

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of the Intensive Outpatient Clinic: Study protocol for a prospective study of high-cost, high-need patients in the University of Utah Health system
AUTHORS	Bannon, Brittany; Lucier, Michelle; Fagerlin, A; Kim, Jaewhan; Kiraly, Bernadette; Weir, Peter; Ozanne, Elissa

VERSION 1 – REVIEW

REVIEWER	Caitlin Thomas-Henkel Center for Health Care Strategies
REVIEW RETURNED	27-Jul-2018

GENERAL COMMENTS	In developing the comparison group, there was no mention of insurance status; outside of mention in the abstract that a majority of enrolled patients are publically insured.
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REVIEWER	Pericles Almeida Delfino Duarte Hospital Universitário do Oeste do Parana, and Hospital do Cancer / Uopeccan. Cascavel/PR. Brazil.
REVIEW RETURNED	03-Sep-2018

GENERAL COMMENTS	<p>REVIEW</p> <p>The study protocol "Evaluation of the Intensive Outpatient Clinic: Study protocol for a prospective study of high-cost, high-need patients in the University of Utah Health System" is very interesting and addresses an exciting topic, current and in a very inteligente method.</p> <p>Only these considerations:</p> <p>-It is necessary in the "Methods - Participants / Inclusion & Exclusion criteria" section to define whether all patients who will be cared for in the IOC will effectively enter into the planned study (although it is written in "Recruitment" that all patients from IOC will be invited). This is because the study presupposes certain variables for evaluation of outcomes (mainly neurological status that allows actual or future evaluation by questionnaire) that not all patients may have, even if they are eventually indicated to be attended in the IOC.</p> <p>-In the exclusion criteria should there not be patients who are (or should be) in current exclusive palliative management? Patients with high prognosis of death in the coming weeks?</p> <p>-In addition: due to the intrinsic severity of the patients, it is expected that there will be a high mortality in the weeks or months following entry into the study (even in patients without palliative management).</p>
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	<p>Besides, it is thought that there will be clinical complications that can provoke a neurological compromise (eg stroke, encephalopathy or dementia) and consequently hinder verbal contact. Therefore, evaluating outcomes based solely on patient interviews (beyond obviously mortality and medical consequences) may result in many patients being unable to be evaluated. Therefore, I suggest (although it is only a suggestion) that interviews with family members / surrogates (satisfaction of quality of care, perception of quality of life, etc.) be included in the results and methodology of evaluation to try to minimize this possible problem.</p> <p>-At last, I couldn't find a STROBE checklist or statement attached (that it's needed in this kind of study).</p>
REVIEWER	Lauran Hardin MSN, RN-BC, CNL, FNAP Senior Advisor National Center for Complex Health and Social Needs United States
REVIEW RETURNED	03-Sep-2018
GENERAL COMMENTS	This is a very interesting study. The number of surveys and the complexity of the population may require an interpreter or translator for the population.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

Reviewer Name: Caitlin Thomas-Henkel

Institution and Country: Center for Health Care Strategies

Please state any competing interests or state 'None declared': None declared

1. In developing the comparison group, there was no mention of insurance status; outside of mention in the abstract that a majority of enrolled patients are publically insured.

[Rev. # 1, # 1] Author Response 1: We now clarify this in the “Control Patient Characteristics for Healthcare Cost and Utilization Analysis” subsection of the Methods (Page # 6, Lines 245-250): “We will match each IOC patient to two control subjects with propensity score matching (i.e., nearest-neighbor matching) using logistic regression models. Matching will be based on variables such as: year of birth, sex, race, baseline Elixhauser Comorbidity Index (or Charlson Comorbidity Index), insurance status (Medicaid), baseline numbers of inpatient, emergency room, and outpatients visits, healthcare costs one year prior to index date, and mental disorder status.”

[Rev. # 1, # 1] Author Response 2: We have also added the following text to the ‘IOC Patient Characteristics’ subsection of the Methods (Page # 6, Lines 218-223): “There are a number of criteria potential patients need to meet in order to be eligible for care at the IOC. Patients are candidates for the IOC if they fall into the category of high-risk and high-cost, defined by a high number of comorbidities, hospitalizations, and emergency department visits, as well as seeing multiple providers and accounting for a high proportion of costs to the healthcare system. Other indicators include insurance status (publically insured through Medicaid), social or behavioral health concerns (e.g., homelessness or food insecurity, substance abuse, or mental health disorder).”

Reviewer 2:

Reviewer Name: Pericles Almeida Delfino Duarte

Institution and Country: Hospital Universitário do Oeste do Parana, and Hospital do Cancer / Uopecan. Cascavel/PR. Brazil.

Please state any competing interests or state 'None declared': None declared.

The study protocol "Evaluation of the Intensive Outpatient Clinic: Study protocol for a prospective study of high-cost, high-need patients in the University of Utah Health System" is very interesting and addresses an exciting topic, current and in a very intelligent method.

Only these considerations:

1. It is necessary in the "Methods - Participants / Inclusion & Exclusion criteria" section to define whether all patients who will be cared for in the IOC will effectively enter into the planned study (although it is written in "Recruitment" that all patients from IOC will be invited). This is because the study presupposes certain variables for evaluation of outcomes (mainly neurological status that allows actual or future evaluation by questionnaire) that not all patients may have, even if they are eventually indicated to be attended in the IOC.

[Rev. # 2, # 1] Author Response: The study design is to invite all patients in the IOC to enroll, but enrollment is voluntary. Further, we envision logistical issues that will not allow for every patient to be invited to enroll (e.g., time off work or illness for study staff, atypical enrollment of patients such as through the emergency department). However, we expect these numbers to be low. We have also added the following text to the 'Participants/Inclusion & Exclusion Criteria' section in the Methods (Page # 6, Lines 231-235) to provide further clarification:

"All patients who receive care at the IOC are invited to enroll in the study; however, for the secondary analysis, all new patients are eligible to participate in the survey at their first clinic visit (i.e. prior to receiving care). Patients with language barriers, cognitive difficulties, or atypical enrollment processes (e.g., acute medical needs requiring emergency department referral) that preclude them from completing the survey are not eligible."

2. In the exclusion criteria should there not be patients who are (or should be) in current exclusive palliative management? Patients with high prognosis of death in the coming weeks?

[Rev. # 2, # 2] Author Response: Patients who fit these characteristics described by Reviewer 2, who are at high risk for mortality and receiving exclusive palliative management, are not considered eligible to receive care at the IOC. Because only patients enrolled at the IOC are invited to participate, they will not be a part of the study. To make this clear, we have added the following text to the 'Participants/Inclusion & Exclusion Criteria' section in the Methods (Page # 6, Lines 227-231):

"Exclusion criteria include: 1) patients whose sole medical problem is a new onset cancer diagnosis or an organ transplant; 2) patients with behavioral health issues that exceed the clinic's ability to assist; 3) patients receiving exclusive palliative care or those at high-risk for mortality in the coming weeks; and 4) patients > 65 years of age (i.e. Medicare)."

3. In addition: due to the intrinsic severity of the patients, it is expected that there will be a high mortality in the weeks or months following entry into the study (even in patients without palliative management). Besides, it is thought that there will be clinical complications that can provoke a neurological compromise (eg stroke, encephalopathy or dementia) and consequently hinder verbal contact. Therefore, evaluating outcomes based solely on patient interviews (beyond obviously mortality and medical consequences) may result in many patients being unable to be evaluated. Therefore, I suggest (although it is only a suggestion) that interviews with family members / surrogates (satisfaction of quality of care, perception of quality of life, etc.) be included in the results and methodology of evaluation to try to minimize this possible problem.

[Rev. # 2, # 3] Author Response: We thank Reviewer 2 for this consideration. They are correct that the medical complexity of this patient population may render some patients unable to be evaluated.

The clinic staff, however, is available to answer questions and help the patient fill out the evaluation survey measures if desired. Unfortunately it is not feasible for us to conduct interviews with family members or surrogates, because many of these patients suffer from lack of social networks and support and may not have someone to call on.

4. At last, I couldn't find a STROBE checklist or statement attached (that it's needed in this kind of study).

[Rev. # 2, # 4] Author Response: We now include a completed STROBE checklist with our revised protocol as suggested.

Reviewer 3:

Reviewer Name: Lauran Hardin MSN, RN-BC, CNL, FNAP

Institution and Country: Senior Advisor, National Center for Complex Health and Social Needs, United States

Please state any competing interests or state 'None declared': None

1. This is a very interesting study. The number of surveys and the complexity of the population may require an interpreter or translator for the population.

[Rev. # 3, # 1] Author Response: Although this population is complex and there are a number of surveys included in the study, clinic or study staff is available to answer questions and help patients to complete survey items as needed. Participants can also report the use of a proxy (family member, friend, or stranger) to complete the survey at the end of the survey. However, patients with language barriers that exceed the clinic's ability to assist are not eligible to participate. To make this clear, we have added the following text to the 'Participants/Inclusion & Exclusion Criteria' section of the Methods (Page # 6, Lines 234-236):

"Patients with language barriers, cognitive difficulties, or atypical enrollment processes (e.g., acute medical needs requiring emergency department referral) that preclude them from completing the survey are not eligible."

VERSION 2 – REVIEW

REVIEWER	Pericles A. D. Duarte Hospital Universitario do Oeste do Parana, and Hospital do Cancer/ Uopeccan. Cascavel/PR. Brazil.
REVIEW RETURNED	25-Oct-2018
GENERAL COMMENTS	The authors made the needed and requested changes.