

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	PATIENT SELF-ASSESSMENT OF HOSPITAL PAIN, MOOD, AND HEALTH RELATED QUALITY OF LIFE IN ADULTS WITH SICKLE CELL DISEASE
AUTHORS	Kofi A Anie, Hannah Grocott, Lauren White, Mendwas Dzingina, Gabriel Rogers and Gavin Cho

VERSION 1 - REVIEW

REVIEWER	Joseph Telfair, University of North Carolina at Greensboro, Center for Social, Community and Health Research and Evaluation
REVIEW RETURNED	13-Apr-2012

THE STUDY	<p>The study attempts to address a very important issue, that of the need for recognition and use of a multidimensional assessment of pain in admitted adults with the blood disorder of sickle cell disease.</p> <p>There is considerable literature on pain assessment, the link between psychological state and immediate and long-term self report of pain and the relativity of adequate treatment physiologically and psychologically. The author present a simple descriptive report of retrospectively reviewed five year archival data on 510 non-repeating clients. While the assumptions and purpose of the study are clear, there are number of scholarship and clinical issues that weaken the import of the manuscript. Relevant to the overall study, these limitations are noted below:</p> <ol style="list-style-type: none">1. There was notable lack of reference to previous literature or research of the authors specific to the papers' main thesis (see page 4, paragraph 2, sentence 3)2. While it is clear the study location was a medical center, it was not clear if the 'clinical staff' referred tho throughout the manuscript is specific to this group or clinicians in general, since this specificity has implications for the study results.3. No specific set of research questions or hypotheses were put forth to guide both the data analyses and discussion of results.4. One assumption by the authors - 'Pain assessment in patients with SCD is usually based on the opinion of clinical staff..' does not take into account the significant literature on assessment, instrument development, training, and the authors own work, as an alternative that poses a challenging caveat.5. It was not clear of the protocol of assessment (see pages 4-5, last and first paragraphs) was based on practice evidence, as important fact given the manuscript's introductory discussion and for potential
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	<p>replication of the reported work</p> <p>6. HRQoL is not defined in general or specifically. Health Utility is one critical domain (measured by the EQ-5D) of HRQoL, but it not singled, so the authors should have limited their description to the domain, not through implication, infer a full consideration of HRQoL, leave out the considerable literature of the relationship between pain and HRQoL.</p> <p>7. Given HRQoL has a strong relationship to psychological state and differential experience in adults with chronic disorders/ pain syndromes, as well as learned coping behaviors; the authors should have been considerate of or explained as a limitation and influence such phenomena on the study results, particularly since this was single group design.</p>
RESULTS & CONCLUSIONS	<p>The study results support one well know fact that adults with SCD report some pain relief after discharge, but seemed surprised by a another fact that adults with SCD rarely report being 'pain free'. Implications of the latter should have been addressed since it is agreed that this influence post-discharge treatment.</p> <p>The implications of the findings specific to psychological state (mood) was inadequately referenced and discussed regards to treatment implications.</p>

REVIEWER	John Green, CNWL NHS Foundation Trust, Psychology
REVIEW RETURNED	23-Apr-2012

GENERAL COMMENTS	<p>There is a surprising gender difference in admissions in Table 1 which might have been worth a comment, although it does not affect the paper's conclusions. I am unconvinced by the person who claimed intense pain on one scale and none on another. I would guess it is more likely that they have misread the measures, and hence contributed to general statistical noise, than anything more significant.</p>
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REVIEWER	Donna McClish, Virginia Commonwealth University, Biostatistics
REVIEW RETURNED	23-Apr-2012

THE STUDY	<p>Need a bit more info on how Day-care pts are being treated in analysis.</p> <p>Not totally clear why only some correlation work is included</p> <p>Title doesn't exactly match objectives.</p>
RESULTS & CONCLUSIONS	<p>One of the figures was very confusing.</p> <p>I think some of the concusions drawn are beyond the scope of what was found.</p>
REPORTING & ETHICS	<p>Authors report on routinely collected data, but it is not clear whether patients need to give (or have given) consent for these data to be used for research.</p>
GENERAL COMMENTS	<p>The title of the manuscript does not entirely match up with the stated objective, which was to look at pain, mood and HRQoL across 3 time periods (admission, discharge and 1 week post discharge). The title implies the focus is on HRQoL. Yet the initial analysis also looks at mood and general health assessment. Thus the stated objective was not clear. Going further, was the actual objective to look at the values of pain, mood and HRQoL across the 3 time</p>

	<p>points, or to look at the relationship between pain, mood and HRQoL at the 3 time points. If the former, then the analysis for Figure 3 is beyond this objects (relating pain and HRQoL). If the latter, then the relationship between pain and mood, and between mood and HRQoL have been left off as relationships with general health assessment.</p> <p>The role of the subjects admitted to day-care is not clear. The comment that day-care cases were being excluded from t-test analyses – does that imply that these patients are not represented in Figures 1 and 2, or are they included in the Admission part of Figures 1 and 2, but simply excluded from analyses? How about the regression analysis?</p> <p>Subjects were often admitted more than once (P7, line 12-13). It was not clear in the methods that this was being taken of in analysis.</p> <p>Figure 2. Missing the information on 1 week followup</p> <p>Figure 3. I found this figure very confusing. Among other things, it is stated that the relationships are shown across all three time points but I don't see that.</p> <p>P 11 (Discussion). Authors mention that mood and general health may be related to hospital length of stay. It would appear that they should have had that data and could thus have addressed this in analysis. If not, why mention it here. In addition, in line 19, after mentioning that mood and general health could contribute to LOS, they follow with "That is, comorbidity could lead to poorer health outcomes...". I don't see how comorbidity is related to the previous statement and how the rest of the paragraph follows from any of the analyses presented.</p> <p>The conclusion that the study results suggest that a multi-dimensional approach to assessing SCD is beneficial is not supported by what is presented in the manuscript. Similarly, comments regarding cost are not supported by the manuscript (i.e., the research reported in the manuscript does not address these issues).</p> <p>Its not clear whether patients sign a waiver of consent to have their psychological assessments used for research.</p>
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VERSION 1 – AUTHOR RESPONSE

Dear Sir / Madam

Manuscript ID bmjopen-2012-001274: "PATIENT SELF-ASSESSMENT OF HOSPITAL PAIN AND HEALTH RELATED QUALITY OF LIFE IN ADULTS WITH SICKLE CELL DISEASE."

Please find a revised version of the manuscript. We have carefully considered all the comments of the reviewers, and have addressed them as below.

The current paper was originally submitted to the BMJ as a short report, and was subsequently transferred to the BMJ Open. We were limited to a word count for a short report.

Reviewer: Joseph Telfair

1. There was notable lack of reference to previous literature or research of the authors specific to the papers' main thesis (see page 4, paragraph 2, sentence 3)

The current study was concerned with quality of life in relation to pain, specifically within an acute hospital setting. There is a distinct lack of research literature into quality of life and pain for adults with SCD in an hospital acute setting, which is why we believe it is an interesting area to explore further.

2. While it is clear the study location was a medical center, it was not clear if the 'clinical staff' referred to throughout the manuscript is specific to this group or clinicians in general, since this specificity has implications for the study results.

In order to clarify that the 'clinical staff' referred to are clinicians in general we have amended the sentence to better reflect that, Pg 3, paragraph 2

3. No specific set of research questions or hypotheses were put forth to guide both the data analyses and discussion of results.

The study was concerned with examining data from a retrospective audit review. As such, no research question or hypotheses is proposed and formal ethics approval was not required. We have amended Pg 4, paragraph 3 to reflect this.

4. One assumption by the authors - 'Pain assessment in patients with SCD is usually based on the opinion of clinical staff..' does not take into account the significant literature on assessment, instrument development, training, and the authors own work, as an alternative that poses a challenging caveat.

We accept that this point was not clear. We have now clarified it on Pg 3 paragraph 2. This is an evaluation of routine clinical practice as opposed to previous empirical research.

5. It was not clear if the protocol of assessment (see pages 4-5, last and first paragraphs) was based on practice evidence, as important fact given the manuscript's introductory discussion and for potential replication of the reported work

We accept that this is unclear and have amended the last paragraph on Pg 4 and the first paragraph on Pg 5 to make it explicit that the assessment protocol used existing standardised measures, the EQ-5D, and the Memorial Pain Assessment Card.

6. HRQoL is not defined in general or specifically. Health Utility is one critical domain (measured by the EQ-5D) of HRQoL, but it not singled, so the authors should have limited their description to the domain, not through implication, infer a full consideration of HRQoL, leave out the considerable literature of the relationship between pain and HRQoL.

We think that in this instance the reviewer is unclear as to how the EQ-5D is utilised. It is commonly used as a measure of HRQoL in the UK and Europe. Also, a single health utility index value is derived from the EQ-5D as an overall indication of quality of life, not a domain.

7. Given HRQoL has a strong relationship to psychological state and differential experience in adults with chronic disorders/ pain syndromes, as well as learned coping behaviors; the authors should have been considerate of or explained as a limitation and influence such phenomena on the study results, particularly since this was single group design.

We accept this point, and have acknowledged this in the discussion on Pg 10, paragraph 2.

8. The study results support one well know fact that adults with SCD report some pain relief after discharge, but seemed surprised by a another fact that adults with SCD rarely report being 'pain free'. Implications of the latter should have been addressed since it is agreed that this influence post-discharge treatment.

We have addressed this point by discussing the benefit of a multidimensional approach to pain management, particularly the use of psychological interventions to manage on-going pain post-discharge, Pg 8, paragraph 1

9. The implications of the findings specific to psychological state (mood) was inadequately referenced and discussed regards to treatment implications.

We acknowledge this and have added some additional information on Pg 10, paragraph 3 however due to word count considerations we were not able to discuss all the literature and implications at length.

Reviewer: John Green

I am unconvinced by the person who claimed intense pain on one scale and none on another. I would guess it is more likely that they have misread the measures, and hence contributed to general statistical noise, than anything more significant.

We have checked the raw data and agree with this comment.

Reviewer: Donna McClish

Need a bit more info on how Day-care pts are being treated in analysis.
Not totally clear why only some correlation work is included Title doesn't exactly match objectives.

We have clarified this point by adding further information around average length of stay for inpatient admissions and day-care attendees; please see Pg 6, paragraph 2

Authors report on routinely collected data, but it is not clear whether patients need to give (or have

given) consent for these data to be used for research.

The study was concerned with examining data from a retrospective audit review. As such, no research question or hypotheses is proposed and formal ethics approval was not required. We have amended Pg 4, paragraph 3 to reflect this.

The title of the manuscript does not entirely match up with the stated objective, which was to look at pain, mood and HRQoL across 3 time periods (admission, discharge and 1 week post discharge). The title implies the focus is on HRQoL. Yet the initial analysis also looks at mood and general health assessment. Thus the stated objective was not clear. Going further, was the actual objective to look at the values of pain, mood and HRQoL across the 3 time points, or to look at the relationship between pain, mood and HRQoL at the 3 time points. If the former, then the analysis for Figure 3 is beyond this objects (relating pain and HRQoL). If the latter, then the relationship between pain and mood, and between mood and HRQoL have been left off as relationships with general health assessment.

The focus of the review was to look at HRQoL in relation to pain for adults with SCD in an acute hospital setting. The general health scale is part of the EQ-5D which is a measure of HRQoL and mood is also a measure of quality of life, in terms of anxiety and depression, therefore we feel that general health assessment has been addressed in relation to the other areas as it is considered a component of HRQoL.

In response to the reviewers comments about the title, we think the title adequately reflects the point of interest of the study, HRQoL, which includes mood and general health status. Nonetheless, we have included 'Mood' in the title.

The role of the subjects admitted to day-care is not clear. The comment that day-care cases were being excluded from t-test analyses – does that imply that these patients are not represented in Figures 1 and 2, or are they included in the Admission part of Figures 1 and 2, but simply excluded from analyses? How about the regression analysis?

We have clarified this point by adding further information around average length of stay for inpatient admissions and day-care attendees, see Pg 6, paragraph 2

Subjects were often admitted more than once (P7, line 12-13). It was not clear in the methods that this was being taken of in analysis.

Each admission was being treated as an individual case therefore, for analysis purposes, it does not matter if the same person contributes more than one data set.

Figure 2. Missing the information on 1 week followup

There was a bar missing from Figure 2 as it did not upload properly during the submission. This was an oversight on our part.

Figure 3. I found this figure very confusing. Among other things, it is stated that the relationships are shown across all three time points but I don't see that.

The utility analysis was only concerned with the relationship between pain and utility therefore the

data from each time point was combined into a single analysis. Figure 3 is a combination of all time points and includes day-care cases because it was the general relationship between the two variable that was of interest opposed to differences between the time points themselves. There is further clarification in Pg 5, paragraph 3.

P 11 (Discussion). Authors mention that mood and general health may be related to hospital length of stay. It would appear that they should have had that data and could thus have addressed this in analysis. If not, why mention it here. In addition, in line 19, after mentioning that mood and general health could contribute to LOS, they follow with “That is, comorbidity could lead to poorer health outcomes...”. I don’t see how comorbidity is related to the previous statement and how the rest of the paragraph follows from any of the analyses presented.

We were not able to provide data for length of stay however we acknowledge that this would be an interesting area to explore further in relation to co-morbid mood disorders and general health status. We have re-worded the paragraph to clarify this and also how co-morbidity can influence length of stay and therefore associated health care costs, Pg 10, paragraph 2.

Its not clear whether patients sign a waiver of consent to have their psychological assessments used for research.

As stated earlier, we conducted a retrospective audit review as opposed to research. Formal ethics approval was not required. We have amended Pg 4, paragraph 3 to reflect this.

We remain in anticipation.

Yours sincerely

Dr Kofi Anie

VERSION 2 – REVIEW

REVIEWER	Joseph Telfair University of North Carolina at Greensboro, Center for Social, Community and Health Research and Evaluation
REVIEW RETURNED	18-May-2012

THE STUDY	<p>The authors indicated that due to the nature of the data no research questions were submitted or needed.</p> <p>This reviewer recognizes that the study is descriptive, however in any kind of research-based evidence building query, clear questions to guide the work for both scholarship and clinical utility (an implied concern of the writers) is necessary.</p>
RESULTS & CONCLUSIONS	<p>While there were no specific research questions, the overall objective of the study was clarified and addressed in this revision. So the criteria must be addressed as both a yes and nno.</p>
REPORTING & ETHICS	<p>The data for the study was from an administrative data set, requiring no consenting procedure, However, the DE-identification procedures for use were not provided.</p>

VERSION 2 – AUTHOR RESPONSE

Dear Sir / Madam

Manuscript ID bmjopen-2012-001274.R1: "PATIENT SELF-ASSESSMENT OF HOSPITAL PAIN, MOOD AND HEALTH RELATED QUALITY OF LIFE IN ADULTS WITH SICKLE CELL DISEASE."

We have addressed the additional Reviewer comments as follows.

Reviewer: Joseph Telfair

1. The data for the study was from an administrative data set, requiring no consenting procedure, However, the DE-identification procedures for use were not provided.

The process of de-identification has now been provided on Pg 6, paragraph 2.

2. The authors need to be clearer about the empirical and clinical questions that guide the work.

We have clarified this with additional information on Pg 4, paragraph 2 and Pg 5, paragraph 2, and additional references Pg 14.

Omitted Reference

We have also added a reference for the Memorial Pain Assessment Card; this was omitted in error Pg 14.

Yours sincerely

Dr Kofi Anie