Improving patient safety through the involvement of patients: development and evaluation of novel interventions to engage patients in preventing patient safety incidents and protecting them against unintended harm

John Wright,[1]* Rebecca Lawton,[1,2] Jane O'Hara,[1,3] Gerry Armitage,[4] Laura Sheard,[1] Claire Marsh,[1] Angela Grange,[1] Rosemary RC McEachan,[1] Kim Cocks,[5] Susan Hrisos,[6] Richard Thomson,[6] Vikram Jha,[7] Liz Thorp,[1] Michael Conway,[8] Ashfaq Gulab,[8] Peter Walsh[9] and Ian Watt[10]

[1]Bradford Institute for Health Research, Bradford Royal Infirmary, Bradford Teaching Hospitals NHS Foundation Trust, Bradford, UK
[2]School of Psychology, Faculty of Medicine and Health, University of Leeds, Leeds, UK
[3]Leeds Institute of Medical Education, Faculty of Medicine and Health, University of Leeds, Leeds, UK
[4]Faculty of Health Studies, University of Bradford, Bradford, UK
[5]York Trials Unit, University of York, York, UK
[6]Institute of Health & Society, University of Newcastle, Newcastle, UK
[7]School of Medicine, University of Liverpool, Liverpool, UK
[8]Patient Panel Cochairperson, Bradford, UK
[9]Action against Medical Accidents, Croydon, UK
[10]Department of Health Sciences, University of York, York, UK

*Corresponding author

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Scientific summary

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Scientific summary

Estimates suggest that, in NHS hospitals, incidents causing harm to patients occur in 10% of admissions with costs to the NHS of over £2B. Strategies to reduce patient safety incidents (PSIs) have focused on changing systems of care and professional behaviour. More recently, there has been an international drive to involve patients in safety initiatives, despite little evidence on how best to achieve this. Recent reviews of the literature have highlighted a lack of initiatives to promote patient/carer involvement in patient safety; major gaps in our knowledge about the nature and effects of patient involvement; little evidence of the feasibility or effectiveness of patient-centred interventions; and uncertainty over their acceptability.

The aim of this programme was to design, develop and evaluate five innovative approaches to engage patients in preventing PSIs:

1. Assessing risk – developing a theoretically informed contributory factors framework from a systematic review of the literature and using this to develop a patient assessment of safety:

   (a) systematic review of factors contributing to safety incidents in hospital
   (b) development of a patient measure of organisational safety.

2. Reporting incidents – identifying methods of patient-based reporting from the literature and developing and evaluating a patient incident reporting tool (PIRT):

   (a) patient reporting of incidents: a systematic review of the literature
   (b) testing three approaches to capturing patient reports about safety
   (c) a comparative study of patient-reported patient safety incidents and existing sources of patient safety data.

3. Combining (1) and (2): evaluation of the Patient Reporting and Action for a Safe Environment (PRASE) tool – combining the assessment and reporting into one measure (PRASE) and evaluating its impact on patient safety in a cluster randomised trial:

   (a) feasibility study for the PRASE intervention
   (b) randomised controlled cluster trial evaulating PRASE.

4. Direct engagement in preventing errors – developing a programme to promote direct patient involvement in improving safety: ThinkSAFE.
5. Education and training – embedding patients' experiences of harm in training: randomised controlled trial (RCT) of the use of personal stories of harm to raise awareness of patient safety for doctors in training.

1. Assessing risk

(a) A systematic review of factors contributing to patient safety incidents in hospital settings

Existing frameworks used to understand the factors contributing to PSIs are theoretically informed but are not derived from empirical evidence. The aim of this systematic review was to develop a contributory factors framework from a synthesis of empirical work that summarises factors contributing to PSIs in hospital settings.

Methods

Search and review of studies reporting data from primary research in secondary care with the aim of identifying the contributory factors to error or threats to patient safety.

Results
In total, 1502 potential articles were identified; 95 papers met the inclusion criteria and 1676 contributory factors were extracted. Coding of contributory factors by two independent reviewers resulted in 20 domains (e.g. team factors, supervision and leadership). The majority of studies identified active failures (errors and violations) as factors contributing to PSIs. Individual factors, communication and equipment and supplies were the other most frequently reported factors within the existing evidence base.

Conclusion
This review developed an empirically based framework of the factors contributing to PSIs. This framework has the potential to be applied across hospital settings to improve the identification and prevention of factors that cause harm to patients.

(b) Development of a patient measure of organisational safety
Patients are often able to provide feedback on the quality and safety of their care when in hospital and can identify safety issues that staff may not have noticed. This study reports on the development and validation of the Patient Measure of Safety (PMOS) tool.

Methods
Qualitative methods were used to ascertain which contributory factors patients could identify as being relevant to patient safety. From these data PMOS items were developed and tested with health professionals and patients to assess face validity. A validation study used a large survey with patients to assess their perceptions of factors contributing to PSIs and another survey with staff in the same hospital to assess convergent validity.

Results
Patients were able to identify a broad range of contributory factors, with communication being the factor most recognised. Patients had a willingness to complete the PMOS tool, with few barriers identified. The results of the validation study showed the tool to be reliable and valid.

Conclusion
The PMOS tool offers an important mechanism for hospitals to engage with their patients about safety and to gather data on how wards are performing in relation to the safety and quality of care they are delivering.

2. Reporting incidents

(a) Patient reporting of incidents: a systematic review of the literature
Patients are increasingly being thought of as central to patient safety. A small but growing body of work suggests that patients may have a role in reporting patient safety problems within a hospital setting. This review investigated (i) what patients can report, (ii) in what settings they can report, (iii) at what times patients have been asked to report and (iv) how patients have been asked to report.

Methods
Search and review of published literature on patient reporting of patient safety 'problems' within a hospital setting.

Results
Thirteen papers were included within this review. All included papers were quality assessed using a framework for comparing both qualitative and quantitative designs.

Conclusions
Patients are clearly able to report on patient safety, but included papers varied considerably in focus, design and analysis, with all lacking a theoretical underpinning. The impact of timing on the accuracy of information is unknown and many vulnerable patients are not currently included in patient reporting studies, possibly introducing bias and underestimating the potential of patient reporting.

(b) Testing three approaches to capturing patient reports about safety

Emergent evidence suggests that patients can identify and report safety issues while in hospital. However, little is known about the best method for collecting feedback, with most work asking patients after discharge and questions being based on predefined clinical categories. This study presents an exploratory pilot of three mechanisms for collecting patient feedback on safety.

Methods

Three mechanisms for capturing patient feedback were coproduced with health-care professionals and patients before being tested in an exploratory trial, using cluster randomisation at a ward level. Patients were asked to feed back safety concerns via the mechanism on their ward (interviewing at the bedside, a paper-based form or a patient safety 'hotline'). Safety concerns were subjected to a two-stage review process to identify PSIs. Differences between mechanisms in reports per patient, the likelihood of reporting, the number of PSIs and ratings of severity and preventability were examined using analysis of variance (ANOVA) and chi-squared analyses. Reported safety concerns were analysed qualitatively and a framework developed.

Results

In total, 178 patients were recruited into the study. Patients in the face-to-face interviewing condition provided more reports per patient and were more likely to report one or more safety concerns. The mechanisms did not differ significantly in the number of classified PSIs.

Conclusion

Interviewing at the patient's bedside is likely to be the most effective means of gathering patient feedback about the safety of care.

(c) A comparative study of patient-reported patient safety incidents and existing sources of patient safety data

Codesigned incident reporting tools make a novel contribution to the vanguard of incident detection methods. We examined the use of PIRT to collect safety concerns from hospitalised patients, compared these data with other established sources of safety data; quantified the overlap and considered organisational implications.

Methods

Trained recruiters collected data from patients in nine wards in a teaching hospital across four specialities. For consenting patients who had submitted concerns, we searched for PSIs in the corresponding patient case notes as part of a two-stage review process; we also reviewed all staff incident reports, complaints and reports to the Patient Advice and Liaison Service (PALS).

Results

In total, 155 patient reports were received from 77 patients; 57 patients who submitted patient reports had their case notes reviewed by nurses who, having identified at least one PSI, then forwarded the notes for doctor review. Only eight clinical PSIs corresponded directly with patient-reported concerns; five patient reports were identified in incident reports and two through PALS.

Conclusions

Patients can and should contribute to the design of PIRTs. When hospitalised patients are asked about the safety of their care they can provide a unique perspective. Overlap between different sources of safety data including patient-sourced data is minimal. Codesigned patient reporting tools should be part of an integrated approach to gathering patient safety information.

3. Combining (1) and (2): evaluation of a combined assessment and reporting measurement tool

(a) The Patient Reporting and Action for Safety intervention: feasibility study

This feasibility study of a patient-centred patient safety intervention had three research aims: (i) to explore the feasibility of systematically collecting feedback from patients; (ii) to explore the feasibility and acceptability of the intervention for staff and how staff use patient feedback for service improvement; and (iii) to explore the feasibility of collecting feedback from staff about the safety culture.

Methods

This study was a feasibility study using a wait-list controlled design across six wards within an acute teaching hospital. Intervention wards were asked to participate in two cycles of the PRASE intervention across a 6-month period. Participants were patients on participating wards and ward staff completing safety culture surveys.

Results

In total, 379 patients were recruited, with 199 staff returning completed safety culture questionnaires. Findings indicated that the PRASE tool can be used successfully to collect patient perspectives on safety. Recommendations were discussed for amendments to the intervention prior to testing within a cluster RCT.

(b) Randomised controlled trial of the Patient Reporting and Action for Safety tool

A multicentre, cluster RCT was undertaken to assess the efficacy of the PRASE intervention in achieving patient safety improvements over a 12-month period.

Methods

The trial was conducted in 33 hospital wards across three NHS trusts. A report to wards summarised feedback from the PRASE intervention and staff were asked to plan and implement actions to improve safety. The control group received care as usual but patients also completed the PMOS outcome measure. The two primary outcomes were (i) the routinely collected harm-free care score and (ii) the PMOS questionnaire. A cost–consequence analysis was used to estimate the impact of the intervention on both costs and outcomes.

Results

Intervention uptake and patient participation were high. However, adherence to the intervention, particularly the implementation of action plans, was poor. We found no significant effect of the intervention on any outcomes at 6 or 12 months. However, we did find some improvements in the intervention wards compared with the control wards for new harms (i.e. those for which the ward are directly accountable) and these differences were largest among wards that showed the greatest compliance with the intervention.

Conclusion

Despite patients being willing and able to provide feedback using the PMOS and PIRT tools and wards engaging with this feedback, we were unable to demonstrate any significant effect of this intervention on patient safety.

4. Direct engagement in preventing errors

Evidence suggests that existing initiatives to promote a patient role in improving their own safety have poor acceptability to patients, relatives and health-care staff and that they have the potential to damage the patient–professional relationship. Initiatives lack user involvement in their development, a theoretical underpinning and evidence of effect. This study reports the development and piloting of an intervention that is fully user informed, grounded in relevant theory and supported by best evidence and practice.

Methods
Systematic development over three phases, guided by the Medical Research Council (MRC) framework, involving users at every stage: (i) evidence collation: scoping of evidence, theory and best practice and elicitation of user experiences; (ii) intervention development: iterative, interactive workshops with users; and (iii) evaluation study: controlled, pre–post exploratory trial using mixed methods to assess feasibility and the impact on user motivation and behaviour and on medication reconciliation at admission and discharge.

Results
Phases 1 and 2 identified the need for a supported, collaborative approach. Four components for ThinkSAFE emerged: a patient safety video; a patient-held health-care logbook incorporating tools to facilitate information sharing; a theory and evidence-based educational session for staff; and Talk Time, a dedicated opportunity for users to interact. Evaluation showed no influence on behaviour but all users were highly motivated to engage with ThinkSAFE. Admission prescriptions on intervention wards showed fewer instances of pharmacist intervention.

Conclusions
ThinkSAFE is a multifaceted intervention that is extensively user informed and robustly developed. Its generic approach to promoting and supporting collaborative interactions between health-care staff and service users provides flexibility for local adaptation without compromising this underlying rationale. Preliminary evaluation suggests that ThinkSAFE is an acceptable and feasible, low-risk intervention approach that has the potential for improving patient safety.

5. Education and training

Patient safety training provides a health professional's perspective rather than the patient's. Personal narratives of health-related error or harm allow patients to share their stories with health professionals and help influence clinical behaviour by rousing emotions and improving attitudes to safety. This study measured the impact of patient narratives used to train junior doctors.

Methods
This study was a RCT of 313 Foundation Year 1 trainees. The intervention consisted of patient narratives followed by discussion relevant to the narratives as well as generic safety issues. The control arm received conventional faculty-delivered teaching. The Attitude to Patient Safety Questionnaire (APSQ) and the Positive and Negative Affect Schedule were used to measure the impact of the intervention. Learning points suggested by trainees were used to measure differences in learning outputs between the two groups.

Results
In total, 142 trainees received the intervention and 141 the control. There was no evidence of a difference in APSQ scores between the groups. There was a statistically significant difference in the underlying distribution of both positive affect and negative affect scores between the two randomised groups ($p < 0.001$), with an indication of both higher positive and higher negative affect scores in the intervention group. Analysis of the learning points revealed five overarching themes: risk management and governance; learning about error; communication; processes related to patient safety; and role of education.

Conclusions
We were unable to demonstrate that the intervention was any more effective than standard teaching in changing general attitudes to patient safety. However, the intervention did impact on emotional engagement and learning about communication.

Overall conclusions

This research programme has developed a number of novel interventions to engage patients in preventing PSIs and protecting them against unintended harm. It has provided a focus and foundation for developing major new movements for applied research and improvement in patient safety both regionally and nationally. The programme found patients to be willing to codesign, coproduce and participate in initiatives to prevent PSIs and the approaches used to be feasible and acceptable. These factors together with recent calls to strengthen the patient voice in health care would suggest that the tools and interventions from this programme would benefit from further development and evaluation.

Trial registration

This trial is registered as ISRCTN07689702.

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Editorial contact: nihredit@southampton.ac.uk

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