Author's response to reviews

Title: The challenges in monitoring and preventing patient safety incidents for people with intellectual disabilities in NHS acute hospitals: evidence from a mixed-methods study

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Version: 4 Date: 17 June 2014

Author's response to reviews: see over
Dear Mr Giary,

Thank you very much for the extremely helpful and constructive feedback received in response to our resubmission of the manuscript “The challenges in monitoring and preventing patient safety incidents for people with intellectual disabilities in NHS acute hospitals: evidence from a mixed-methods study”.

We have made further changes to the manuscript and provide a point-by-point response to all reviewer comments (including those received following the first review of the manuscript). We hope that we have addressed these points adequately and look forward to your response.

Kind regards

Lucy Goulding

(On behalf of all authors)

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Editorial comment on revision 2:

The paper is substantially improved but the reviewer has highlighted that not all of the revisions previously requested have been adequately addressed. In addition an point-by-point explanation of the changes has not been made. All the revisions identified by the reviewer should be fully addressed, with particular attention paid to improving the clarity of the Results and changes carefully explained point by point as a subsequent round of revisions is not permitted.

Thank you for your comment. We now provide a detailed point-by-point response to all reviewer comments (including those made during the initial review of the paper).

We have improved the clarity of the results section of the manuscript by signposting to the reader how the results are to be presented and by ensuring that the results section clearly presents the findings whereas the discussion section addresses the broader interpretation of the findings in relation to the methodology adopted and the wider literature.
Reviewer comments on revised manuscript

Reviewer's report (Reviewer 2)

Title: The challenges in monitoring and preventing patient safety incidents for people with intellectual disabilities in NHS acute hospitals: evidence from a mixed-methods study

Version: Date: 23 April 2014

Reviewer: Pauline Heslop

Reviewer's report:

Major Compulsory Revisions

1. The 'background' is much improved, with more clarity about what is understood by the term 'patient safety'. However, the first sentence of the second paragraph might not make sense to the reader ‘…one in ten patients experience preventable harm or adverse events in hospital and that around 50% of these are preventable’. This sentence needs to be clarified, and the references (all of which are a decade or more old) should be updated.

We have amended the manuscript to ensure that the terminology we use (e.g. adverse events, patient safety issue, patient safety incident) is clearly defined and used consistently. The particular sentence that the reviewer highlights as being unclear now reads “It is estimated that one in ten patients experience adverse events in hospital [1, 5], and that around 50% of these are preventable”. A definition of an ‘adverse event’ is given in the preceding paragraph.

2. The ‘Results’ section is somewhat improved, but remains confusing overall and still requires attention. The advice of one referee about distinguishing between different sorts of risks has not been followed, nor has the request by the other reviewer for clarification of why some issues have been included as being of relevance. It would be helpful to signpost the reader about how the authors will take them through the findings eg discuss general methodological issues related to incident reports, complaints and obtaining the views of staff first, before looking in more detail at the patient safety issues highlighted.
a. The section about ‘staff perspectives’ requires some clarification and rewriting. At present it conflates methodological issues with findings, and it would be more helpful for these to be kept separate. In this section I would expect to only have a summary of findings related to obtaining the views of staff. This would lessen the confusing overlap that there currently is between this and the next section.

The results and discussion sections of the manuscript have been re-written to provide clarity and an improved structure, ensuring that the results section presents the findings and the discussion considers these findings in relation to the methods adopted and the wider literature on the subject. The background section of the manuscript now better addresses the different sorts of risks. Table 1 provides the questions within the research framework that were relevant to the safety of patients with intellectual disabilities and the methods describes the way in which the different safety issues were derived as a result of the analysis (thus explaining why certain issues have been included as being of relevance.

b. The section about ‘patient safety issues’ also requires some reworking and expanding. The commentary in the text, and the issues identified in Table 5 should be consistent – for example I am unsure what the rationale is for commenting on ‘delayed treatment or non-treatment decisions related to consent issues’ in the text, whereas this does not feature as a heading in Table 5.

This section has been re-written. Attention has been paid to ensuring that the findings presented in the text are backed up by data in tables.

Minor Essential Revisions

1. Results section: Staff perspectives. Table 4 refers to clinical staff questionnaires. The sub-heading and Table should use the same term ie either ‘staff’ or ‘clinical staff’

We have corrected this and refer to ‘clinical staff questionnaires’ throughout the manuscript.
Original Editor's comments (following first review of manuscript)

Editor's Comment:

This paper is on a very important topic in an under researched area. The relatively poor levels of health care in people with learning disability is increasingly being recognised and so this paper is timely. However, in accordance with the reviewers, it is my view that the paper needs substantial revision before it is reconsidered for publication. Both reviewers have provided detailed and practical advice on improving the presentation of the paper and their comments should be considered carefully. In particular, reviewer 1 identifies improvement in practice as the important area to take forward rather than more research. Comments by Reviewer 2 support this focus.

Further changes to be made during revision: Please place 'keywords' after the abstract section of the manuscript.

The 'keywords' now appear after the abstract section of the manuscript.

Original reviewers' comments

Reviewer's report

Title: Investigating the patient safety issues for people with intellectual disabilities in NHS acute hospitals: evidence from a mixed-methods study

Please note that we changed the title and focus of the manuscript following the helpful feedback provided following the first review of the manuscript.

Version: 1 Date: 2 February 2014

Reviewer: Pauline Heslop

Reviewer's report:

This article describes the findings from a study of patient safety issues for people with intellectual disabilities in NHS acute hospitals. The article has potential, but requires revision before it is ready for publication.

Major Compulsory Revisions

There is considerable scope for the article to be tightened up, with increased precision required in a number of areas. In part this is about the use of language; in other places in the article, it is about the description and interpretation of the
study. The majority of my comments relate to this overarching issue. Places where I think that clarification and precision should be improved are described below, and together constitute major compulsory revisions.

We thank reviewer 2 for constructive feedback. We are pleased that reviewer 2 believes that the article has potential. We hope that we have now addressed the points made by reviewer 2 by re-focussing and tightening up the entire article through re-visiting our description and interpretation of the study.

• The abstract. The phrase 'harmful healthcare' is emotive and deserves clarifying. Do the authors mean healthcare that is harmful in its intention, delivery or consequences?

We have removed the phrase ‘harmful healthcare’ from the abstract and have endeavoured to provide clear and consistent definitions of the terminology used throughout the manuscript. For example, in the introduction section of the manuscript, we define patient safety issues, adverse events and contributory factors.

Also in the abstract, the authors suggest (in the findings) patient safety issues that ‘may be’ or are ‘potentially due’ to certain factors. Again this needs to be clarified, and more precision is required based on the findings of this particular study.

In light of the helpful reviewer comments, we have re-visited the focus of this manuscript and hope that we now provide a clearer presentation of our interpretation of the findings of the study (in both the abstract and the body of the manuscript). We have endeavoured to ensure that our methods section provides a transparent description of the way in which the study findings were generated.

• A much clearer definition and explanation is needed as to what the authors understand to be ‘patient safety issues’. An overview (drawn from the literature) is given in Table 1, although I do not understand the authors’ distinction between the issues and the contributory factors (e.g. poor recognition of swallowing difficulties could be a contributory factor and the patient safety issue would be choking or aspiration). Nor are ‘never events’ either mentioned or included in the list of safety issues. The potential issues in Table 1 are also different from those described in Tables 2 and 3, leading to further confusion. The article would be considerably improved if there was a clear discussion in the introductory text about what defines and constitutes a patient safety issue and why, perhaps with categorisation of types of issue.

The introduction section of the manuscript has been revised and now includes definitions of ‘patient safety issues’, ‘adverse events’, ‘contributory factors’ and ‘never events’.

Table 5 in our results section now clearly depicts specific patient safety issues, the contributory factors underlying these and provides examples from the study in illustration.
Clarification is required regarding the methods of the study.

- The author should describe how many questionnaires were returned by family carers and paid care staff separately.

Table 2 now provides a breakdown of the number of questionnaires returned by family carers and the number returned by paid care staff.

- Other than mentioning the observation of in-patients with intellectual disabilities, there is no mention about how this was undertaken, the information gained from doing so, and whether this was a useful way of obtaining data. This requires clarification or a note to state that the data is being reported elsewhere.

Observation of in-patients with intellectual disabilities is briefly described in the methods section and the reader is referred to the full study report for in-depth description of the methods adopted and the findings.

- The rationale for the inclusion of items in interview schedules and questionnaires should be given. For example, why were the specific patient safety incidents as described in Table 3 chosen? How was the wording of each item selected, and does it adequately identify patient safety issues (for example, the use of ‘certain tests or treatments’ rather than ‘essential tests or treatments’)? Why was the time period of 3 years used?

We have updated the methods section of the manuscript as follows:

“Interview schedules and questionnaires were derived from a research framework, which included general queries around the prevention of adverse outcomes as well as a number of questions about specific patient safety issues that had been identified in the literature. A scoping review published at the outset of the research [27] suggested that preventable deterioration and, in particular, medication errors and misdiagnosis (due to problems with communication and comprehension) were specific and pertinent issues faced by patients with intellectual disabilities; these safety issues therefore formed specific lines of enquiry (see table 1). Staff interviewees were asked to expand on their views and experiences of patient safety incidents, including medication errors and preventable deterioration. Carers were asked to comment on the standard of medical care provided to the patient, on the specific needs of the patient, and on the hospital’s ability to meet those needs. All interviewees were invited to contribute examples of what they perceived as good hospital care, as well as examples of practice where the patient was at perceived risk or had suffered actual harm. Data collection tools were piloted and revised accordingly.”

- No mention is made about how the interview participants were identified and recruited, or by whom or where the interviews were undertaken. This requires amending.

Due to the need to provide a concise description of the methods adopted, we now refer readers to our full study report for an in-depth description of the methodology and study findings (citation [27]).

The section about data analysis also requires clarification – who was the
multi-disciplinary team that undertook the data analysis? Was the coding in NVivo predetermined, or were new codes added as different themes emerged? Was the coding double checked by different researchers?

We have amended the data analysis section of the methods as follows:

“Analysis of the large amount of qualitative data involved line-by-line coding and was facilitated by the data management programme NVivo 9. The analytic framework included codes for patient safety incidents as well as for participants’ views and experiences with regards to patient safety, and as such enabled the extraction of patient safety incidents throughout the data set. These examples were scrutinised with a focus on determining the contributory factors that underpinned them.

Data analysis was undertaken throughout the study period and with involvement from all members of the research team to ensure reliability. Weekly research team meetings were held to discuss coding and emerging themes, and to amend the coding framework as necessary. Members of the research advisory board joined in these discussions to add their perspective as needed; this included national patient safety experts, the Chief Executive of an NHS trust, and family carers.”

Readers are referred to the full report of the study for further details of the methods if this is required.

Regarding the findings: I am unclear about the selection of the four particular safety issues described in the results. Are these the issues that occurred most frequently (and if so are they presented in order of frequency with which they were reported) or are they the issues that the authors suggest are the most important? Placing ‘lack of basic nursing care’ first suggests that it is of most concern, but the wording ‘several carers and hospital staff’ (in relation to an assumed 272 incidents) leads to a lack of clarity with this assumption. In addition, the section about ‘delayed investigations and treatment’ only seems to refer to ‘several’ examples.

We now clearly state that the safety issues identified are not presented in order of importance or frequency, rather, these were the key issues derived from synthesis of the mixed-methods data.

We have revisited the focus of this manuscript and therefore the structure and description of the results. We hope that you will now find this section much improved. Table 5 has been constructed to clearly depict the patient safety issues and contributory factors underlying these that were derived from the analysis. This table also provides examples of data from the study.

We now include the following paragraph:

“Synthesis of all data demonstrated that the following safety issues were of particular significance to patients with intellectual disabilities in acute hospitals (not in order of importance or frequency): inadequate provision of basic nursing care; misdiagnosis; delayed investigations and treatment; and non-treatment decisions and Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) orders. Further descriptions and examples of these issues are given in table 5.”
In addition, clarification is required in the results section in relation to:

- The phrase ‘lack of basic nursing care’ requires justification. Was this a complete lack, or was it inconsistent, inadequate or poor quality provision?

We now provide examples of the lack of provision of basic nursing care to make this theme clearer, e.g. “lack of monitoring of patients’ general wellbeing and comfort, insufficient feeding or hydration and lack of pressure are care”. Excerpts from the data are used to illustrate this theme within Table 5.

- The quotations do not always describe the issue at point e.g. p.11 the fact that a person was inappropriately given a drink whilst waiting a theatre slot has little to do with misdiagnosis.

The original example was as follows:

“A man with intellectual disabilities attended A&E on his own as he had noticed blood in his underwear. He had difficulty articulating his symptoms and was sent home from A&E as staff incorrectly believed the man was drunk. Later on, a carer noticed the blood and the man returned to A&E. He had a rectal prolapse which required emergency surgery. Whilst awaiting his theatre slot, the man was inappropriately given a hot drink. Because of this, the surgery was delayed.”

We agree that the final two sentences within this passage was not relevant to the theme ‘misdiagnosis’ and have removed these from the example (which is now presented in Table 5). The example provides a clear description of misdiagnosis (not being correctly diagnosed with a rectal prolapse at first presentation at A&E) and we believe that the other examples provided all clearly illustrate the issue at point.

- The explanation about delays to investigations and treatments in relation to the Mental Capacity Act also requires more attention to detail. The Mental Capacity Act should be implemented at all times, not just after a patient’s capacity has been established (p.13). It would also be appropriate not to go ahead with tests or treatments without patient consent – what would be of concern would be inappropriate delays in the decision-making process about what would be in the person’s best interests. Finally the assumption that junior staff would be more likely than senior clinical staff to misunderstand the MCA or lack confidence in using it must be questioned. It may well be that junior staff have received more recent training than senior medical staff and would be expected to be more up-to-date.

We intend to write an additional paper on our findings in relation to misuse of the Mental Capacity Act. As we have now refocused the manuscript and altered the presentation of our findings, we hope that this point will no longer be of concern.

- DNAR should be referred to as Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) to distinguish this treatment from other forms of resuscitation e.g. fluid resuscitation.

We have amended this within the manuscript.
The Discussion does not clearly follow on from the findings presented in this paper, leading to some confusion on the part of the author. For example:

- In the findings (and described in Table 1), diagnostic overshadowing is described as a patient safety issue, but in the discussion it is described as a contributory factor.

We have amended this within the manuscript (see table 5). Diagnostic overshadowing is a contributory factor to misdiagnosis. Misdiagnosis is a patient safety issue as defined in our introduction section.

- The authors report that ‘gaps in access, treatment and care’ remain (p.16), but gaps in access have not been addressed in the findings of the study.

This has been removed from the manuscript.

- The discussion about acts of omissions and acts of commission is interesting but confusing. The authors note that acts of omission are thought to be twice as prevalent as acts of commission, but this is not reflected in the findings of the study where acts of commission (providing the wrong care) are emphasised more.

We openly state “acts of omission are known to be more difficult to recognise, capture and monitor” which is precisely why acts of commission are more likely to be derived in studies of this type. However, the study clearly demonstrated that acts of omission are of specific concern for patients with intellectual disabilities and this is reflected in a great number of examples in the results section (e.g. those examples relating to lack of provision of basic nursing care, one of the examples of misdiagnosis and many of the examples of delayed investigations and treatment and non-treatment decisions). We do not feel that acts of commission are emphasised more.

Minor Essential Revisions
The Table numbers given in the text do not refer to the correct Tables. Tables 2 and 3 should be reordered into a logical order, for example with the types of incidents most commonly reported placed first.

Table numbering has been amended.

Discretionary Revisions
The discussion could usefully explore a number of issues raised in the paper. First, why, for example, were issues described by interviewees on p.15 not reported or acted upon? If an order not to resuscitate a person was inappropriately based on staff assumptions about the quality of life of a person, why did the ward manager not challenge this? There seems to be two issues here – the occurrence of the patient safety issues, and whether or not patient safety issues are reported. The authors could usefully disaggregate these issues.
We have refocused the paper to address the challenges in monitoring and preventing patient safety incidents for people with intellectual disabilities in NHS acute hospitals. We hope that we now provide a more in depth discussion of the key issues identified within the paper.

The second issue that could be usefully expanded on in the discussion relates to what could be done to address the problems identified. The authors suggest that healthcare providers should be encouraged to scrutinise the provision of care and treatment with expert coordination of care, but the basis for this assertion is not clear. I would suggest that a more focused discussion could be presented that is based on ways of preventing, reporting and monitoring patient safety issues.

Again, we have refocused the paper and amended the discussion. We now make a clear recommendation of what could be done to address the problems identified:

“"The authors suggest that identifying and documenting the reasonable adjustments needed for each individual patient would go some way in reducing the safety risk of people with intellectual disabilities. A national requirement to do this for all patients, subject to inspection and reporting, could make a significant contribution to improving patient safety. In addition, there is a need for acute hospital trusts to ensure that their staff are adequately trained in the use of the Mental Capacity Act and of DNACPR decisions. General staff training to improve understanding of reasonable adjustments and the needs of patients with intellectual disabilities will also help to improve patient safety."

Finally, one of the potentially interesting aspects of this paper is the perceptions of different patient or professional groups about what constitutes a patient safety incident. This could usefully be drawn out a little more.

We have added a section on ‘staff perspectives’ to the results section of the manuscript. Due to the need to keep the manuscript to a reasonable length we have not been able to offer a full discussion of the perceptions of different staff groups but the reader is free to refer to our full report of the findings for additional information. We will take this comment on board and consider writing another paper that addresses this point.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I declare that I have no competing interests
Reviewer’s report:

The topic is important and topical – there is a good deal of current interest in the physical health of adults with learning disability, as cited in the introduction. Given what we know about the acute hospital care received by other vulnerable groups such as people with dementia, it is reasonable to ask what happens to people with learning disability. There were however a number of ways in which I found the research as presented rather disappointing.

[1] Definitions

a. The term “patient safety issues” is used repeatedly and is a catch-all for at least three phenomena: events in hospital that might lead to harm; reports of actual harm that befell patients; possible reasons for either risky events or actual harms.

b. The report doesn’t distinguish between actual events and perceived events or risks. Thus it is difficult to judge what it means to say that management of challenging behaviour was inappropriate, that treatment took place in an inappropriate clinical area or that communication was inadequate or not as good as it should have been.

Major revision – the introduction and methods should be rewritten with more clarity about the terms used.

We have amended the manuscript to include clear definitions of the terminology used in the paper.

It is difficult to get a feel for what was collected when the questionnaires and topic guides for the interviews are not provided.

Major revision – more detail is required, probably as supplementary material

We now refer the reader to the full study report for a detailed description of the methods and findings.

[3] Analysis

There are at least three possibilities here:

- Poor care is the same for adults with learning disability as it is for everybody else, and there isn't a learning disability-specific problem
- Poor care is the same for adults with learning disability as it is for everybody else, but people with learning disability are more likely to suffer harm as a consequence
- Poor care is more likely for adults with learning disability and they are more likely to suffer harm as a consequence.

Failure to distinguish between these options makes it difficult to link results to proposed solutions.

Major revision – more attention in the presentation of the results is needed to distinguish these possibilities, or the inability to do so should be discussed as a limitation.

We clearly describe the fact that the intention of the paper is not to quantify the incidence of patient safety issues nor to compare the incidence of patient safety issues experienced by people with intellectual disabilities in comparison to other groups.
Results

a. The results seem reasonable as far as they go, although given the scale of the project they do seem a little meagre. There is for example no indication of what was gained by studying six Trusts in different locations or so many staff of different grades.

b. It is disappointing that there is no attempt to distinguish different sorts of risk. For example:

   o Age – children and adults were included, but it is difficult to believe that the experience of an 8 year old on a paediatric ward is the same as that of a 50 year old on an adult medical ward

   o Physical disorder – severity, need for special nursing, length of stay, surgical or medical care for example

   o Nature of learning disability – do people with a visible condition like Down Syndrome have the same exposure as others?

Major revision – additional results need to be presented, at the very least indicating what differences there were between children and adults.

We have re-written the results section and altered the focus of the report in light of the helpful reviewer comments. Please note that this study concerned adults with intellectual disabilities and this is clearly stated within the manuscript.

Discussion

I don't see the case for a large research study as the next step. A number of rather more obvious interventions seem immediately indicated without need for more research.

a. Lack of understanding and confidence in the use of the Mental Capacity Act is common in general hospitals. All staff should be familiar with the basics and this is a matter for staff training.
b. Indiscriminate use of DNAR decisions is something that should be dealt with by a policy directive.

c. Recording of learning disability in general hospital, like recording of dementia or severe mental disorder, is poor and again could be dealt with by policy and training rather than more research.

The authors conclude by saying that research is needed to act as a catalyst for tailored interventions, which rather suggests that they have already decided what the research would show. An alternative and plausible proposition is that what is needed is organisation-level change to improve hospital environments for all those with cognitive deficits like delirium or dementia, learning disability, or severe mental illness.

Major revision – additions to the discussion are required. At the moment the call for a major new research project isn’t as convincing as some obvious practical steps to improve care.

We have revised the discussion and conclusion of the paper. Our recommendations now focus on practical steps to improve care rather than research recommendations.

Level of interest: An article whose findings are important to those with closely related research interests.

Quality of written English: Acceptable.

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

Your associate editor Dr Bryant works in the same Institute as me but I have not discussed the manuscript with her and do not know her own views on it.