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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Author's response to reviews: see over
Dear Sir or Madam,

We have checked our manuscript to ensure that it conforms to the RATS guidelines. Please see evidence of this below.

Kind regards,

Lucy Goulding on behalf of all authors

RATS GUIDELINES

RESEARCH QUESTION EXPLICITLY STATED

Our research questions are explicitly stated at the end of the introduction section on p7. The paragraph states:

*The aim of this paper is threefold: to describe the challenges in preventing and monitoring patient safety issues for people with intellectual disabilities in NHS acute hospitals, to describe the range of the patient safety issues faced by patients with intellectual disabilities in the study (from those that caused potential harm but no known harm, to those that caused actual harm); and to explore the underlying contributory factors to these safety issues*

RESEARCH QUESTION JUSTIFIED AND LINKED TO THE EXISTING KNOWLEDGE BASE (EMPIRICAL RESEARCH, THEORY, POLICY)

The research questions follow a review of the extant literature. The background literature demonstrates the need for this additional piece of research.

STUDY DESIGN DESCRIBED AND JUSTIFIED I.E., WHY WAS A PARTICULAR METHOD (E.G., INTERVIEWS) CHOSEN?

The study design is described and justified on pages 7-9. The reader is referred to the full report of the study for an in-depth discussion of the methods adopted. We explicitly tell the reader that the mixed methods design was based on an initial literature review and development of a research framework.

CRITERIA FOR SELECTING THE STUDY SAMPLE JUSTIFIED AND EXPLAINED

- THEORETICAL: BASED ON PRECONCEIVED OR EMERGENT THEORY
- PURPOSIVE: DIVERSITY OF OPINION
This was a mixed methods study involving both quantitative and qualitative data collection. The sampling for each element of the study is clearly described on page 8:

(a) electronic questionnaires were sent to all clinical hospital staff; (b) semi-structured interviews were conducted with hospital staff including all nursing directors, medical directors and other purposively selected senior managers, and managers of up to three purposively selected wards per hospital as well as nurses on those wards; (c) questionnaires were given or sent to carers of patients with intellectual disabilities during a 12 month data collection period; (d) semi-structured interviews were held with carers who had indicated willingness to be interviewed and provided contact details on the questionnaires; (e) hospital-based expert panels were convened to discuss emerging findings, consisting of purposively selected senior managers and clinicians with knowledge and expertise in providing hospital care to vulnerable groups; (f) incident report data that involved a patient with intellectual disabilities over a 12 month period, as well as data on complaints involving a patient with intellectual disabilities, were scrutinised.

DETAILS OF HOW RECRUITMENT WAS CONDUCTED AND BY WHOM

On page 7/8, we state: Recruitment of participants was facilitated by a study collaborator at each site, who helped to identify potential participants (the nursing director, deputy nursing director, or intellectual disability liaison nurse (IDLN)).

DETAILS OF WHO CHOSE NOT TO PARTICIPATE AND WHY

In the ‘limitations’ section of the discussion we state:

The numbers of carers who participated in this study was relatively low. This was in part due to the difficulties inherent in identifying patients with intellectual disabilities at the point of care. However, this is one of the largest studies to date focusing on the safety of patients with intellectual disabilities in acute hospitals. The number of participants who were carers was large compared to existing studies, and the extended research team agreed that data saturation had been achieved. The staff participants may include over-representation of people with a specific interest in intellectual disability. However, recruitment of a large number of staff enabled capture of a variety of perspectives from people with varying degrees of prior experience.

METHOD(S) OUTLINED AND EXAMPLES GIVEN (E.G., INTERVIEW QUESTIONS)

We refer to the full report of the study for in depth detail of the methods adopted and the data collection tools used.

We state:
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 [25] 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.

STUDY GROUP AND SETTING CLEARLY DESCRIBED

Setting and study participants described on pages 7-8. A detailed breakdown of participants is provided in Table 2.

END OF DATA COLLECTION JUSTIFIED AND DESCRIBED

In the limitations section we state that qualitative data collection ceased when saturation was achieved.

DO THE RESEARCHERS OCCUPY DUAL ROLES (CLINICIAN AND RESEARCHER)? ARE THE ETHICS OF THIS DISCUSSED? DO THE RESEARCHER(S) CRITICALLY EXAMINE THEIR OWN INFLUENCE ON THE FORMULATION OF THE RESEARCH QUESTION, DATA COLLECTION, AND INTERPRETATION?

The researchers on this project were not involved in the health care of any of the individuals in the study. We state:

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.

INFORMED CONSENT PROCESS EXPLICITLY AND CLEARLY DETAILED

We state: Participants gave their informed consent (or where appropriate a consultee provided assent in line with the requirements of the Mental Capacity Act 2005) to take part in the study.
ANONYMITY AND CONFIDENTIALITY DISCUSSED

We have been careful to protect anonymity and confidentiality and assurances of this were given as part of the informed consent process. On p7 we state: *Anonymity and confidentiality was clarified with participants.*

ETHICS APPROVAL CITED

We state: *The study obtained ethics approval from London East Research Ethics Committee (reference 11-LO-0428). R&D approval was granted at each of the six research sites.*

ANALYTIC APPROACH DESCRIBED IN DEPTH AND JUSTIFIED

We state: *Data from the two questionnaires were analysed using SPSS Statistics 19 and descriptive statistics were calculated. 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. Attention was paid to divergent cases. 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.*

INDICATORS OF QUALITY: DESCRIPTION OF HOW THEMES WERE DERIVED FROM THE DATA (INDUCTIVE OR DEDUCTIVE)

See above answer.

EVIDENCE OF ALTERNATIVE EXPLANATIONS BEING SOUGHT

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.

ANALYSIS AND PRESENTATION OF NEGATIVE OR DEVIANT CASES DESCRIPTION OF THE BASIS ON WHICH QUOTES WERE CHOSEN

We state: *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. Attention*
was paid to divergent cases. 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.

SEMI-QUANTIFICATION WHEN APPROPRIATE

N/A.

ILLUMINATION OF CONTEXT AND/OR MEANING, RICHLY DETAILED

We describe the emerging themes throughout the results section of the manuscript and offer supporting excerpts from the data both within the body of the manuscript and in Tables 3, 4 and 5.

METHOD OF RELIABILITY CHECK DESCRIBED AND JUSTIFIED E.G., WAS AN AUDIT TRAIL, TRIANGULATION, OR MEMBER CHECKING EMPLOYED? DID AN INDEPENDENT ANALYST REVIEW DATA AND CONTEST THEMES? HOW WERE DISAGREEMENTS RESOLVED?

We state: 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. Attention was paid to divergent cases. 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.

FINDINGS PRESENTED WITH REFERENCE TO EXISTING THEORETICAL AND EMPIRICAL LITERATURE, AND HOW THEY CONTRIBUTE

A literature review is presented in the background section of the manuscript. The discussion section places the findings in the context of the existing literature.

STRENGTHS AND LIMITATIONS EXPLICITLY DESCRIBED AND DISCUSSED

We include a limitations section within the discussion.

EVIDENCE OF FOLLOWING GUIDELINES (FORMAT, WORD COUNT)

We have followed the author guidelines.

DETAIL OF METHODS OR ADDITIONAL QUOTES CONTAINED IN APPENDIX

We refer the reader to the full report of our study for further detail.

WRITTEN FOR A HEALTH SCIENCES AUDIENCE

Yes.