Critical Care Nutrition

# Preparing for Ethics Submission:

## International Nutrition Survey 2014

## Preparing for Ethics Submission

Ethics approval for conducting the International Nutrition Survey 2014 has been obtained from the Research Ethics Board at Queen's University, Kingston, Canada. Since this is a quality improvement initiative using data collected as part of routine care, we do not think that *additional* local ethics approval is needed. However, you may wish to consult your local research ethics board as to the procedures that need to be completed. This document has been produced to assist you in this process.

In the 2009 survey 64.9% of participating ICUs were asked to complete a local ethics submission for approval by the local ethics committee. We believe that this concern for an additional review was generated because the survey involves human subjects, the results may potentially impact on patient care, and it uses contemporary data that may potentially implicate living subjects or organizations. We hope that following the steps described below will help to alleviate any concerns raised by your local ethics committee.

### Steps to Gaining Ethics Approval for the QI Project

1. Seek the advice of representative from the ethics committee or other appropriate colleague as to local ethics procedure. Indicate that there are no significant ethical implications associated with the project. You may also wish to review your hospital / university ethics website.
2. Send a letter outlining the study to the Chair or representative (see template for letter). Attach a copy of the information letter and certificate of ethics approval from Queen's University.
3. If the project is approved without an ethics submission, you may proceed. If the project is not approved, you will be asked to complete an ethics submission. As there are no significant ethics implications associated with the study, this will likely be an expedited or fast-track ethical approval form.
4. You should aim to complete this form and submit for approval as early as possible. Please refer to the section 'Issues to be considered when completing ethics approval forms' and feel free to 'cut and paste' text into the relevant sections of your local ethics submission form. Additional materials such as the Research Protocol, Information letter, and Instruction Manual may be requested on submission to support your application. These documents are available on our website (www.criticalcarenutrition.com) under the international survey/resources tab.
5. If the project is approved, you will receive an approval letter that will indicate the timescale within which the project must be completed. If the ethics committee requests amendments to the protocol or requires clarification on any minor points prior to granting approval, please contact Margot Viola, Project Assistant, for assistance.
6. The project needs to be signed off from an ethics perspective before you can enter data online and transmit to the methods centre. You may still proceed with data collection (using paper forms) on September 17th 2014, but please do not delay in contacting your ethics committee as the process can be take some time. The hospital / university ethics website should post information about dates of meetings and submission deadlines.

## Issues to be Considered when Completing Ethics Approval Form

### Type of Project: Quality Assurance (QA)

The international survey is a quality improvement project, which may also be referred to as quality assurance or a clinical audit. Your local ethics committee may have different approval procedures in place for QA and research projects. The following table highlights the main differences between quality assurance and research:

| Yes/No | RESEARCH | Yes/No | QUALITY ASSURANCE |
|---|---|---|---|
| No | The goal of the project is to test an hypothesis | Yes | The goal of the project is to improve service delivery |
| No | You are using scientific methods (e.g., controls, blinding, randomization) and the outcome of the project is uncertain | Yes | The project has a reasonable expectation of success |
| No | The planned procedures deviate from normal clinical care | Yes | There is no change in normal clinical care |
| No | You expect to draw generalizable conclusions | Yes | The findings will be used to improve local patient service delivery |
| - | You expect to publish your findings in a scientific journal | - | Publication is not intended |

The International Nutrition Survey differs from local quality improvement activities in two ways: 1) Data is being sent to an external research institution (i.e. CERU) and 2) the results of the study will be published. However no personal identifiers of patients or staff will be sent to CERU and all results will be presented in aggregate and not at the individual patient level.

Ethics approval for publishing the aggregated results of the international component of the study has been obtained from the Research Ethics Board at Queen's University and a copy of the signed approval letter is attached. Participating sites are permitted to publish their individual ICU results following publication of the aggregated results, if desired.

### Purpose of the Research

- Study Objectives

1. To describe nutrition practices in Intensive Care Units (ICUs) across the World.
2. To compare nutrition practices in ICUs between specific hospital and ICU site characteristics (e.g. geographic location, ICU structure, ICU size, hospital type)
3. To identify gaps between current nutrition practice and the recommendations of the Canadian Critical Care Nutrition Clinical Practice Guidelines (CPGs).
4. To monitor changes in nutrition practices in ICUs across time.

- Academic Rationale

The proposed study is part of ongoing research activities at the Clinical Evaluation Research Unit (CERU) at Kingston General Hospital that aim to improve the practice of nutrition therapy in the critical care setting through knowledge generation, synthesis, and translation. Critical care is a specialty within medicine

primarily concerned with the management of patients with acute life-threatening disorders (e.g. respiratory failure, trauma). Enteral nutrition (EN) is the delivery of a nutritionally-complete feed directly into the gastrointestinal tract via a tube, while parenteral nutrition (PN) is the delivery of nutrients via the intravenous route. Nutrition therapy in the form of enteral or parenteral nutrition is considered an integral part of standard care of the critically-ill patient. Nutrition therapy can prevent complications associated with malnutrition and when used appropriately has a positive influence on clinically important outcomes, such as length of stay, morbidity and mortality. Making decisions regarding the most effective and safe nutrition strategy can be challenging, and consequently considerable variation exists in nutrition practices in ICUs. The Canadian Critical Care Nutrition Clinical Practice Guidelines published in 2003 and updated in 2012 sought to improve nutrition practices in ICUs across Canada and worldwide by providing 17 recommendations to assist health practitioners to select and deliver the most appropriate form of nutrition therapy at the appropriate time via the most appropriate route.

CERU has previously completed several surveys of nutrition support practices in ICUs in Canada and internationally, i.e. in 2001, 2003, 2004, 2007, 2008, 2009, 2011 and most recently in 2013. Therefore completion of this survey is timely, to expand this existing database, and monitor changes in nutrition practices over time. Describing the nutrition practices in ICUs throughout the World will aid in highlighting the importance of this therapeutic intervention, and inform us about the differences and similarities that currently exist. Comparing actual practices to best practices defined by the Canadian Critical Care Nutrition CPGs will highlight gaps, and identify opportunities for improvement. It is hoped that this survey will aid in stimulating collaborative international quality improvement interventions, helping to optimize feeding practices, thus improving patient care and potentially leading to better clinical outcomes.

- Description of Study Design

This study involves a period prevalence survey of nutrition therapies in critically ill patients in Intensive Care Units (ICU) across the World.
To be eligible ICUs must have a minimum of 8 beds and have a registered dietitian (or healthcare practitioner responsible for data collection). On September 17th 2014 data collection will commence. Data elements to be collected include hospital and ICU characteristics, patient demographics and APACHE II score. Nutrition practices such as route of nutrition, kilocalorie and protein levels prescribed and received, interruptions, supplementation, blood sugars, insulin, etc will also be collected on a daily basis on a minimum of 20 consecutive patients from ICU admission onwards, for a maximum of 12 days or until death or discharge. Data on clinical outcomes (e.g. duration of mechanical ventilation, ICU stay, hospital stay, death) will be collected up to 60 days after admission to the ICU.

Most of the data collection will be done retrospectively and entered online via a secure website (www.criticalcarenutrition.com). The only direct observational data is head of the bed elevation and the collection of this data element is optional.

- Assessment of Risks and Benefits

There are no risks for patients participating in the survey since no intervention is involved and data collected is part of routine care in an ICU.

The time required to complete data collection (approximately 2 hours per patient) may be burdensome to the individual collecting the data in the study. However, it is believed that these individuals will benefit personally from the experience of participating in a large International study and through local dissemination of the results of the survey.

Participating sites will benefit from a 28-page benchmarked performance report created from data collected during the study. These reports will highlight their strengths and weaknesses in comparison to other ICUs within the same geographic area and to all ICUs in the database and illuminate opportunities for improvement. Sites that distribute the questionnaire to ICU staff will also receive an additional report, which ranks barriers to optimal nutrition performance by importance, based on responses to the questionnaire in their ICU.

## Patient Participation

- Description of patient population

The study will involve collecting data on 20 adult critically-ill patients who stay in the ICU for a minimum of 3 days, because this is the population who receive nutrition therapy, and to whom the Canadian Critical Care Nutrition Clinical Practice Guidelines are directed. Patients admitted to the ICU but who are under the age of 18 years, or are not mechanically ventilated within the first 48 hours of admission will be excluded from the study to ensure only data from adult patients who were truly critically ill (i.e. had an acute life threatening condition) are captured. Twenty patients are required in order to ensure an accurate representation of usual nutrition practices.

- Need for informed consent

This study is an observational quality improvement initiative. Patient information will be collected retrospectively. The nature of the data being collected is information recorded in patients' charts during routine care. The data collected as part of this study does not include any specific intervention or additional information. No information that would enable identification of a patient will be collected.
In previous surveys the need for informed consent was waived and we request that it is also waived for this survey.

## Information and Data

- Maintaining Privacy and Confidentiality

Confidentiality will be maintained at all times. No personal identifiers will be placed on any study documentation. The patients' hospital number will be used by the ICU site for tracking purposes only and will not be entered online. In order to enter data online individuals from each ICU will be provided with a username and will be asked to choose a password. Only authorized personnel will be granted access to information. All information in a computer database will be password protected, encrypted and stored in a secure area.

Any presentation or publication of the results will be aggregated to the site and not patient level. Individual ICU sites will not be identified.

It is not foreseen that any situation will arise whereby confidentiality or anonymity cannot be guaranteed or must be breached.

- Security and Storage of Data

The following steps will be taken to protect patient information during the conduct of the study:

- All paper documents pertaining to the study will not leave the hospital and will be stored as per local policy.
- No patient identifiers will be entered online, all patients will be identified as their study number only.
- The server itself will be in a physically secure location.
- The server will be on a private network at Queen's University, only accessible through specifically created portals.
- Access will be granted to users to enter, edit and view data on a specific ICU basis.
- Access will be based on a unique username and password.
- The password will be a minimum of 6 characters long.
- Password may be changed by the user after account creation, if desired.
- Password fields will always be non-readable (characters replaced with dots).
- The address of all attempts to access the server, successful or otherwise, will be logged.
- An SSL secure connection will be used for the website. This prevents network traffic between a user and the server from being read by malicious third parties.
- Data will be encrypted
- The database will be stored in a physically secure location.

Please see http://www.hpcvl.org for additional information regarding the High Performance Computing Virtual Laboratory where the server and database are located.

## Financial Disclosures

. This is an unfunded study. The investigators have no conflicts of interest to declare.

## Ethics Approval from Queen's University

**QUEEN'S UNIVERSITY HEALTH SCIENCES AND AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD ANNUAL RENEWAL**

Queen's University, in accordance with the "Tri-Council Policy Statement 2, 2010" prepared by the Interagency Advisory Panel on Research Ethics for the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada requires that research projects involving human participants be reviewed annually to determine their acceptability on ethical grounds.

A Research Ethics Board composed of:

**Dr. A.F. Clark**, Emeritus Professor, Department of Biomedical and Molecular Sciences, Queen's University (Chair)
**Dr. H. Abdollah**, Professor, Department of Medicine, Queen's University
**Dr. R. Brison**, Professor, Department of Emergency Medicine, Queen's University
**Dr. M. Evans**, Community Member
**Ms. J. Hudacin,** Community Member
**Mr. D. McNaughton**, Community Member
**Ms. S. Rohland,** Privacy Officer, ICES-Queen's Health Services Research Facility, Research Associate, Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute
**Dr. M. Sawhney**, Assistant Professor, School of Nursing, Queen's University
**Dr. A. Singh**, Professor, Department of Psychiatry, Queen's University
**Dr. J. Walia,** Assistant Professor and Clinical Geneticist, Department of Paediatrics, Queen's University and Kingston General Hospital
**Ms. K. Weisbaum,** LL.B. and Adjunct Instructor, Department of Family Medicine (Bioethics)
**Dr. J. Whiteley**, Community Member

has reviewed the request for renewal of Research Ethics Board approval for the project **"Improving the Practice of Nutrition Therapy in the Critically Ill: An International Quality Improvement Project"** as proposed by **Dr. D. Heyland** of the **Department of Medicine,** at **Queen's University**. The approval is renewed for one year, effective **October 10, 2014.** If there are any further amendments or changes to the protocol affecting the participants in this study, it is the responsibility of the principal investigator to notify the Research Ethics Board. Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other adverse events must be reported within 15 days after becoming aware of the information.

Albert F. Clark

Date: September 11, 2014
Chair, Health Sciences Research Ethics Board
Renewal 1[ ] Renewal 2 [ ] Extension [x] **Code# DMED-984-06 Romeo file# 6004791**