

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Transitional care quality indicators to assess quality of care following hospitalization for chronic obstructive pulmonary disease and heart failure: a systematic review protocol
AUTHORS	Michael, Faith; Whitelaw, Sera; Van Spall, Harriette Gillian Christine

VERSION 1 - REVIEW

REVIEWER	Natalie E. Leland University of Pittsburgh United States of America
REVIEW RETURNED	22-Jul-2019

GENERAL COMMENTS	<p>BMJ Open protocol review</p> <p>Transitional care indicators to assess quality of care following hospitalization for chronic obstructive pulmonary disease and heart failure: a systematic scoping review protocol</p> <p>Overall, this manuscript describes addressing an important topic. However, the methods of executing the protocol are unclear and language ambiguity need further clarification as the terms used each have distinct meanings (e.g., quality measures, indicators, best practices), which each have implications for the scope of and how a scoping review protocol would be executed.</p> <p>Introduction talks about this scoping review being used to identify a set of transitional care indicators- however what the author means is unclear.—what does this group of authors mean by indicators. Please clarify language regarding “measures” vs. indicators vs. best practices. Unclear what the authors intend to do. The term quality measure has a distinct definition and there is an extensive procedure that a concept has to go through to be considered and approved as a “quality measure”- please refer to the National Quality Form quality measure protocol process. Is the intent to look at best practices in the literature to guide future quality measure development, which can be used to assess the effectiveness of care transition programs? Please clarify the terms, define them, and clarify specific objectives, particularly given the diverse types of publications that are being included- various research studies will answer different questions.</p>
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	<p>Research questions- manuscript states the objective is to “generate a comprehensive list of transitional care indicators that will allow decision-makers and clinicians to assess the quality transitional care services provided to patients hospitalized for COPD and HF” however, to achieve this objective it is not clear what the research question(s) are that are driving the scoping review, as this is a review of the literature. Please state the question(s) that are driving the lit search, which will inform the above objective? These question(s) will need to take into account the diverse types of literature that are being included. For example what question(s) will RCTs provide answers to as compared to observational and cross sectional studies in the context of this manuscript?</p> <p>Methods-</p> <ul style="list-style-type: none"> -Protocols exist for developing and proposing quality measures; this methodology is not acknowledged or integrated into this process. How is this protocol building on, using, or no relying on existing methods for quality measures? - How is the methodological process outlined in this protocol as indicator development similar or different than existing validated measure development? - What and how is an underlying theoretical framework guiding the research questions, data analysis, and the analysis?
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VERSION 1 – AUTHOR RESPONSE

Reviewer comment:

What does this group of authors mean by indicators. Please clarify language regarding “measures” vs. indicators vs. best practices. Unclear what the authors intend to do. The term quality measure has a distinct definition and there is an extensive procedure that a concept has to go through to be considered and approved as a “quality measure”- please refer to the National Quality Form quality measure protocol process.

Response:

Thank you for your comment. We have defined “indicator” and clarified “quality measure” in the introduction of our manuscript.

Change:

Transitional care services – those that provide coordination and continuity as patients transition between health care settings – can improve clinical outcomes following hospitalization for COPD and HF. Health care authorities have prioritized efforts that improve the quality of transitional care in COPD and HF. However, to date, there are no standard indicators to assess the quality of transitional care. Such indicators, once developed, could be used to improve the quality of care provided to patients as they transition from hospital to home.

There are no standard measures to assess the quality of transitional care services provided to patients hospitalized for COPD and HF. Furthermore, there are no clear outcomes measures that can be used to assess the quality of transition care interventions in research. This systematic review aims

to generate a comprehensive list of transitional care indicators – measures of transitional care quality – and assess their associations with clinical, patient-reported, and cost outcomes.

Reviewer comment:

Is the intent to look at best practices in the literature to guide future quality measure development, which can be used to assess the effectiveness of care transition programs?

Response:

Thank you for your comment. The intent of our project is to generate a comprehensive list of transitional care indicators. In other words, we will search the literature to identify all the indicators that assess the quality of care patients with HF or COPD receive as they transition from hospital to home. We will also summarize if associations with outcomes exist, but will not rank or compare indicators as conclusions are limited by heterogeneity. We expect that our work will provide the opportunity for researchers to select indicators to test in the clinical setting, and lay the foundation for best practices to be elucidated.

Change:

N/A

Reviewer comment:

Please clarify the terms, define them, and clarify specific objectives, particularly given the diverse types of publications that are being included- various research studies will answer different questions.

Response:

Thank you for your comment. We have clarified the terms, provided definitions, and clarified specific objectives in our manuscript.

Change:

There are no standard measures to assess the quality of transitional care services provided to patients hospitalized for COPD and HF. Furthermore, there are no clear outcomes measures that can be used to assess the quality of transition care interventions in research. This systematic review aims to generate a comprehensive list of transitional care indicators – measures of transitional care quality – and assess their associations with clinical, patient-reported, and cost outcomes.

Reviewer comment:

Manuscript states the objective is to “generate a comprehensive list of transitional care indicators that will allow decision-makers and clinicians to assess the quality transitional care services provided to

patients hospitalized for COPD and HF” however, to achieve this objective it is not clear what the research question(s) are that are driving the scoping review, as this is a review of the literature. Please state the question(s) that are driving the lit search, which will inform the above objective? These question(s) will need to take into account the diverse types of literature that are being included. For example what question(s) will RCTs provide answers to as compared to observational and cross sectional studies in the context of this manuscript?

Response:

Thank you for your comment. We have stated our research questions at the end of the Introduction.

With regards to study designs, we will include randomized controlled trials (RCTs), cohort studies, cross-sectional studies, interrupted time series studies and before-after studies. All included studies, regardless of the design, will answer our research questions. However, the study designs would affect our confidence in associations with outcomes. For example, a RCT and a cohort study may both test the intervention of medication reconciliation. Both studies would provide information on the same indicator – the proportion of patients receiving a medication management intervention – and we will summarize associations with outcomes measured in both studies. However, our confidence in cumulative findings may differ based on the differences in design between RCTs and cohort studies. To address this, we will assess the risk of bias.

Change:

This systematic review aims to generate a comprehensive list of transitional care indicators – measures of transitional care quality – and assess their associations with clinical, patient-reported, and cost outcomes.

Reviewer comment:

Protocols exist for developing and proposing quality measures; this methodology is not acknowledged or integrated into this process. How is this protocol building on, using, or no relying on existing methods for quality measures? How is the methodological process outlined in this protocol as indicator development similar or different than existing validated measure development? What and how is an underlying theoretical framework guiding the research questions, data analysis, and the analysis?

Response:

Thank you for your comment. The purpose of our study is to gather all indicators that assess the quality of transitional care received by HF and COPD patients, and to determine if the measures are associated with clinical, patient-reported and cost outcomes. As such, we are not developing new indicators, but summarizing existing indicators in the literature. Future studies may build on our work by testing a subset of measures in the clinical setting, and commenting on attributes, such as feasibility, reliability and acceptability.

Change:

N/A

VERSION 2 – REVIEW

REVIEWER	Natalie Leland University of Pittsburgh
REVIEW RETURNED	30-Sep-2019

GENERAL COMMENTS	<p>BMJ Review #2</p> <p>Overall, the paper continues to have gaps in knowledge with respect to operationalization of terms by the research team and how they align with existing standardize methods for developing indicators of quality. Moreover, the methods they propose do not detail how they will identify, define, and extract indicators from clinical trials and lower levels of evidence evaluating clinical interventions.</p> <p>Introduction: In this revision of the manuscript, the authors have revised the text replacing the term quality measure with indicators, but there is no clear definition of the term. The response to reviewers state that a definition of the term has been added to the introduction, but it is unclear where that definition is? Lies 23-24 state that there are no standard indicators and once created can improve care- put no definition is provided?</p> <p>Additionally, the authors assert that there are no clear outcome measures that can assess the quality of the care transition? Yet, they do not acknowledge the implementation of the hospital readmission measure which is a National Quality forum endorsed quality measure that quantifies the failure of a care transition— poor quality? If this research team defines outcome measures differently than readmissions, then they need also define how they operationalize outcome measures to assess quality of the care transition.</p> <p>There is a large group of entities both researchers, think tanks, and others working on developing quality measures according to the National Quality Forum measure development protocol around care coordination. For example, the 2013 ASPE report discusses the constructs of quality measures to capture care coordination. https://aspe.hhs.gov/report/long-term-and-post-acute-care-providers-engaged-health-information-exchange-final-report/351-care-coordination-measures</p> <p>Finally, in the response to reviewers, the authors state that they are not developing new measures but instead are summarizing existing indicators. However, the methods and sources they are proposing to draw from do not reflect where the development of measures is published. Despite all the work in this area, the measure specification process is often not published in peer review manuscripts or executed through randomized clinical trials. The approval process for measures and the documentation of these measures is housed outside the traditional peer review process through the agencies that approve quality measures (e.g., National quality forum). The manuscript would benefit from a discussion of why their approach of going to the traditional scientific literature is the appropriate approach if trying to summarize all existing measures?</p> <p>Methods</p> <p>Please clarify how a sample of articles that include clinical trials, cohort studies, etc will translate to a list of quality indicators. The data extraction processes states interventions will be extracted.</p>
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	<p>Please provide more detail to clarify how “intervention” will be extracted and how that will be converted to “indicators”</p> <p>Extraction methods state for each article, that the type of quality indicator (structure, process, outcome) will be extracted, however there is no detail provided on how a clinical trial publication (or other publication) informs this data point. Given the ambiguity of how the team is operationalizing indicator and in the introduction, it is not clear how they will then operationalize randomized control trials to construct structure, process, and outcome quality indicators?</p> <p>How are the authors defining studies that “test the quality of a care transition”</p> <p>Please augment the discussion about the second sample of studies that are also being included, which evaluate patient reported outcomes. It is unclear how this second sample of studies, answers the research question? What are the inclusion and exclusion for this sample of articles?</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer comment:

Introduction: In this revision of the manuscript, the authors have revised the text replacing the term quality measure with indicators, but there is no clear definition of the term. The response to reviewers state that a definition of the term has been added to the introduction, but it is unclear where that definition is? Lines 23-24 state that there are no standard indicators and once created can improve care- but no definition is provided?

Response:

Thank you for your comment. We have changed the nomenclature to “quality indicators” throughout the manuscript to provide greater clarity. The purpose of transitional care quality indicators is to “assess the quality of transitional care as patients transition from hospital to home.”

Change:

Transitional care services – those that provide coordination and continuity as patients transition between health care settings – can improve clinical outcomes following hospitalization for COPD and HF.[1,7] Health care authorities have prioritized efforts that improve the quality of transitional care in COPD and HF.[8] However, to date, there are no standard quality indicators to assess the quality of transitional care as patients transition from hospital to home. Such transitional care quality indicators, once identified, could be used to improve the quality of care provided to patients during this period. (Page 2, paragraph 3 of Introduction)

Reviewer comment:

Additionally, the authors assert that there are no clear outcome measures that can assess the quality of the care transition? Yet, they do not acknowledge the implementation of the hospital readmission measure which is a National Quality forum endorsed quality measure that quantifies the failure of a care transition—poor quality? If this research team defines outcome measures differently than readmissions, then they need also define how they operationalize outcome measures to assess quality of the care transition.

There is a large group of entities both researchers, think tanks, and others working on developing quality measures according to the National Quality Forum measure development protocol around care coordination. For example, the 2013 ASPE report discusses the constructs of quality measures to capture care coordination. <https://aspe.hhs.gov/report/long-term-and-post-acute-care-providers-engaged-health-information-exchange-final-report/351-care-coordination-measures>

Finally, in the response to reviewers, the authors state that they are not developing new measures but instead are summarizing existing indicators. However, the methods and sources they are proposing to draw from do not reflect where the development of measures is published. Despite all the work in this area, the measure specification process is often not published in peer review manuscripts or executed through randomized clinical trials. The approval process for measures and the documentation of these measures is housed outside the traditional peer review process through the agencies that approve quality measures (e.g., National quality forum). The manuscript would benefit from a discussion of why their approach of going to the traditional scientific literature is the appropriate approach if trying to summarize all existing measures?

Response:

Thank you for your comment. We have clarified the introduction as below.

We have acknowledged the efforts and process of the National Quality Forum (NQF) in the Introduction. The NQF relies on developers to submit measures. Indeed, several task forces derive measures through rapid review and consensus, rather than a systematic review of the literature, which is effort-intensive, but comprehensive. However, it is unclear whether the quality indicators developed by task forces, including the NQF, are associated with outcomes that are meaningful to patients and to the health care system. The evidence to support many quality indicators is unclear, and using the wrong indicators can introduce measurement burden with no tangible improvement in patient-important outcomes.

Our systematic review of the literature will identify a comprehensive set of transitional care quality indicators and also assess the evidence to support their use. Our work will be broader than the NQF's 2015 All-Cause Admissions and Readmissions Measures report, which correlates quality indicators with the outcome of admissions and readmissions. We would suggest that a poor transition of care can result in more than readmission. For example, the patient may present to the emergency department, but not be readmitted; or, the patient may die shortly after discharge and therefore not be readmitted as death is a competing risk for readmission. Thus, measuring readmission alone does not capture the burden of clinical illness. Furthermore, patient-important outcomes, such as quality of life, and health care system outcomes, such as cost, are not captured. Our study will assess associations between transitional care quality indicators and all these important outcomes.

Change:

Organizations such as the National Quality Forum (NQF) generate healthcare quality indicators with the goal of improving outcomes in conditions such as COPD and HF.[6] Their quality indicator development process relies on individuals to submit indicators and stakeholders to approve the indicators via consensus.[6] While this process engages stakeholders, it is effort-intensive. Furthermore, the association between the quality indicators and clinically meaningful outcomes is unclear; the evidence to support many transitional care quality indicators is uncertain, and using the wrong indicators can introduce measurement burden with no tangible improvement in patient-important outcomes.

Transitional care services – those that provide coordination and continuity as patients transition between health care settings – can improve clinical outcomes following hospitalization for COPD and HF.[1,7] Health care authorities have prioritized efforts that improve the quality of transitional care in

COPD and HF.[8] However, to date, there are no standard quality indicators to assess the quality of transitional care as patients transition from hospital to home. Such transitional care quality indicators, once identified, could be used to improve the quality of care provided to patients during this period. While several task forces have demonstrated interest in linking transitional care quality indicators with all-cause readmissions,[9] this outcome alone can be misleading as it does not account for other important outcomes, such as emergency department visits or death. (Page 2, paragraphs 2-3 of Introduction)

Reviewer comment:

Please clarify how a sample of articles that include clinical trials, cohort studies, etc will translate to a list of quality indicators. The data extraction processes states interventions will be extracted. Please provide more detail to clarify how “intervention” will be extracted and how that will be converted to “indicators”

Response:

Thank you for your comment.

The included studies generally test a health service intervention to improve transitional care quality in hospitalized patients with heart failure and/or chronic obstructive pulmonary disease (COPD), and report on outcomes. The indicators will be derived from the intervention or outcome measures. For example, a study may test the intervention of medication reconciliation at discharge. The quality indicator would be “proportion of patients receiving medication reconciliation at discharge.” In other cases, the outcome may itself be a transitional care quality indicator, such as the B-PREPARED score (for discharge preparedness). In this case, the quality indicator would be B-PREPARED score.

In either case, we would then examine the association between the indicator (e.g. Medication reconciliation, B-PREPARED score) and clinical outcomes, such as readmission or death, and cost outcomes. A strong association between quality indicators and clinical or cost outcomes may provide decision makers the evidence to justify measurement of the quality indicators.

Change:

We will use both interventions (e.g. medication reconciliation at discharge) and outcomes (e.g. discharge preparedness, as measured by the B-PREPARED score) to generate a list of quality indicators. We will classify each quality indicator as structure (assess physical care setting, including material and human resources), process (assess actions of providers), or outcome (assess impact of intervention on patient/population health).[11] (Page 4, paragraph 1 of Data synthesis)

Reviewer comment:

Extraction methods state for each article, that the type of quality indicator (structure, process, outcome) will be extracted, however there is no detail provided on how a clinical trial publication (or other publication) informs this data point. Given the ambiguity of how the team is operationalizing indicator and in the introduction, it is not clear how they will then operationalize randomized control trials to construct structure, process, and outcome quality indicators?

Response:

Thank you for your comment. We have clarified how we will determine the indicator from the studies in the above response.

We will organize indicators as structure, process, and outcome, which is a standard classification scheme. We have defined these in the “data synthesis” section of the manuscript: structure (assess physical care setting, including material and human resources), process (assess actions of providers), and outcome (assess impact of intervention on patient/population health).

Change:

We will use both interventions (e.g. medication reconciliation at discharge) and outcomes (e.g. discharge preparedness, as measured by the B-PREPARED score) to generate a list of quality indicators. We will classify each quality indicator as structure (assess physical care setting, including material and human resources), process (assess actions of providers), or outcome (assess impact of intervention on patient/population health).[11] (Page 4, paragraph 1 of Data synthesis)

Reviewer comment:

How are the authors defining studies that “test the quality of a care transition”

Response:

Thank you for your comment. We have clarified the wording of the eligibility criteria.

We will include studies that 1) test an intervention that aims to improve the hospital to home transition and 2) measure outcomes that are suggestive of the quality of care transition. Outcomes include clinical, health care system, and patient-reported ones.

Change:

Inclusion criteria will follow the PICOS (Population, Intervention, Comparison, Outcomes, Study) framework. To generate a list of transitional care quality indicators, we will include studies with adult patients (≥ 19 years old) hospitalized for COPD or HF. We will screen all studies that 1) test an intervention that aims to improve the hospital to home transition, and 2) measure at least one of the following outcomes of interest: hospital readmissions, emergency department (ED) visits, mortality, length of subsequent hospitalizations, adverse medication events, healthcare costs and patient-reported outcomes. (Page 3, paragraph 1 of Eligibility criteria)

Reviewer comment:

Please augment the discussion about the second sample of studies that are also being included, which evaluate patient reported outcomes. It is unclear how this second sample of studies, answers the research question? What are the inclusion and exclusion for this sample of articles?

Response:

We will use a single search strategy and method to obtain all of the studies for our review. However, we will evaluate further studies that describe the validation of patient-reported indicators in order to assess associations between the patient-reported quality indicators, such as the B-PREPARED score, and clinical outcomes, such as readmissions or death.

Change:

Inclusion criteria will follow the PICOS (Population, Intervention, Comparison, Outcomes, Study) framework. To generate a list of transitional care quality indicators, we will include studies with adult patients (≥ 19 years old) hospitalized for COPD or HF. We will screen all studies 1) test an intervention

that aims to improve the hospital to home transition, and 2) measure at least one of the following outcomes of interest: hospital readmissions, emergency department (ED) visits, mortality, length of subsequent hospitalizations, adverse medication events, healthcare costs and patient-reported outcomes. Both the intervention and the outcomes will be used to generate a list of transitional care quality indicators. For the process and patient-reported transitional care indicators, we will identify additional studies that describe the validation of the measurement tools to assess associations with clinical outcomes, such as readmission or death. We will include randomized controlled trials (RCTs), cohort studies, cross-sectional studies, interrupted time series studies and before-after studies. We will exclude systematic reviews and meta-analyses (primary articles will be reviewed for inclusion instead), editorials, letters to the editor, and studies published prior to 1990. (Page 3, paragraph 1 of Eligibility criteria)