANT CPR
	Your family member answered: If I was confined to bed and dependent on others, I would PROBABLY WANT CPR
	Your family member answered: If I was confined to bed and dependent on others, I would DEFINITELY WANT CPR

Matrix for clinician Jumpstart forms – "Our Recommendations/Study Suggestion"

**Ideally we want to have programmable text available to use to create the forms.

**Is there any alternate text for some that may be dependent on answers to other items (e.g. a discrepancy like 'wants to focus on Quality of Life over Extending Life' but endorses wanting CPR)?

Item 1: **Is your patient ready?**

		b. Want to discuss / discuss more?		
		Yes*	No	Don't Know
a. Ever discussed preferences if/when too sick to speak for self?	Yes	Go for it! Ask if there have been any changes since the last time your patient talked to you or to another clinician.	Check what you know; reinforce why it's important to repeat periodically. Try saying: "It is helpful for me if I make sure I am up-to-date on your views about the care you want."	Ask the patient's permission to talk about preferences; reinforce why these discussions are important. Try saying: "It is helpful for me if I make sure I understand your views about the care you want."
	No*	Go for it! Try saying: "I am interested in knowing your thoughts about that Jumpstart form."	Ask the patient's permission to talk about preferences; reinforce why these discussions are important. Try saying: "It is helpful for me if I make sure I understand your views about the care you want."	Ask the patient's permission to talk about preferences; reinforce why these discussions are important. Try saying: "It is helpful for me if I make sure I understand your views about the care you want."
	Don't remember	Go for it! Try saying: "I am interested in knowing your thoughts about that Jumpstart form."	Ask the patient's permission to talk about preferences; reinforce why these discussions are important. Try saying: "It is helpful for me if I make sure I understand your views about the care you want."	Ask the patient's permission to talk about preferences; reinforce why these discussions are important. Try saying: "It is helpful for me if I make sure I understand your views about the care you want."

*check pall care referral, see Item #2

Item 2: **What is your patient's perception of care currently? [quality of life or extending life]**
** normalize, talk about options

		b. Patient perceives that healthcare currently received is focused on:		
		EXTENDING LIFE	QUALITY OF LIFE	NOT SURE
a. At this time, if patient had to choose, he/she prefers to focus on:	EXTENDING LIFE	Your patient seems to feel he/she is getting the care he/she wants at this point. Because the patient is focused on extending life, see the items below about thinking about the future.	Your patient seems to feel his/her current care does not match his/her goals. It may be worthwhile to check this. Try saying: "Some people prefer care focused on extending life even if it means they might be uncomfortable; other people prefer care focused on quality of life even if it means they may not live as long. If you had to choose, what would you say is more important?"	It would be worthwhile to review what you perceive to be the focus of the patient's care since the patient isn't sure. Because the patient prefers to focus on extending life, see the items below about thinking about the future. Try saying: "Would it be helpful for me to clarify how I see the focus of your care?"
	*QUALITY OF LIFE	Your patient seems to feel his/her current care does not match his/her goals. It may be worthwhile to check this. Try saying: "Some people prefer care focused on extending life even if it means they might be uncomfortable; other people prefer care focused on quality of life even if it means they may not live as long. If you had to choose, what would you say is more important?" [*If ever=NO and want=YES then add: Assess if patient is interested in Palliative Care referral.]	Your patient seems to feel he/she is getting the care he/she wants at this point. Because the patient is focused on quality of life, consider whether completion of a POLST form or identifying a surrogate decision-maker would be useful. [*If ever=NO and want=YES then add:] Assess if the patient is interested in Palliative Care referral.	It would be worthwhile to review what you perceive to be the focus of the patient's care since the patient isn't sure. Try saying: "Would it be helpful for me to clarify how I see the focus of your care?" Because the patient prefers to focus on quality of life, consider whether completion of a POLST form or identifying a surrogate decision-maker would be useful.
	NOT SURE	Since your patient isn't sure what he/she would choose as his/her focus of care, try saying: "Some people prefer care focused on extending life even if it means they might be uncomfortable; other people prefer care focused on quality of life even if it means they may not live as long. If you had to choose, what would you say is more important?"	Since your patient isn't sure what his/her focus of care is, try saying: "Some people prefer care focused on extending life even if it means they might be uncomfortable; other people prefer care focused on quality of life even if it means they may not live as long. If you had to choose, what would you say is more important?"	Since your patient isn't sure what his/her focus of care is, try saying: "Some people prefer care focused on extending life even if it means they might be uncomfortable; other people prefer care focused on quality of life even if it means they may not live as long. If you had to choose, what would you say is more important?"

Item 3: **<u>What makes it harder for your patient to talk about this? [barriers]</u>**

1. I don't know what kind of care I would want if I were to get very sick.	Explain that the patient doesn't need to know what he/she wants. Try saying: "Even if you aren't sure what kind of care you want in the future, it is very helpful to me if we talk about the things that are most important to you about your quality of life and healthcare."
2. I'm not ready to talk about the care I would want if I were to get very sick.	Acknowledge patient's uncertainty and worry (emotion). Try saying: "Some people find it hard to talk about their healthcare in the future. Would you consider giving it a try for a few minutes? At any time, you can just say, 'Ok, that's enough for today.'"
3. I don't like to talk about getting very sick.	
~~My clinician doesn't like to talk about my getting very sick.~~	Explore patient's beliefs and acknowledge discomfort. Try saying: "Sometimes people worry that doctors don't have enough time or wouldn't agree with your thoughts. I want you to know that I consider this topic really important."
4. My doctor never seems to have the time to talk about issues like end-of-life care.	
5. I would rather concentrate on staying alive than talk about death.	Acknowledge patient's worry (emotion). Try saying: "Some people find it hard to talk about their healthcare in the future. Would you consider giving it a try for a few minutes? At any time, you can just say, 'Ok, that's enough for today.'"
6. I feel that talking about death can bring death closer.	
7. I have a living will, and that means I don't need to talk with my doctor about the care I would want if I were too sick to speak for myself.	Explore patient's beliefs, acknowledge discomfort, explain why it's good to check-in and verify. Try saying: "If I have worked with a patient, I usually have some idea of how he/she feels about these decisions; but I appreciate checking with you to make sure I have it right."
8. My ideas about the kind of medical care I want change at different times.	Explain that talking now starts a process of learning for you and your patient. Try saying: "This is a big topic. Some people need time before they know what decisions would be best. Others worry that they might change their mind in the future. Either way, it still helps me to know something about what you think, even if it's not final."
9. I have <u>not</u> felt sick enough to talk with my doctor about end-of-life care.	Encourage patient to be thinking and talking with you about this topic. Try saying: "If I am taking care of a patient, I usually have some idea of how he/she feels about these decisions. But I appreciate checking with you to make sure I have it right."
10. I'm not sure which doctor would be taking care of me if I were to get very sick.	Explain that the patient doesn't need to know which clinician will be caring for him/her at the end of life. Try saying: "Although you may see a lot of doctors and it is hard to know which of us will be there if you get very sick, it is still important to talk with me about these issues and I will document it so other doctors have access to this information."

** If there is no single "biggest / most important" barrier endorsed, we will feedback one barrier, chosen at random, of those that were endorsed.

** If no barriers are endorsed, then facilitators will be included.

** If no barriers OR facilitators are endorsed then use… Explain that talking now starts a process of learning for you and your patient. Try saying: "If I am taking care of a patient, I usually have some idea of how he/she feels about these decisions, but I appreciate checking with you to make sure I have it right."

Item 3{alt}: **What makes it easier for your patient to talk about this? [facilitators]**

1. I have been very sick so it is easier to talk about.	Reinforce patient's decision-making that was helped by prior experiences. Try saying: "You mentioned on the survey that you have some personal experience with this. Could you tell me about how your experience influences your thinking?"
2. I have had family or friends who have died so it is easier to talk about.	
3. I worry about the quality of my life in the future.	Acknowledge that concerns about quality of life make advance care planning important. Try saying: "You mentioned on the survey that you worry about your quality of life in the future. It would be helpful for me if I understood what you consider to be important for your quality of life."
4. I worry that I could be a burden on my friends and family if I were to become very sick.	Acknowledge that advance care planning can reduce burden on family/friends. Try saying: "It can reduce the burden on your family and friends if you talk with me and with them about the kind of care you would want if you got very sick."

** If there is no "biggest / most important" facilitator endorsed, we will feedback one facilitator, chosen at random, of those that were endorsed.

** If no barriers OR facilitators are endorsed then use… Explain that talking now starts a process of learning for you and your patient. Try saying: "If I am taking care of a patient, I usually have some idea of how he/she feels about these decisions, but I appreciate checking with you to make sure I have it right."

Item 4: **In the future: [want/don't want CPR]**

		b. In state of dependence on others for ADLs [confined to bed]	
		DEFINITELY or PROBABLY WANTS CPR	DEFINITELY or PROBABLY DOES NOT WANT CPR
a. In current state of health	DEFINITELY or PROBABLY WANTS CPR	Confirm patient's desire to receive CPR. Try saying: "You have indicated that you would want to receive CPR if your heart were to stop beating. Is that correct? Are there any other treatments or situations that we should talk about?"	Confirm patient's desire to receive CPR. Try saying: "You have indicated that you would want to receive CPR if your heart were to stop beating in your current health, but not if you were to get much sicker and be dependent on others. Is that correct?"
	DEFINITELY or PROBABLY DOES NOT WANT CPR	These responses seem inconsistent. Assess patient's wishes about CPR. Try saying: "You have indicated that you would not want to receive CPR if your heart was to stop beating in your current health, but you would want it if you were much sicker and dependent on others. Is that correct? Can you tell me more about that?"	Confirm patient's desire not to receive CPR. Try saying: "You have indicated that you would not want to receive CPR if your heart were to stop beating. Is that correct?" If yes, consider completing a POLST form or a referral to Palliative Care.

** If there is no information for this section, e.g. patient skipped this page, then use: "[skipped this page of survey]" or "[skipped this item]" and recommend:

Because your patient did not provide any answers to this item/these items, our recommendation is only to address this topic in light of the patient's answer about his/her preferences for focusing on extending life/quality of life.

Item 5: **Wrap-up (instead of a reminder to thank the patient…)**

Please don't forget to document any discussions you have with the patient in the medical record.

Improving Communication about Serious Illness (ICSI) Study: Chart Abstraction Protocol/Manual

Revision Date: January 30, 2017

Table of Contents

General Data Collection Rules

- No patient-identifying, family-identifying or clinician-identifying information should be recorded on any data collection forms. The "Patient Tracking Form" includes this information so that patient charts may be identified and/ordered. After data collection is complete, tracking forms will be removed from data collection forms and destroyed.

- Do not discuss patient cases with non-study personnel. Respect confidentiality of all patient data.

- Data can be recorded on paper form for entry into database or entered directly into the database upon abstraction.

- Do not abstract patients without the patient tracking form. Keep the tracking forms and spreadsheets up-to-date with data collection progress to avoid duplication.

- Record comments and questions for the research nurse/coordinator on the "Patient Tracking Form" or spreadsheet or email directly.

- Contact the research nurse/coordinator regularly (as scheduled and required) to communicate status.

- Backs of pages and margins of paper abstracting form may be used for notes, as necessary. Notes can also be entered on the spreadsheet. Clarify atypical or potentially conflicting data with a note. These notes may not be systematically reviewed by the research nurse/coordinator or other study personnel. Questions or comments that need to be reviewed should be noted on the tracking form and brought to research nurse/coordinator attention.

- "777" indicates missing data, and should be used only after all other attempts to locate information have failed.

- When data collection is complete, do the following to reduce the likelihood of errors:
    - Make sure each paper form has all of its pages and that the pages are in order.
    - Review each page of each form to look for skipped items. If a data item was not collected because the information was not available in the medical record, slash through the data item on the form. Do not leave blanks.
    - Complete the relevant sections of the "Patient Tracking Form". Record any problems on the "Notes" section of the form for review by the research coordinator. Date any notes made.
    - Attach all forms together with the "Patient Tracking Form" on top. File in the locked filing cabinet in correct numerical order by PID.

- When data is entered directly from chart – and not also recorded on paper form – make a notation on the "Patient Tracking Form" to the effect of "paper form incomplete, data entered directly into db" on the abstraction form.

Quality Control Procedures ("Doubling")

- The research coordinator will randomly designate which charts are to be double-abstracted for quality control purposes. After initial abstraction, the "Patient Tracking Form" and completed abstraction form will be assigned to a different abstractor for abstraction a second time (double abstraction).

- The abstractor is to complete double-abstraction according to the same rules and in the same manner as the original chart abstraction without looking at the original abstraction.

- Upon completion of chart abstraction, with the actual patient chart open, compare the original abstraction data set with the second set of data. Indicate on the doubling form where data items are different (e.g. "X").

- Rules: If the original chart abstraction does not include questions that are on the doubled chart abstraction form, do not count these as discrepancies. Anything that has changed between the two abstractions needs to be reviewed and corrected, e.g. now not collecting Treatment Preference Discussions, check if these should be Advance Care Planning Discussed/Completed.

- Count up the differences and record them in the "Notes" section of the "Patient Tracking Form". Mark, initial and date the "Double Abstracted" box on the "Patient Tracking Form" in the "Quality Control Information" section.

- Edit the second abstraction, correcting any errors and confirming data discrepancies using the patient chart for reference. If possible, the two abstractors should discuss the differences for learning purposes as well as an informed resolution of discrepancies.

- Indicate on the "Patient Tracking Form" and page one of the abstraction form which version is the corrected abstraction, and return to the research nurse/coordinator. Corrected information should be entered into the database. The nurse/coordinator will record the date that the chart was doubled and the number of discrepancies in the database.

- In situations where paper forms are incomplete because data has been entered directly from the chart to the database, count errors as differences in what is entered in the database compared with what the second abstractor has obtained.

Patient Tracking Form (PTF)

A "Patient Tracking Form" (PTF) will be completed for each patient. This form contains the following sections:

1. Patient Information – This section includes:
   Medical Record Number
   Assigned study number
   Patient Initials
   Initial study screening date
   Study enrollment date [-] 6 months (database will calculate exact date)
   Study enrollment date (database will provide date)
   Study target visit date (database will provide date)
   Study target visit date [+] 6 months (database will calculate exact date)

2. Abstraction Information – This section records who abstracted the patient medical record and documents that all data collection forms have been completed. If an abstractor needs help completing a form, the problem should be marked and further described in the "Notes" section of the PTF or on an additional page if necessary.

3. Data Entry Information – This section records who edited the forms for completion and who entered the abstracted data into the database.

4. Quality Control Information – This section details any quality control reviews done for either data entry or data abstraction. Dates and initials of individuals completing reviews are recorded. If there is a difficult case or a need for a sample case, mark the case presentation box and return forms to research nurse/coordinator. Mark the data verified box when all forms are complete, entered, and data verified.

5. Notes – Any problems, questions, or comments should be recorded here for use by research staff. Notes should always be dated and initialed to clearly indicate how and when problems are being corrected.

Next, the abstractor is to read through each chart individually and collect the data as requested on the ICSI abstraction form.

After the database manager inspects the corrected/verified data for out-of-range values and other problems, the PTF with the patient-identifying data will be removed from all other data collection forms and destroyed.

Chart Abstraction

Rules: In general, we are interested in the data six months prior to the enrollment date (enrollment [-] 6 months) to six months after the 'target' visit (target visit [+] 6 months). If there is an obvious error in date or any discrepancies in date, use the date that is supported by other information within the chart.

Initials: Record your initials to document who abstracted the chart. When doing direct chart-to-database entry, choose your name from the drop down menu.

I. DATES

The following information is recorded in the BASIC CHART section of the database. The dates are calculated by the database and will appear in read at the top of the screen. All dates are recorded in the following manner: (MM/DD/YYYY).

Date of enrollment - 6 months:	Database calculates exactly 6 months; use those dates. Calculate -18 months by subtracting one year from the -6 month date.
Date of enrollment:	This is taken from the PTF "study enrollment date". USE DATES FROM DATABASE.
Date of target visit:	This is taken from the PTF "study target visit date". USE DATES FROM DATABASE.
Date of target visit + 6 months:	Database calculates exactly 6 months; use those dates; for withdrawals we do the period of enrollment to 6m after enrollment (no target visit) - the correct dates are generated by the database.
Date Abstracted:	Record the current date [by selecting it from the drop down menu]

II. PATIENT DEMOGRAPHICS

Date of Birth: CONFRIM DATE FROM DATABASE.

- Record the month, day, and year the patient was born. (MM/DD/YYYY)
- *Where to look*: Take this information from the demographic section of the chart or the chart header. In general, use ORCA, Mindscape and EPIC records for all data collection.
- *Rules*: If the date of birth is not documented or is documented incorrectly, the birth date should be recorded as occurring halfway through the patient's year of birth (i.e. 07/01/YYYY) so that the approximate age may be computed.

Died (yes/no):

This item is answered "yes" if the patient died during the study period which ends at enrollment date + 6 months. If you answer "yes" another field will pop up asking for the date of death. If the patient died AFTER the study period, choose "no" to this item. Make a note in the notes section of the patient's

death date if it is available. If there is a note in the chart that says the patient died 'last week' it is acceptable to enter 'patient died approximately 3/15/15'.

Date of death:

- Record the month, day, and year the patient died. (MM/DD/YYYY)
- *Where to look*: Take this information from the "Discharge Progress" notes if the patient died in the UW healthcare system. If the patient died elsewhere and there is a note in the transcripts section that states patient died, record as much detail as possible. Look under "Clinical Documents" under the subtitle 'Outside Records' in case documents were obtained. Also look in Mindscape under the last few telephone or email entries ("Transcripts") because sometimes a family member will call the clinic to inform them of the death.
- *Rules*: *Patient deaths outside of 6-months post-target visit* -- If a patient does not die within 6 months of the target visit, check the n/a box on paper and "no" in the database. In the notes section of the database record as much as known about the date and place of death.

Gender: CONFRIM FROM DATABASE.

- Indicate if the patient is Male, Female or Other
- *Where to Look*: the Demographic section of ORCA/EPIC/Mindscape.

III. ILLNESS/COMORBIDITIES

These are identified prior to/present at date of enrollment.

Choose any and all qualifying diagnoses that were present at the time of enrollment. Look in the "Transcripts" and the "Problem List" to see the diagnoses. Make sure the diagnoses were present at time of enrollment. Do not code a diagnosis that was made after enrollment. The point of this data is to get a snapshot of how sick the patient was at the time of enrollment. Same holds true for comorbidities.

Time Frame: Ideally we will only be looking back about 6 months from enrollment date. However, because of long term chronic illnesses, long relationships with providers and other irregularities in documentation it may be necessary to review further back than 6 months. For example: subspecialist started treatment with patient ~1 year ago and that initial note is more complete than subsequent notes re: fully medical and social history. This is necessary to ensure that eligibility criteria are met. [**This will affect doubling if the time frame is different; note changes November 2016.]

Where to Look: Remember to look under sub-specialty notes (if primary care) or primary care (if sub-specialty) for complete information. For example: cardiologist may not document patient's diabetes, primary care doc may not document full information about patient's heart failure.

Diagnosis
metastatic cancer
inoperable lung cancer
COPD w. FEV1 < 35% predicted
COPD w. oxygen dependence
NYHA Class III or IV heart failure
LVAD, or ICD with age over 65 years
PAH w. 6MWD <250m

PAH w. NYHA III or IV HF
Child's Class C cirrhosis
End-stage Liver Disease MELD score > 17
dialysis-dep. renal failure w. diabetes
dialysis-dep. renal failure w. albumin <2.5
restrictive lung disease (IPF, ILD) w/ TLC <50%
cystic fibrosis with FEV1 < 30%
age ≥ 75 years with at least 1 life-limiting chronic illness: [_____];
age ≥90
Number of hospitalization within the last 18 months [_____]: *This includes any hospitalization that is documented. It can be a UW hospital where ORCA indicates Inpatient stay or Limited Stay or OBS (observation) status of greater than 24 hours. This number includes non-UW hospital stays also, if evidence is found describing that a hospitalization occurred. Review progress notes for reference to INPATIENT stays*.

Comorbidity		
___	AIDS (HIV C3)	[1 point]**
___	Myocardial Infarction	[1 point] MI, NSTEMI, STEMI, myocardial infarction, CAD
___	Congestive heart failure	[1 point] CHF, all HF (e.g. diastolic, etc.)
___	Peripheral vascular disease	[1 point] PVD, PAD
___	Cerebrovascular disease*	[1 point] TIA, CVD, CVA, stroke
___	Dementia	[1 point]
___	COPD	[1 point] emphysema, chronic bronchitis
___	Connective tissue disease	[1 point] lupus, scleroderma, RA, polymyositis, dermatomyositis)
___	Peptic ulcer disease	[1 point] PUD, duodenal ulcer, gastric ulcer
___	Mild liver disease	[1 point] any liver disease that is not noted above, e.g. fatty liver
___	Diabetes*	[1 point] DM, DM1, DM2
___	Hemiplegia*	[2 points]
___	Mod to severe renal disease	[2 points] baseline creatinine ≥3, on hemodialysis (HD), ESRD, chronic renal insufficiency (CRI), chronic kidney disease (CKD) but has to have baseline creatinine ≥3 or be on hemodialysis
___	Diabetes w/ organ damage*	[2 points] DM with kidney disease, e.g. renal insufficiency
___	Any tumor in the last 5 yrs*	[2 points] any tumor or cancer stage I-IIIb
___	Lymphoma	[2 points] Hodgkin's disease, Non-Hodgkin lymphoma
___	Leukemia	[2 points] acute lymphocytic leukemia (ALL), acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), myelofibrosis
___	Mod to severe liver disease	[3 points] cirrhosis w portal hypertension, ascites, chronic jaundice, hx liver txplant
___	Metastatic solid tumor*	[6 points] stage IV cancer, mets; meets diagnosis criteria above
___	Points for age:	50+ [1pt]; 60+[2pts]; 70+[3pts]; 80+[4pts]; 90+[5pts]; 100+[6pts]

The total Charlson score is calculated by the database upon entry.

IV. ADVANCE CARE PLANNING

[at Valley: Look under "Media" tab for scans of advance directive documentation; check telephone call notes; often family member is in contact with provider; also with the specialists (e.g. Nephrology) may have to go back to first visit to collect social history info, including LNOK]

Note: SEARCHING -- In ORCA under "Results Review" is a tab for "Chart Search". If you type in "POLST", it will show you everywhere POLST appears. Do searches for "POLST", "advance directive", "living will" and "DPOA"/"POA"/"durable power of attorney", etc. on every patient that doesn't have the documents in the designated place.

A. POLST form?

1=Yes; 0=No; 888=Undocumented, no information; 999=Documented as "not known"
If yes, Legal Document in Chart?
1=Yes; 0=No; (666) Not applicable, true skip'

- Look for documentation in the "Advanced Directives" tab. If there is a scanned copy of the POLST form present, endorse yes. If there is a note in "Transcripts" that says a POLST was completed with the patient, also endorse yes.
- Look in "Media" tab in EPIC for copies of scanned documents as well.
- If yes is endorsed, complete the section about the legal document in the chart. If the document is not in the chart, choose NO. Only endorse YES if the scanned copy is present. Only endorse YES if the document is a legal document, with proper signatures. Look also in '"Outside Records" to see if the POLST may have been brought from an outside institution.
- For care preferences summary, read the POLST and mark the answer that most closely reflects what is on the POLST. [Care preference categories correspond with "Part B: Medical Intervention".] If the POLST is not present in the medical record but the clinician has written a summary note in 'Transcripts' you may use that information. For example if a clinician writes, "Completed POLST with patient today, pt desires time limited additional interventions," you would choose 'Limited additional interventions'. If a patient states a desire for full code and aggressive treatment, choose the 'full treatment' option.
- Enter the date of completion in the usual format. If the completion date is after the study period, the database will not permit this entry. In that case, select "no" for POLST and make a note in the comment field. The database will allow dates prior to enrollment.
- If there is more than one POLST on file in the EMR, enter the information from the *most recent* version, AS LONG AS it is still within the study period.
- On the paper form the choices are: 1. Comfort measures only/DNAR; 2. Limited additional interventions (might allow CPR or be DNAR); 3. Full treatment (CPR); and, 4. 888. There will be some cases were the pt. chooses NO CPR in part A of the POLST (pulseless interventions) but chooses limited or full treatment in part B of the POLST (has pulse). In this case, we would choose #2 (limited interventions) because not having CPR is a limitation of additional interventions; thus thinking CPR as just another treatment.

B. Does patient have a LIVING WILL or HEALTH CARE DIRECTIVE?

1=Yes; 0=No; 888=Undocumented, no information; 999=Documented as "not known"
If yes, Legal Document in Chart?
1=Yes; 0=No; (666) Not applicable, true skip'

- This will be similar or same as looking for POLST (above). If present, the living will should be located in the "Advance Directive" section of ORCA, "Outside Records" or "Transcripts". If the patient has a hospital stay, also check nursing, social work and MD progress notes for mention of any advance directives.

- Follow the same directions above if the form is not in the chart but there is a narrative description of the contents.
- ~~Social workers' notes take precedence.~~ Answer "Yes" if the notes indicate the patient has a living will, regardless of whether the actual living will is located in the chart. A living will includes those that have directives in support of life sustaining measures
- Enter the date of completion in the usual format. The database will allow dates prior to enrollment.
- "Non-standard" examples include things like: hand-written wishes on a piece of paper signed by patient. MOST are going to be marked standard.

C. Does the patient have a DPOAHC (Durable Power of Attorney for Health Care) or POA (Power of Attorney)?
1=Yes; 0=No; 888=Undocumented, no information; 999=Documented as "not known"
If yes, Relationship to patient?
1=Family member; 2=Non-family member; 888=Unspecified; 999=Documented as not known
If yes, Legal Document in Chart?
1=Yes; 0=No;

- *Definition*: A Durable Power of Attorney for Health Care is a written document in which a patient selects an individual to make health care decisions in the event that the patient becomes unable to speak for herself. A person who is designated to make such decisions may be called an "agent" or "attorney in fact." It is a signed and dated document that may or may not be notarized.
- Take this information from patient history, either social worker, nursing notes or "Transcript" section. Also look in the "Advanced Directives" or sometimes "Demographics" section. Sometimes also scanned in "Media" tab.
- ~~Social workers notes take precedence.~~ If family says "not aware" or "none known" of DPOA enter as "documented as unknown." If the chart has a section for POA documentation, and no information is recorded, then select "undocumented, no information". Significant other is considered family.

D. LNOK (Legal Next of Kin) identified?
1=Yes; 0=No; 888=Undocumented, no information; 999=Documented as "not known"
If yes, relationship to patient?
Spouse; Adult child(ren); Parent(s); Sibling(s); Guardian or Court Appointed (GAL) Guardian Ad Litem; Unspecified (888); Not applicable, true skip (666)

- Indicate "Yes" for all that apply. We have to follow WA State Law (WAC) and in this document, grandparents, aunts/uncles, nieces/nephews, have NO LEGAL STANDING. So, you mark "no" to LNOK, even if the chart says they are the legal next of kin. If one of these categories has been designated the DPOA, they then ALSO get to be LNOK.
- Take this information from patient history, either social worker, nursing notes or "Transcripts". Read palliative care notes as well as social work and other clinicians.
- If the LNOK information is noted in the EMR outside of the study period (e.g. in a note more than [+] 6 month follow-up, or in a note more than 18 months before enrollment) it is permissible to accept that information for abstraction: "yes" to LNOK.

V. INSURANCE

In the BASIC CHART page of the database this field requires only a yes or no answer. The actual types of insurance are entered in the INSURANCE section of the database. If using the paper abstraction form record the data about insurance for the dates included from 6 months before enrollment through enrollment date.

Where to Look: In the Mindscape starting screen, choose the subtitle "Coverage". Sometimes it is also noted in the visit notes at the top.
[at Valley: Look under "media" tab for scans of insurance cards]
[at WWC: Look under "registration" tab for insurance info]

Select the types of insurance (primary, secondary, etc.) from the drop down menu or write in the information if it is not on the drop down menu. If insurance is listed as "Charity", record and enter as such. If it is an "odd" or "unique" insurance, enter the contact information listed into the notes section (so Lois could look up).

Timing: In case of insurance changes, record only the valid insurance coverage during the study period as defined by enrollment through target visit [+]6 months. For example, if the enrollment date is 4/5/15 and there is an insurance policy that is identified as 'effective from' in the patient chart that is AFTER 4/5/15 do not use that one. Use the insurance in place before enrollment. If the date that corresponds to the study period is not visible, click on "Show All" and more coverage plans will be visible.

V. Health History Info : ICD-9/ICD-10 Principal Diagnosis (1st space) AND OTHER ICD-9/ICD-10 CODES

ICD-9/ICD-10 codes will no longer be collected SEPT 2016.

ICD-9/ICD-10 codes will be collected via AMALGA for all reporting UW Medicine clinics. Other sites – Swedish, Valley, NW/WWC – will be collected manually as directed below.

ICD-9/ICD-10 codes are indicators of diagnoses, and are comprised of a 3-digit number followed by a decimal point and further numbers, which are diagnosis qualifiers. Some ICD-9 codes may contain a "V" instead of the first number in the 3 digit series. Other codes may be the 3-digit series proceeded by an "E". ICD-10 codes typically have a capital letter followed by 2 digits, a decimal point and then one or two more digits. Rarely, there is a 3rd digit after the decimal point.

ICD-9 codes:
- If there are ICD-9 codes, mark yes in the database box. Copy ICD-9 codes into spaces available.

ICD-10 codes:
- If there are ICD-10 codes, mark yes in that box. Copy ICD-10 codes into spaces available. If there are no ICD-10 codes, simply record No in the box. Not all charts will have ICD-10 codes.

Where to Look:

1) Look in the "problems" or "problem list" area of an individual record and also check each individual progress note. Many will have codes listed in the upper right corner. Some do not have them listed in the upper right corner but are found in the text, after the written diagnosis. The ones written after a diagnosis are frequently ICD-9 and there won't be any ICD-10s.

2) Look for ICD-9 and/or ICD-10 codes in the "chart notes" or "transcripts" section where problems are listed at the top. Also, check in the "Problems" section and click on the small icon to get the ICD-9 codes. If there was an inpatient stay at UW, check the ORCA listing for "discharge codes". Check 'Problem list' at the bottom of the progress note by clicking on "view". Please note any date associated with the problem and do not include problems that have been resolved.

Rules:

- Be sure to put only ICD-9 codes in the ICD-9 area and ICD-10 codes in the ICD-10 area. Do not combine them.
- Copy the codes exactly as written on the discharge coding sheet, except in the case that the codes are missing decimal point. In this case, include the decimal point in the appropriate place (i.e. following the 3 digit string of numbers, "V" and 2 numbers, or "E" and 3 numbers).
- If there are more than 18 ICD-9 or ICD-10 codes, focus on the codes that mirror the comorbidities found in the Charlson, e.g. organ failures. If there are no ICD-9 or 10 codes, choose '888'.

V. OUTPATIENT VISITS

In the database, open "Pre-enrollment OP Visits". Select the patient from the drop down list. Click on the "Add" button. Record the date of the visit in the box and select from the menu which activities occurred at the visit.

Were there any outpatient visits in the 6 months before enrollment?

- Answer "yes" or "no" depending on what evidence you found.

Were there any outpatient visits between enrollment and six months after the target visit?

- Answer "yes" or "no" depending on what evidence you found.

Was there an outpatient visit on the same date as enrollment (e.g. pt. enrolled at clinic appointment)?

- Enter the Outpatient Visit in the POST-ENROLLMENT OP table.

OUTPATIENT CARE TABLE

These data are collected from 6 months prior to enrollment (enrollment [-] 6m) through target date plus 6 months (target date [+] 6m).

Date of Visit	POLST form discussed or completed	Advance care planning- discussed or completed	Prognosis discussion	~~Treatment preferences discussion~~[1]	Discussion of hospice	Discussion of referral to palliative care	Discussion of study participation [2]	Palliative care Referral	Hospice Referral	Social Work Referral	Spiritual Care Referral

[1] ~~Treatment preferences- discussion: to include discussions that may not necessarily result in a POLST or Advanced Directive form completed; for example, clinician notes "patient wants DNR" but there is no standardized documentation, then this would be checked here.~~

[2] ~~Not needed for pre-enrollment period~~

Complete the table using data from the transcripts of outpatient visits with the patient's study-enrolled provider (Clinician). Record the date of the visit. If supporting documentation is found, mark an affirmative "X" in the box of the paper form, or an "O" if no evidence found.

For all "X" items, copy the supporting text from the transcript into the database.
For all entries that are all "O", document "none" in the text box in the database.

If entering information directly into the database, affirmative marks are made by clicking the box next to the list of options. The clinician note that earned the affirmative mark should be copied from the medical record and pasted into the note box at the bottom of the screen. Any clarifying remarks by the abstractor should be prefaced by: "Abstractor's note".

Note: if the outpatient visit and the enrollment visit are on the same day (e.g. patient enrolled at appointment visit), then enter this visit into the POST-ENROLLMENT OP table.

Note: if the outpatient visit note's primary author is a e.g. resident but was co-signed or a joint visit with the enrolled clinician, this counts as a visit.

1. POLST Form Discussed or Completed -- Read notes in transcript for a note that says "completed POLST today" or "POLST form given to patient, will bring back next visit". If provider describes this indicate with an X in the table. If not, put a 0 in the box so you know you checked for that. [Note: if the POLST form in the chart was completed/signed with the study clinician on the date of a visit but there is no documentation about this activity in the chart note, put a X in the box for YES.

2. Advance Care Planning Discussed or Completed -- Read notes for documentation about advance care planning. For example, "Patient desires no CPR, intubation or artificial nutrition; he would prefer to extend his quality of life over quantity." "Patient and wife brought in Living Will today and we discussed patient preferences if his illness should progress." Any notes that describe what the patients would want in the future, as they become sicker, gets an affirmative "X" mark.

3. Prognosis Discussion -- Mark in the affirmative "X" if the notes state something about discussions about prognosis or what is likely to happen in the future. For example, "discussed with patient today that the CT scan shows further metastasis and previous tumors have grown despite 3rd line chemotherapy. Unfortunately, he is no longer responding to treatment and his life expectancy is limited." "Patient asked about chances of recovery and we had a long talk about his prognosis and what the future holds". "Discussed prognosis."

~~4. Treatment Preferences Discussion -- Mark in the affirmative if a discussion where patient's preferences are described or are documented as discussed. For example, "Patient brought in a Living Will which states he would like limited intervention". "We discussed what the patient would like as far as life-extending therapies if his condition should decline." "Patient stated today that she would not want aggressive interventions if she were not able to interact with her family."~~

5. Discussion of Hospice -- Any documentation of discussions about hospice gets an affirmative mark. For example, "I recommended patient and husband consider hospice today as she is no longer responding to treatment." "Patient prefers to die at home, I suggested hospice may be helpful." "Patient wishes to stop chemotherapy and asked about hospice." "Patient says hospice has been very helpful."

6. Discussion of Referral to Palliative Care -- Any documentation about explaining, suggesting or recommending a palliative care referral be made gets an affirmative mark. For example, “Patient states he continues to suffer from severe anxiety since stopping chemo. I suggested that talking with a palliative care specialist may help ease his anxiety.” “Described options to patient- 3rd line chemo vs palliative care.” “Explained to patient what palliative care is and how they might help.” “Patient is seeing Dr. Green from Pall Care and this is going well; continue.”

7. Discussion of Study Participation -- Any mention of the patient being in the study gets an affirmative “X” mark. For example, “The patient comes in with her Jumpstart form and we discussed it at length.” “Patient states that completing the ICSI survey really got her thinking about what she wants with regard to life-extending therapies.” “The patient has a letter from a UW study about communication and wants to know if she should participate.”

8. Palliative Care Referral -- Mark in the affirmative “X” if there is a note stating, “Palliative care referral made.” Also read Palliative Care notes and look for a note that indicates a referral was made by the enrolled Clinician. For example, “thank you for this referral, we look forward to working with you both.” To get an affirmative mark in this category the referral must actually be made. A note that says : “Plan: 1. Increase MS Contin dosage 2. Consider Palliative Care referral if pain is not managed” would NOT earn an affirmative mark.

9. Hospice Referral -- Mark in the affirmative “X” if there is a note stating, “Hospice referral made.” “Will refer to hospice.” “Arrangements made for hospice at the SNF.” To get an affirmative mark in this category the referral must actually be made. A note that says: “Plan: 1. Increase MS Contin dosage 2. Consider hospice referral” would NOT earn an affirmative mark.

10. Social Work Referral -- An affirmative mark “X” is made if the provider documents an actual referral to Social Work. For example, the provider may write, “arranged for patient to see Edward for help with emotional support”. Check the Social Worker’s documentation to see if their name is Edward. Several clinics have the same social worker all the time and they frequently refer to social work referrals by the social worker’s name and not as “social work”. Also read Social Work notes to see if the social worker has documented something to the effect of “Dr. Jones referred Ms. Smith to work on relaxation techniques.”

11. Spiritual Care Referral -- An affirmative mark is earned if, for example, the provider states, “asked Spiritual Care to see pt for spiritual support.” Providers may also refer to Spiritual Care staff by first name (read and follow directions written for social work referral). Some Spiritual Care visits are spontaneous so just because there is a Spiritual Care note does not necessarily mean there was a referral. Read the Spiritual Care notes to see if the Spiritual Care staff documented something to the effect of “received referral for existential discussion.”

VI. HOSPITAL AND ICU ADMISSIONS

Were there any hospital admits between enrollment and six months after the target visit or death?

- Answer “yes” or “no” depending on what evidence you found.
- This field only gets a “Yes” if the hospitalization occurred at HMC or UWMC or VMC (or SMC, where access has been permitted). All others get “No”. Other hospital stays will be documented as “Non-UW Hospital Stay” as we do not have access to details from those hospital stays.

- You may scroll through EMR looking for "Inpatient" documents, being careful to note that certain procedures will show as inpatient when in reality they are a short stay for example, an endoscopy or a bronchoscopy. This will included "Limited Stay" or "OBS" (observation) status if greater than or = to 24 hours.

Record hospitalizations in the [+] 6 months after target visit or up until death.

Two types of data will be available to record here. The first is data from the UWMC, VMC, Swedish or HMC system and the second is data that is from outside our system. If a patient was hospitalized at an outside hospital, record as much data as you can find. It may be as vague as a note from "Transcripts" that says, "pt reports he was hospitalized at Swedish with a stroke last month". Record the date of the transcript/note that describes a non-UW hospital stay ["when did you learn about it"]. For example, if Dr. Smith records on 10/20/2015 "patient was hospitalized for most of the month of September at St. Francis hospital", you should record 10/20/2015 in the database. If the patient was hospitalized in the UW/HMC system, open ORCA/Mindscape and check the dates of inpatient stays.

If patients at Valley or Swedish have had a UWMC or HMC hospital stay during the follow-up period, those hospital stays WILL BE abstracted. [at Valley: Look under "media" tab for scans of outside documentation including hospital records and discharge summaries] Information about other hospital stays may also be found under the "Care Everywhere" entries in EPIC, where available.

Note: If there is information about advance directives (for example) that is only present in the UWMC/HMC record and not in the Valley outpatient EMR or notes this *should* be abstracted because the providers *would* have access to this information.

A. Date and time of hospital admission are taken from ORCA, "Status", "Encounter location". If more than one hospitalization, complete separate forms for each. If patient is admitted to the hospital with a status of OBS (Observation) or Limited Stay treat as if it is a hospital admission if it is greater than 24 hours. If less than 24 hours, do not count. [Getting hospital LOS from Amalga, but need ADT dates and times for data entry.]

B. Date and time of ICU admission information is taken from ORCA, "Status", "Encounter location". [Getting ICU LOS from Amalga, but need ADT dates and times for data entry.]*

C. Date and time of ICU discharge are taken from ORCA, "Status", "Encounter location". [Getting ICU LOS from Amalga, but need ADT dates and times for data entry.]*

D. Date and time of hospital discharge are taken from ORCA, "Status", "Encounter location". [Getting hospital LOS from Amalga, but need ADT dates and times for data entry.]

*For finding specific admit and discharge times for ICU in ORCA: open chart anew via search, select specific inpatient stay, then can look at "Status Plan Summary" and look under "Encounter Location History" under 'Reports' – this will show all movement during that inpatient stay, including admit and transfer dates and time to ICU.

E. Reason for admission is taken from "MD Progress Notes" in ORCA, labelled 'Admit'. If no diagnosis is listed there, check in ORCA under "Discharge Records" and note what the MD wrote

there. If the admit progress note states something to the effect of "elevated WBC, infiltrate on CXR" and the discharge record says the reason for admission was "pneumonia", record pneumonia. If there is a discrepancy between admit and discharge reason for admission, use what was recorded for discharge.

F. Site. Choose the site to where the patient has been admitted.

G. Living situation prior to hospitalization. Choose the living situation that most clearly describes patient circumstances just prior to admission. Adult Family Home will be selected as a Group Home/structured living arrangement. Prison or rehab halfway houses will be categorized in the same manner. Homeless includes patients who routinely sleep in shelters or who sleep outside but not in a shelter.

H. Discharge from hospital. Is the same as admission criteria (above)as far as where the patient is being discharged to. Died is chosen if the patient did not survive the hospitalization.

I. DNR orders present. Look in "MD Progress Notes" for code status; this should be documented in the attending's note on every day of a patient's hospital stay. Record as "none", "DNR/DNI", DNR only, intubation OK", or "not abstracted". If a patient, for example, starts out as 'full code' but then becomes DNR/DNI during the stay, enter into database as DNR/DNI, and note when the change occurred in the comment/notes area. [JUNE 2016: WILL BE GETTING THIS FROM Amalga for UW HOSPITALIZATIONS – pending]

J. Consults during this hospital stay. Consult ORCA under each category listed and see if progress notes are written from the service. Also check under "Consultations" in ORCA and see if any are from any of the services listed. Record date of first consult note.

K. CPR received. Look in progress notes of MD's and RN's to see if CPR was given. Also look for entries by STAT nurse. Look for entries that may say "rhythm deteriorated to v-fib and pt was defibrillated" or "patient lost BP and HR, ACLS protocol initiated". Look in progress notes and also on the "Vital Signs Review" sheet inside the small data cells. Entry on "Vital Signs Review" may just say "CPR in progress" or "CPR". There is frequently not a lot of fanfare or detail around this type of event in the electronic record. There may be a scan of a paper CPR form if it was completed. Look at the category Outside records and Other Records. [JUNE 2016: WILL BE GETTING THIS FROM Amalga for UW HOSPITALIZATIONS --pending.]

L. Mechanical ventilation. Look on the "Respiratory Therapy" record in ORCA. Dates and times for initiation should be taken from the "Respiratory Therapy" record if possible. If not present, look at "Nursing Progress Notes" and also the "Vital Signs Review" sheet. [JUNE 2016: WILL BE GETTING THIS FROM Amalga for UW HOSPITALIZATIONS -- pending.]

The reason for discontinuation of mechanical ventilation can be determined from the "MD Progress Notes", "Nursing Progress Notes" and "Respiratory Therapy" progress notes. If a patient passes their SBT (Spontaneous Breathing Trial) and meets criteria for extubation, the likely reason for discontinuing the ventilator is that it is no longer needed. If the patient is removed from the ventilator and extubated in the setting of withdrawal of life support, it is likely the ventilator was discontinued for comfort measures. The rationale for discontinuation should be found in the physician and nursing progress notes. In addition, if the patient is moving

to comfort care, there should also be a set of "Physician Orders for the initiation of Comfort Care." These will be found in ORCA under "Physician's Orders". Frequently, they are labelled "Withdrawal of Life Sustaining Therapy".

M. Non-invasive mechanical ventilation is documented in the "Respiratory Therapy" progress notes. It may be referred to as CPAP, BiPAP or NIPPV. There will be a record of how much pressure was being used and there will also be notes about how the patient is tolerating the therapy. Also check the "Physician's Orders" section for details about non-invasive mechanical ventilation. Sometimes, patients do not tolerate the therapy and pull the mask off and staff will have to work with them to make it comfortable enough to keep on. Initiation date and time is when respiratory therapy documents they have begun the therapy and also the Results Review – "Vital Signs Review" sheet ("Oxygenation Data"). [JUNE 2016: WILL BE GETTING THIS FROM Amalga for UW HOSPITALIZATIONS. – pending.]

The discontinuation is when the RT removes the treatment in response to a physician's order, not just when the patient removes the therapy themselves. The RT will write the note when it is discontinued (sometimes will be off, but still in the room this is not discontinued). **If the patient is on CPAP at home for OSA and uses CPAP for sleeping while admitted to the hospital, this does NOT count as NMV.** NMV is initiated when a patient needs more support than can be supplied via cannula or mask and is sometimes a precursor to being intubated or may be used to see if intubation can be avoided. Sometimes the patients will fail NMV and progress to intubation (#4).

N. Comfort Care orders are completed when a physician's order sheet entitled "Comfort Care orders" is completed by virtue of the physician having checked the appropriate boxes and ordered the appropriate medications and dosages. If a specific order form entitled "Comfort Care Orders" is signed by the physician that qualifies as the ~~standardized~~ comfort care orders. ~~If, on the other hand, there is a series of orders that discontinues unwanted therapies (i.e., ventilator, feeding tube, vital signs, medications, labs) or there is an order that says "discontinue all previous orders" and the orders written are medications to be used for comfort in a setting of withdrawal of life support, this would be comfort care without standardized orders.~~ The date and time should come from the "Physician's Orders" entry. [JUNE 2016: WILL BE GETTING THIS FROM Amalga for UW HOSPITALIZATIONS. -- pending]

Entering new data:

1. Open the chart abstraction database.
   - The database is password protected

2. Click the NEW BASIC CHART button, and begin entering the data from the abstraction tool and patient tracking form. Please see the data entry rules for specific instructions.

3. Mark, initial and date the Data Entry section of the PTF when data entry is complete. The software will automatically save the information to the corresponding data tables.

Data entry rules:

- All dates should be entered as MM/DD/YYYY – note: in some sections slashes are automatically entered. If date not documented, use 11/11/1111.
- Move from one field to the next using the Tab key or the Enter key
- All times should be entered as 00:00
- Select insurance type from drop down menu or write in if not on the list.
- ~~Type in ICD9/ICD10 codes exactly as written including zeroes on the end.~~
- Select the applicable items on the Charlson score and the database will total the number.
- Use the note section to record any irregularities in data collection or to explain data recorded by clinicians in error. If for example a clinician would write “POLST form signed today 10/4/17” but the date on the POLST is 10/4/16 and the date of abstraction is prior to 10/4/17 write a note that says- Abstractor’s note: clinician recorded date as 10/4/17. Date on POLST is 10/4/16. Date appears to be written in error.

Quality Control:

Refer to doubling procedures.

IMPROVING COMMUNICATION ABOUT SERIOUS ILLNESS (ICSI)

UNIVERSITY OF WASHINGTON

BASELINE QUESTIONNAIRE for CLINICIANS

This booklet contains two types of questions: 1) questions we would like you to answer about the care you provide for patients with serious, life-limiting illnesses; and 2) questions about yourself and your clinical training.

All information you provide is confidential. Your questionnaire will be marked with study identification numbers only. You may skip any question you do not want to answer.

If you have any questions, please call the study office at 206-744-9516, or you may contact the program manager by email at: eniels9@uw.edu.

Thank you very much. We appreciate your participation.

Please fill in today's date: _____ / _____ /_____
Month Day Year

COMPETENCE IN COMMUNICATION AND END-OF-LIFE CARE

The following questions ask you to evaluate how competent you feel talking with patients about end-of-life care. Please rate each of the following questions using a scale from "Not very competent" to "Very competent". Check **ONE** response for each statement.

Overall, how competent do you feel to do the following:	**Not very competent**		**Somewhat competent**		**Very competent**
1. Give bad news to a patient about his or her illness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. Conduct a family conference?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. Elicit a patient's emotional reaction to his or her illness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. Express empathy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. Respond to a patient who asks, "Why did this happen to me?"	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. Discuss treatment options, e.g. palliative chemotherapy vs. best supportive care?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. Respond to patients who deny the seriousness of their illness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. Respond to patients or family members who want treatments that you believe are not indicated?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. Discuss how a patient can maintain hope?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. Discuss code status (Do Not Resuscitate), with a patient?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. Discuss code status (Do Not Resuscitate), with a family member?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. Discuss a hospice referral?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Overall, how competent do you feel to do the following:	Not very competent		Somewhat competent		Very competent
13. Discuss religious or spiritual issues with patients and families?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
14. Elicit a patient's goals for the end of life?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
15. Elicit a patient's fears for the end of life?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
16. Manage pain in patients at the end of life?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
17. Deal with conflict between you and other medical professionals	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please continue to the next page.

ABOUT YOU

In this last section, we have included a few questions about you.

1. What year were you born? *(Please fill in)* 1 9 _____

2. What is your discipline/specialty? *(Please check one box)*

1 ☐ ARNP
3 ☐ MD/DO
5 ☐ PA
8 ☐ Other: *please specify* _____

3. What is your ethnicity? *(Please check <u>one</u> box)*

1 ☐ Hispanic / Latino
0 ☐ Non- Hispanic / Non- Latino

4. What is your race? *(Please check <u>all</u> that apply)*

1 ☐ Asian
1 ☐ Black / African-American
1 ☐ Native American / Alaska Native
1 ☐ Native Hawaiian / Samoan / Pacific Islander
1 ☐ White
1 ☐ Other: *please specify* _____

Thank you very much for completing this questionnaire. We appreciate your willingness to participate in the ICSI Study. If you have any comments, questions or suggestions about this questionnaire, please include them below.

IMPROVING COMMUNICATION ABOUT SERIOUS ILLNESS (ICSI)
UNIVERSITY OF WASHINGTON

POST-VISIT QUESTIONNAIRE for CLINICIANS

Thank you for your willingness to participate in this study. We would like to ask you a few questions about your patient, his/her family, and the health care team. If you have any questions, a member of our research staff would be glad to answer them at 206-744-9516.

0. [*Item for intervention version only:*] **During or prior to this visit, did you use the "Jumpstart" form that the study staff provided you?**

- ☐ Yes
- ☐ No

1. **During this visit, did you talk with <u>this patient</u> about:** *(Check all that apply)*

- ☐ His/her goals of care
- ☐ His/her preferences for end-of-life care
- ☐ Neither of these was addressed because *(Check all that apply):-*
  - ☐ No time during the appointment
  - ☐ Topics were addressed previously, didn't need to revisit
  - ☐ Not appropriate for this patient (Go to 1a.)
  - ☐ Other - _____
    (Please fill in)

1a. If "not appropriate for this patient," please select a reason: *(Check all that apply)*

- ☐ Patient not ready
- ☐ Another clinician is responsible for these discussions
- ☐ I'm not comfortable discussing end-of-life with this patient
- ☐ Other - _____
  (Please fill in)

2. **During this same visit, did you talk with the patient's <u>family member/friend</u> about:** *(Check all that apply)*

- ☐ The patient's goals of care
- ☐ The patient's preferences for end-of-life care
- ☐ Neither of these was addressed, and a family member/friend was present
- ☐ No family member/friend was present

3. **Regarding this visit, did you talk with anyone in the <u>interdisciplinary team</u> at your clinic about:** *(Check all that apply)*

- ☐ The patient's goals of care
- ☐ The patient's preferences for end-of-life care
- ☐ Neither of these was addressed, and an interdisciplinary team member was present
- ☐ No interdisciplinary team member was available

Please continue onto next page.

4. If this patient had to make a choice at this time, is it your understanding that s/he would prefer a course of treatment that focused on <u>extending life as much as possible</u>, even if it meant having more pain and discomfort, or a plan of care that focused on <u>relieving pain and discomfort</u> as much as possible, even if it meant not living as long? *(Please check one)*

- ☐ Course of treatment focusing on extending life
- ☐ Course of treatment focusing on relieving pain, discomfort
- ☐ Unsure of patient's preference

Please enter today's date: _____ / _____ /_____
Month Day Year

Please return this survey to ICSI Study, University of Washington, 325 Ninth Avenue, Box 359765, Seattle WA 98104,
or via Fax to 206-744-9982,
at your earliest convenience. Thank you for your participation

IMPROVING COMMUNICATION ABOUT SERIOUS ILLNESS (ICSI)

UNIVERSITY OF WASHINGTON

BASELINE QUESTIONNAIRE for PATIENTS

Thank you for participating in our study to improve communication among doctors, their patients and patients' families. We hope that by improving communication among patients, families and doctors, we will help ensure that patients receive the care they want.

The questions in this booklet concern a number of topics. Some are about your health and emotions. Others ask for general information about you so that we can understand more about the people who are participating in this study. It will take about 20 minutes to complete the questions.

Because many people will be answering these questions, **some may not apply to you**. Please feel free to skip any questions that you do not want to answer or that you feel do not apply to you. Also, some of the questions may seem quite similar to each other. Because we are using questions from other surveys, this occurs occasionally and we appreciate your patience with going through all the items, even if they are similar.

All of your answers are confidential.

If you have questions, or if you would like to complete this by phone, a member of our research staff would be glad to help you. You can reach us at 206-744-9516 or at our toll free number 1-888-288-7323.

Thank you very much. We appreciate your participation.

GETTING STARTED

First, it will help us if we can know when you completed this questionnaire. Please fill in today's date in the space below.

_____ / _____ /_____
Month Day Year

TALKING ABOUT HEALTH CARE

This group of questions is about discussions you may have had with _____, (the doctor or nurse practitioner who is in this study with you) and your family and/or friends. We are interested in knowing about discussions concerning the medical care you would want if you were too sick and couldn't speak for yourself. For example, these discussions might include whether you would want to receive the following types of medical care if you needed any of them: the intensive care unit (ICU), CPR, a nursing home, or hospice.

1. **Have you ever discussed with <u>this doctor</u>, in a face-to-face discussion, the kind of medical care you would want if you were too sick to speak for yourself?** *(Please check one box)*

1 ☐ Yes → GO TO # 3
0 ☐ No → GO TO # 2
9 ☐ I don't know → GO TO # 2

2. If "NO" or "I DON'T KNOW": **Would you like to have a discussion of this type with this doctor?** *(Please check one box)*

1 ☐ Yes
0 ☐ No → GO TO # 5 (page 3)
9 ☐ I don't know → GO TO # 5 (page 3)

3. If "YES": **To what extent did these discussion(s) with this doctor meet your needs for information about your medical care?** *(Please check one box)*

Not at all — Completely

0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

4. Would you like to have additional discussions with this doctor about this? *(Please check one box)*

1 ☐ Yes

0 ☐ No

9 ☐ I don't know

These next questions are about discussions about your medical care that you may have had with a family member or friend who is involved in your care.

5. Have you discussed with a <u>family member or friend</u> who is involved in your care the kind of medical care you would want if you were too sick to speak for yourself? *(Please check one box)*

1 ☐ Yes → GO TO # 7

0 ☐ No → GO TO # 6

9 ☐ I don't know → GO TO # 6

8 ☐ Not applicable, I don't have a family member or friend involved in my care at this time → GO TO **"CHOOSING CARE"** (page 5)

Please continue to the next page.

6. If "NO" or "I DON'T KNOW": **Would you like to have a discussion of this type with this family member or friend?** *(Please check one box)*

1 ☐ Yes

0 ☐ No → GO TO "**CHOOSING CARE**" (page 5)

9 ☐ I don't know

7. If "YES": **To what extent did the discussion(s) with this family member or friend meet your needs for sharing your choices about medical care with him/her?** *(Please check one box)*

Not at all										Completely
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. Would you like to have additional discussions with this family member or friend about this? *(Please check one box)*

1 ☐ Yes

0 ☐ No

9 ☐ I don't know

Please continue to the next page.

CHOOSING CARE

We are also interested in the kind of care you might choose at this time. The next questions are about those choices.

1. **If you had to make a choice at this time, would you prefer a plan of medical care that focuses on <u>extending your life as much as possible</u>, even if it means having more pain and discomfort, or would you want a plan of medical care that focuses on <u>relieving your pain and discomfort as much as possible</u>, even if that means not living as long?** *(Please check one box)*

   0 ☐ Extending life, even if it means having more pain and discomfort

   1 ☐ Relieving pain and discomfort as much as possible, even if that means not living as long

   9 ☐ I'm not sure which I would choose

2. **Using those same categories, which of the following best describes the focus of the medical care you are currently receiving?** *(Please check one box)*

   0 ☐ Extending life, even if it means having more pain and discomfort

   1 ☐ Relieving pain and discomfort as much as possible, even if that means not living as long

   9 ☐ I don't know, not sure

Please continue to the next page.

For these next questions, we would like to ask you about your preferences about CPR, a treatment that is administered if a person's heart stops. CPR, or cardiopulmonary resuscitation, consists of electric shocks to the heart, pumping on the chest, and help with breathing. Possible side effects of CPR include broken ribs and memory loss. It is important to realize that, for most people, CPR doesn't work and they do not survive the attempt of CPR.

3. **In your <u>current health</u>, would you want CPR if your heart were to stop beating?** *(Please check one box)*

0 ☐ Definitely No
1 ☐ Probably No
2 ☐ Probably Yes
3 ☐ Definitely Yes

4. **If you were confined to bed and <u>dependent on others</u> for all your care, would you want CPR if your heart were to stop?** *(Please check one box)*

0 ☐ Definitely No
1 ☐ Probably No
2 ☐ Probably Yes
3 ☐ Definitely Yes

Please continue to the next page.

TALKING ABOUT CARE: WHAT MAKES TALKING HARDER?

Which, if any, of the following statements are reasons that you might not want to talk with _____ about care that you would choose if you were to become very sick?

Barriers	Applies To Me (True)	Does Not Apply To Me (False)
1. I don't know what kind of care I would want if I were to get very sick.	1☐	0☐
2. I'm not ready to talk about the care I would want if I were to get very sick.	1☐	0☐
3. I don't like to talk about getting very sick.	1☐	0☐
4. My doctor never seems to have the time to talk about issues like end-of-life care.	1☐	0☐
5. I would rather concentrate on staying alive than talk about death.	1☐	0☐
6. I feel that talking about death can bring death closer.	1☐	0☐
7. I have a living will, and that means I don't need to talk with my doctor about the care I would want if I were too sick to speak for myself.	1☐	0☐
8. My ideas about the kind of medical care I want change at different times.	1☐	0☐
9. I have not felt sick enough to talk with my doctor about end-of-life care.	1☐	0☐
10. I'm not sure which doctor would be taking care of me if I were to get very sick.	1☐	0☐
11. If any of these reasons apply to you, which ONE is the biggest barrier that makes you not want to talk with your doctor about care you might choose? *Please fill in the number of that item in this box.* →	☐	

TALKING ABOUT CARE: WHAT MAKES TALKING EASIER?

People also have a number of reasons for wanting to talk about care that they might choose if they were to become very sick. Which, if any, of the following statements are reasons you might want to discuss care choices with _____?

Facilitators	Applies To Me (True)	Does Not Apply To Me (False)
1. I have been very sick so it is easier to talk about.	1☐	0☐
2. I have had family or friends who have died so it is easier to talk about.	1☐	0☐
3. I worry about the quality of my life in the future.	1☐	0☐
4. I worry that I could be a burden on my friends and family if I were to become very sick.	1☐	0☐
5. If any of these reasons apply to you, which ONE is the biggest facilitator that makes you want to talk with your doctor about care you might choose? *Please fill in the number of that item in this box.* →	☐	

Please continue to the next page.

QUALITY OF COMMUNICATION

The following questions are about how well _____ talks with you about your care. We know that many people think very highly of their doctors. To help us improve communication between doctors and patients, please be critical.

Please rate _____ on each of the following questions using a scale from 0, "The very worst I could imagine" to 10, "The very best I could imagine." If you cannot rate your doctor on a question because he or she has not done it, please check the box, "My doctor has not done this." You may also check the box, "I do not know."

How good is your doctor at: *(Please check one box for each item)*

1. Talking with you about your <u>feelings</u> concerning the possibility that you might get sicker?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

2. Talking with you about the <u>details</u> concerning the possibility that you might get sicker?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How good is your doctor at: *(Please check one box for each item)*

3. Talking to you about how long you might have to live?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. Talking with you about what dying might be like?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. Involving you in the decisions about the treatments that you want if you get too sick to speak for yourself?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

6. Asking about the things in life that are important to you?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How good is your doctor at: *(Please check one box for each item)*

7. Asking about your spiritual or religious beliefs?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please continue to the next page.

TRUST

The following questions ask about how much you trust _____, the doctor or nurse practitioner who is in this study with you, to provide your medical care. The answers range from "strongly disagree" to "strongly agree." Your answers are confidential and will not be shared.

	Strongly Disagree				**Strongly Agree**
1. Sometimes this doctor cares more about what is convenient for him/her than about your medical needs.	0☐	1☐	2☐	3☐	4☐
2. This doctor is extremely thorough and careful	0☐	1☐	2☐	3☐	4☐
3. You completely trust this doctor's decisions about which medical treatments are best for you.	0☐	1☐	2☐	3☐	4☐
4. This doctor is totally honest in telling you about all of the different treatment options available for your condition.	0☐	1☐	2☐	3☐	4☐
5. All in all, you have complete trust in this doctor.	0☐	1☐	2☐	3☐	4☐

Please continue to the next page

YOUR FEELINGS

These questions are about feelings you may have experienced **over the last two weeks**. We are interested in your feelings because having a serious illness may affect how you feel emotionally as well as physically. Please check the box that best describes how often, over the **last two weeks**, you have been bothered by any of the following problems. Answers range from "Not at all" to "Nearly every day". Please check **one** box for each problem. You may skip any question that you do not want to answer.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0☐	1☐	2☐	3☐
2. Feeling down, depressed or hopeless	0☐	1☐	2☐	3☐
3. Trouble falling, staying asleep, or sleeping too much	0☐	1☐	2☐	3☐
4. Feeling tired or having little energy	0☐	1☐	2☐	3☐
5. Poor appetite or overeating	0☐	1☐	2☐	3☐
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down	0☐	1☐	2☐	3☐
7. Trouble concentrating on things, such as reading the newspaper or watching television	0☐	1☐	2☐	3☐
8. Moving or speaking so slowly that other people could have noticed, or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0☐	1☐	2☐	3☐

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people? *(Please check one box)*

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
0☐	1☐	2☐	3☐

YOUR FEELINGS - A FEW MORE QUESTIONS

Over the **last two weeks**, how often have you been bothered by any of the following problems? Answers range from "Not at all" to "Nearly every day". Please check **one** box for each problem.

	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0☐	1☐	2☐	3☐
2. Not being able to stop or control worrying	0☐	1☐	2☐	3☐
3. Worrying too much about different things	0☐	1☐	2☐	3☐
4. Trouble relaxing	0☐	1☐	2☐	3☐
5. Being so restless that it is hard to sit still	0☐	1☐	2☐	3☐
6. Becoming easily annoyed or irritated	0☐	1☐	2☐	3☐
7. Feeling afraid as if something awful might happen	0☐	1☐	2☐	3☐

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people? *(Please check one box)*

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
0☐	1☐	2☐	3☐

Please continue to the next page.

RELIGION AND SPIRITUALITY

These questions ask about your religious beliefs and spirituality. Because religious beliefs and spirituality have been found to affect the choices people make about their health care, we have included these questions. If any of these do not apply to you, please check the "Does not apply to me" box.

1. My religious or spiritual beliefs are what really lie behind my whole approach to life. *(Please check one box)*

- 0 ☐ Definitely *not* true
- 1 ☐ Tends *not* to be true
- 2 ☐ Unsure
- 3 ☐ Tends to be true
- 4 ☐ Definitely true of me
- 8 ☐ Does not apply to me

2. If/When you are able, how often do you attend church or other religious meetings? *(Please check one box)*

- 0 ☐ Never
- 1 ☐ Once a year or less
- 2 ☐ A few times a year
- 3 ☐ A few times a month
- 4 ☐ Once a week
- 5 ☐ More than once/week
- 8 ☐ Does not apply to me

3. How often do you spend time in private religious activities, such as prayer, meditation or Bible study? *(Please check one box)*

0 ☐ Rarely or never
1 ☐ A few times a month
2 ☐ Once a week
3 ☐ Two or more times/week
4 ☐ Daily
5 ☐ More than once a day
8 ☐ Does not apply to me

4. To what extent do your religious or spiritual beliefs influence your preferences for medical care? *(Please check one box)*

0 ☐ Not at all
1 ☐ Slightly
2 ☐ Somewhat
3 ☐ Quite a bit
4 ☐ Completely
8 ☐ Does not apply to me

Please continue to the next page.

ABOUT YOU

Lastly, we would like to ask a few questions about you. These questions help us describe the people who have participated in the study. Some of the questions, like those about race and ethnicity, are required by the agency that is funding this study.

1. What year were you born? *(Please fill in)* 1 9 _____

2. What is your gender? *(Please check one box)*

0☐ Male
1☐ Female

3. What is your <u>current</u> marital status? *(Please check one box)*

0☐ Single or never married
1☐ Married or living with partner
2☐ Divorced or separated
3☐ Widowed

4. What is the highest level of schooling that you have completed? *(Please check one box)*

0☐ 8th grade or less
1☐ Some high school
2☐ High school diploma or GED
3☐ Some college or trade school
4☐ 4-year college degree (ex. BA or BS)
5☐ Some graduate school
6☐ Graduate degree (ex. MA, MS, PhD, MD)

5. In general, would you say your health is: *(Please check one box)*

0☐ Excellent
1☐ Very good
2☐ Good
3☐ Fair
4☐ Poor

6. What is your ethnicity? *(Please check one box)*

1☐ Hispanic / Latino

0☐ Non- Hispanic / Latino

7. What is your race? *(Please check ALL that apply)*

1☐ Asian

1☐ Black / African-American

1☐ Native American / Alaska Native

1☐ Native Hawaiian / Samoan / Pacific Islander

1☐ White

1☐ Other: *please specify* _____

8. Approximately what was your average household monthly income from all sources before taxes in the last three years? *(Please check one box)*

0☐ No income

1☐ $1 - $500

2☐ $501 - $1000

3☐ $1001 - $1500

4☐ $1501 - $2000

5☐ $2001 - $3000

6☐ $3001 - $4000

7☐ $4001 or more

Thank you for taking the time to complete this survey. If you have any comments, please feel free to add them to the margins of the survey or to the space below, or call (206) 744-9516 to talk with a member of our study team.

Thank you again for your help.

IMPROVING COMMUNICATION ABOUT SERIOUS ILLNESS (ICSI)

UNIVERSITY OF WASHINGTON

A FOLLOW-UP QUESTIONNAIRE for PATIENTS

Thank you for participating in our study to improve communication among doctors, their patients and patients' families. We hope that by improving communication among patients, families and doctors, we will help ensure that patients receive the care they want.

The questions in this booklet are about discussions with your clinician and family that you may have had during or following your recent visit on _____ with _____ who is participating in this study with you.

Please feel free to skip any questions that you do not want to answer or that you feel do not apply to you. All of your answers are confidential.

If you have questions, or if you would like to complete this by phone, a member of our research staff would be glad to help you. You can reach us at 206-744-9516 or at our toll free number 1-888-288-7323.

Thank you very much. We appreciate your participation.

Please fill in today's date: _____ / _____ /_____
Month Day Year

TALKING ABOUT HEALTH CARE

This first group of questions is about discussions you may have recently had with the doctor who is in this study with you. Your doctor, in some cases, may be a nurse practitioner.

During your appointment on _____with _____:

0. [*Item for intervention version only*:] **Did you use the "Jumpstart" tip sheet that the study researchers provided you?** *(Please check one box)*

1☐ Yes

0☐ No

1. Did you discuss with <u>this doctor</u>, the kind of medical care you would want if you were too sick to speak for yourself? *(Please check one box)*

1☐ Yes → GO TO # 3

0☐ No → GO TO # 2

9☐ I don't know → GO TO # 2

2. If "NO" or "I DON'T KNOW": **Would you have liked to have a discussion of this type with this doctor?** *(Please check one box)*

1☐ Yes

0☐ No → GO TO # 5 (next page)

9☐ I don't know → GO TO # 5 (next page)

3. If "YES": **To what extent did the discussion meet your needs for information about your medical care?** *(Please check one box)*

Not at all — Completely

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. Would you like to have additional discussions with this doctor about this? *(Please check one box)*

1 ☐ Yes

0 ☐ No

9 ☐ I don't know

These next questions are about discussions about your medical care that you may have had with a family member or friend who is involved in your care.

Since you enrolled in this study:

5. Did you and your <u>family member or friend</u> who is involved in your care discuss the kind of medical care you would want if you were too sick to speak for yourself? *(Please check one box)*

1 ☐ Yes → GO TO # 7

0 ☐ No → GO TO # 6

9 ☐ I don't know → GO TO # 6

8 ☐ Not applicable, I don't have a family member or friend involved in my care at this time → GO TO **"CHOOSING CARE"** (page 5)

6. If "NO" or "I DON'T KNOW": **Would you like to have a discussion of this type with this family member or friend?** *(Please check one box)*

1

1 ☐ Yes

0 ☐ No → GO TO **"CHOOSING CARE"** (page 5)

9 ☐ I don't know → GO TO **"CHOOSING CARE"** (page 5)

7. If "YES": **To what extent did the discussion with this family member or friend meet your needs for sharing your choices about medical care with him/her?** *(Please check one box)*

Not at all										Completely
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. Would you like to have additional discussions with this family member or friend about this?

(Please check one box)

1 ☐ Yes

0 ☐ No

9 ☐ I don't know

Please continue to the next page

CHOOSING CARE

We are also interested in the kind of care you might choose at this time. We asked you similar questions before when you joined the study, but because individual choices sometimes change, we are asking these questions again.

1. **If you had to make a choice at this time, would you prefer a plan of medical care that focuses on <u>extending life as much as possible</u>, even if it means having more pain and discomfort, or would you want a plan of medical care that focuses on <u>relieving pain and discomfort as much as possible</u>, even if that means not living as long?** *(Please check one box)*

   0 ☐ Extending life, even if it means having more pain and discomfort

   1 ☐ Relieving pain and discomfort as much as possible, even if that means not living as long

   9 ☐ I'm not sure which I would choose

2. **Using those same categories, which of the following best describes the focus of the medical care you are currently receiving?** *(Please check one box)*

   0 ☐ Extending life, even if it means having more pain and discomfort

   1 ☐ Relieving pain and discomfort as much as possible, even if that means not living as long

   9 ☐ I don't know, not sure

Please continue to the next page.

For these next questions, we would like to ask you about your preferences about CPR, a treatment that is administered if a person's heart stops. CPR, or cardiopulmonary resuscitation, consists of electric shocks to the heart, pumping on the chest, and help with breathing. Possible side effects of CPR include broken ribs and memory loss. It is important to realize that, for most people, CPR doesn't work and they do not survive the attempt of CPR.

3. **In your <u>current health</u>, would you want CPR if your heart were to stop beating?** *(Please check one box)*

0 ☐ Definitely No
1 ☐ Probably No
2 ☐ Probably Yes
3 ☐ Definitely Yes

4. **If you were confined to bed and <u>dependent on others</u> for all your care, would you want CPR if your heart were to stop?** *(Please check one box)*

0 ☐ Definitely No
1 ☐ Probably No
2 ☐ Probably Yes
3 ☐ Definitely Yes

Please continue to the next page.

QUALITY OF COMMUNICATION

The following questions are about how well _____ talks with you about your care. We know that many people think very highly of their doctors. To help us improve communication between doctors and patients, please be critical.

Please rate _____ on each of the following questions using a scale from 0, "The very worst I could imagine" to 10, "The very best I could imagine." If you cannot rate your doctor on a question because he or she has not done it, please check the box, "My doctor has not done this." You may also check the box, "I do not know."

How good is your doctor at: *(Please check one box for each item)*

1. Talking with you about your <u>feelings</u> concerning the possibility that you might get sicker?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

2. Talking with you about the <u>details</u> concerning the possibility that you might get sicker?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How good is your doctor at: *(Please check one box for each item)*

3. Talking to you about how long you might have to live?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. Talking with you about what dying might be like?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. Involving you in the decisions about the treatments that you want if you get too sick to speak for yourself?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

6. Asking about the things in life that are important to you?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

How good is your doctor at: *(Please check one box for each item)*

7. Asking about your spiritual or religious beliefs?

The very worst I could imagine										The very best I could imagine	*My doctor has not done this*	*I do not know*
0	1	2	3	4	5	6	7	8	9	10	888	999
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Thank you for taking the time to complete this survey. If you have any comments, please feel free to add them to the margins of the survey or to the space below, or call (206) 744-9516 to talk with a member of our study team.

Thank you again for your help.