

Wristbands as aids to reduce misidentification: an ethnographically guided task analysis

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Abstract

Objectives. Wristbands are recommended in the UK as a means of verifying patient identity but have been little studied. We aimed to document how wristbands are used in practice.

Design and participants. Task analysis of wristband application and use, drawing on qualitative analysis of workplace observation of, and interviews with, clinical and non-clinical staff.

Setting. Two acute district general hospitals in northern England.

Results. Our findings indicate high levels of awareness amongst clinical staff of local and national policies on wristband use, but some ambiguity about the details therein. In contrast, non-clinical staff such as ward clerks and porters were less aware of policy, although their actions also expose patients to risks resulting from misidentification. Of seven subtasks identified by the task analysis of wristband application and use, three appeared to offer particular opportunity for error. Making the decision to apply, especially in emergency patients, is important because delay in application can delay correct identification. Advance preparation of wristbands for elective admission without the patient being present can risk erroneous data or misapplication. Lastly, utilization of wristbands to verify patient identity was greater in some clinical circumstances (blood transfusion and medication administration) than in others (before transferring patients around the hospital and during handovers of care).

Conclusions. Wristbands for patient identification are not being used to their full potential. Attention to detail in application and use, especially during handover and transfer, and an appreciation of the role played by ‘non-clinical’ staff, may offer further gains in patient safety.

Keywords: patient safety, patient identification, wrist bands

Introduction

Modern hospitals are complex organizations characterized by high technology, production pressure and a range of safety-critical activities. Hospitals not only generate hazards but also present difficult managerial problems in terms of performance and control [1–3]. Patients invariably interface with healthcare organizations at the point at which they are vulnerable. Managers need to attempt to ensure that the systems that they put in place are sufficiently robust as to provide patients with the best chance of recovery [2–6]. They are also required to ensure that their actions do not create conditions in which those working at the ‘sharp end’ of the

system are forced into situations where the prevailing conditions can ‘encourage’ them to make mistakes. The move towards ‘evidence-based medicine’ [7, 8] means that new solutions should ideally be well evaluated or at the very least, supported by research.

It is against this background that patient safety has emerged as an important issue for practice [9–13]. Research outside health care provided different perspectives on the processes surrounding failure and the symbiotic relationships that can be seen to exist between failures on the part of individuals and the wider organizational and environmental contexts in which those errors occurred. The result of this has been a shift towards a systems

perspective on failure—where there is a recognition that it is the interaction between elements of the system that can give rise to failure, rather than simply being seen as a function of the actions of individuals [12, 14–19]. Wider factors influencing events at the system level include, but are not limited to, issues relating to design, communication and information transfer (at handover), culture, latent and active errors, management style and training [15, 17–28]. Further, following a number of high profile ‘adverse events’ [29–33], with their substantial human and financial cost, the issue of patient safety has emerged as a problem for healthcare policy-makers in several countries and across the range of medical disciplines and activities [9–12, 28, 34–36].

One area that remains key to the management of adverse events is the process of checking wristbands at the bedside. This can be seen as an important process in the interaction between the patient and healthcare staff, as it not only has the potential to give rise to errors further down the chain of events, but can also act as a point where previous errors can be detected and put right. Wristbands are a frequently used method of identifying patients. Common hospital policy in the UK is to ask the patient to wear a wristband carrying details of his/her name and other information to confirm his/her identity. However, this is not completely effective in eliminating misidentification. Wristbands can only work if the patient consents to wearing one, if information is accurately entered onto them initially, and crucially if healthcare providers use wristbands in their checking processes. Mismatching errors can still occur if patients do not wear a wristband or if the wristband does not carry reliable and unique identifiers. Given that there is specific guidance on the use of wristbands for healthcare staff, we set out to explore why wristbands are not used to their full safety potential.

The purpose of this study was to assess how the process of bedside checking and, in particular, the verification of identity using wristband information, are built into routines of healthcare work at the ‘sharp end’ and how these relate to formal guidelines and procedures issued at managerial level to govern these activities. The paper is based on an ethnographic study of the processes around bedside checking and the use of wristband-based information as a means of ensuring patient safety on wards. (The empirical data for the project were collected within the approved frameworks set out by both the NHS and University research ethics frameworks. Full approvals for the study were obtained and those staff who were interviewed as part of the research signed consent forms.)

Methodology

The research used two streams of analysis, a task analysis to explore the functional aspects of the checking process and an ethnographic part (observation and interview) aimed at eliciting staff perceptions and other contextual factors

influencing the process. The task analysis provided a means of allowing participants to identify the main elements of their work-related tasks and to do so in a structured manner. This was enhanced firstly by direct observations of staff on the ward, paying particular attention to the manner in which they interacted with patients and their use of wristband information, and secondly by in-depth interviews with staff, focused particularly on their perceptions of the likely ways bedside checking acts, or fails to act, as a system defence.

The ethnographic element of the research not only provided basic data for incorporation in the task analysis, but also enabled a more subtle understanding of how practitioners understand safety-related aspects of patient identification. Ethnography is, typically, considered as small-scale social research that is carried out in everyday settings, using a range of methods to focus on the meanings of individuals’ actions and explanations rather than their quantification [37]. The aim is to build up a picture of the phenomena under study which ‘makes sense’ [38, 39] to participants but which also allows, along with other qualitative approaches, for the inductive development of more general theories [40]. Thus, it is suitable for situations which are less amenable to quantification and where discrepancies between ‘official’ discourse and informal practice may be in play.

Task analysis

In broad terms, task analysis is a functional approach to knowledge elicitation, which involves breaking down a problem into a hierarchy of tasks that must be performed [41, 42]. Thus, it offers a methodology for examining the actions or cognitive processes involved in a given work activity [43]. It has been used in the healthcare context to map errors in the process of giving general anaesthesia [27], in an intensive care unit [44] and in the analysis of clinical pathways [45]. This begins with a general task goal (for example, ‘apply wristband’) and breaks this down into the subtasks and operations that must be performed in order to achieve the main goal. It includes the definition of the objectives of the task, the procedures used and any actions and objects used. The end result is a hierarchy of task steps that represent the behaviours that must be executed in the performance of a task.

In our study, we planned to use such a hierarchical task analysis [46], and also to employ, as an analytical framework, a modification of the systematic human error reduction and prediction approach (SHERPA) [27]. Specifically, we excluded attempts to estimate probability of occurrence of a particular error, or its criticality. Estimates of probability can be quite problematic [27], and with respect to criticality, we believe that an error in any of the subtasks could easily result in a critical event, whose severity is likely to depend not on the subtask but on the clinical context in which the error takes place. This facilitates the identification of errors that could occur, and of the points during the task at which they might occur. We aimed to break down (decompose) relevant clinical

activities into their constituent subtasks and operations [41, 43] as shown in Box 1.

Box 1 Generic steps in tasks analysis

- Break down the primary task into a number of subtasks—usually between four and eight. These subtasks will be specified in terms of their objectives.
- Map out the subtasks into a layered diagram to ensure that the whole task is accounted for.
- Decide on the level of detail for decomposition (task flow diagrams to be used as necessary.)
- Continue decomposition process to produce a written account as the diagram is constructed. Note redundant checks and errors committed earlier in the process of care, which only become evident at this point.
- Present the analysis to someone who has not been involved in it but is familiar with the task, to check consistency and validity.

Intelligence gathering. Background material to support the task analysis was collected from a literature review as well as the observations and interviews. The literature identified was drawn from a variety of published sources. An assessment of published peer reviewed journal articles was supplemented with both ‘grey literature’ along with material published in official policies and guidance. The aim of this review was both to capture and gain an understanding of the processes around the use of wristbands as a defensive element in patient safety and to ground this in a broader assessment of ward-based errors in general, as well as an understanding of existing ‘good practice’ for risk minimization on the ward.

Observation. This phase of the research involved the direct observation of wristband use in a clinical context. Members of staff gave their written consent to be observed. Members of the research team spent time with different groups of staff within a single trust with an aim of observing their day-to-day work. These were purposively chosen to represent a variety of clinical areas and grades of staff. Extensive field notes were taken of these observations. Initial observations (1–5) were designed to understand the background routines of nursing work on hospital wards over a period of time. Not only did this enable us to set subsequent work in context, it also allowed the nursing staff under observation to become accustomed to the presence of the researcher(s). During this period we observed the activities of nurses, ward clerks and other staff, handovers between shifts, visiting time and how safety in general, and identity checking in particular, are enacted in practice.

The second aspect to the observation strategy was to follow what might be called the ‘patient journey’. One session followed a patient from admission through the accident and emergency department, whilst others followed patients for elective surgery from admission, through the pre-operative period. We also focused specifically on transfers

and handovers of care by shadowing hospital porters. The third group of observations focused on more specific issues in context, namely the application and use of wristbands and how identity was established and checked throughout the patient’s hospital stay.

Interviews. The interviews were conducted using a semi-structured format and were tape-recorded and later transcribed. In addition, the research team held one focus group interview in order to explore the issues relating to bedside checking. The interviews typically lasted between 30 and 60 min.

The analysis of interview and observational transcripts proceeded by two means. Firstly, we analysed the data using largely descriptive methods in an attempt to identify whether existing practice was derived from any published standard. Following this, we tried to delineate both current controls and barriers in the system and highlight any variance from standard practice. Secondly, we also adopted an ethnographic approach to the analysis of the transcript data [47], drawing on inductive techniques to allow further themes to emerge from the data themselves, rather than being specifically sought to confirm or refute a predetermined hypothesis [48]. By bringing data from different sources together, the process of triangulation allowed us to test the validity of our data, whilst analysis of relevant documents provided a complementary version of organizational safety for comparison.

The ethnographic work had a further purpose. As task analysis is not intended to capture the underlying knowledge structure directly, it must be complemented by more in-depth elicitation of perceptions and influencing factors. As well as providing data for the task analysis, the more subtle intelligence gathering about real-life practice by interview and observation allowed the documentation of contextual aspects relevant to a fuller understanding.

Table 1 List of interviewees

Respondent
Ward manager, critical care
Chief pharmacy technician
Operating theatre sister
Clinical risk manager
Staff nurse, radiology department
Sister, acute medical ward
Nurse transfusion co-ordinator and student nurse
Ward manager, medicine for the elderly
Senior nurse
Patient
Ward clerk
Nursing staff, accident and emergency (staff nurse and sister)
Nursing staff, admissions lounge
Day care surgery, sister
Focus group, surgical assessment unit

Table 2 Summary of observation data

Observation number	Location/focus	Duration (h)
1	High dependency unit (am)	1.5
2	Surgical ward	1.5
3	High dependency unit (pm)	1.5
4	Oncology	1.5
5	Oncology	1.5
6	Oncology day-case unit (shadowing one nurse)	6.5
7	Day-care surgical unit	1
8	Accident and emergency	3
9	Medical admissions unit	2
10	Porters	2
11	Operating theatre porters	4
12	Medical admissions unit	3
13	Porters	3

Results

The data generated for analysis were obtained from 9 of 14 individual interviews with healthcare staff (Table 1), the findings of 1 focus group and over 20 h of direct observation of practice with healthcare staff (Table 2) in a multi-site acute hospital trust in the North West of England. From the research findings, seven subtasks were identified. These were determined to be as follows: (1) decision to apply wristband; (2) preparation of wristband; (3) inscription; (4) initial verification of patient's identity; (5) application to patient; (6) utilization; and (7) re-application if removed from patient. The full task analysis for all seven tasks is presented in Table 3; three particular subtasks are discussed in more detail here.

Subtask 1: Decision to apply wristband

Whilst it appears to be standard UK practice for all inpatients to wear a wristband, there remain two problem areas. The first is the timing of the decision to apply a wristband to patients admitted to hospital as an emergency, usually through the accident and emergency department. Our data suggest that wristbands are not usually applied to patients until the decision has been taken to admit them to a ward. Conversely, it appeared from the data that some nurses in accident and emergency would not administer controlled drugs to a patient without a wristband, so some people are given a wristband even if they are not to be kept in as inpatients. The second problem area relates to people who attend hospital repeatedly—for instance, for cancer chemotherapy—who are not technically inpatients. Not only might they spend some hours in the hospital receiving treatment, but their frequent attendance means that the nursing staff get to know them personally, reducing the perception of need for a formal verification of identity.

Subtask 2: Preparation of wristband

In many wards and units, it was common practice for wristbands to be prepared in advance of the patient's admission for elective admissions. Typically, the patient's details are entered onto the wristband by the ward clerk during the preparation of the patient's other admission documentation. It is then attached to the patient's case notes to await the arrival of the patient. It was not clear to us how much formal training in safety issues ward clerks receive and there are risks here associated with coding and transcribing errors. As a practice, however, this carries both potential benefits and potential risks. The wristband can be prepared in good time, making the appropriate cross-checks of the patient's identifiers on the hospital computer system. However, wristbands can be inadvertently swapped between case notes before the relevant patients are admitted. For this and other reasons, subtask 4, verification of identity, is vital.

Subtask 6: Utilization of wristbands

Wristbands were used much more commonly to check patient identity before some tasks were undertaken (for instance, the administration of drugs or blood) than for others. It was uncommon for staff to verify the patient's identity against their wristband when first meeting them. It was also uncommon for porters to use wristbands to identify patients when collecting them from wards to be transferred elsewhere in the hospital for investigation or procedures. Such patients are usually identified by the nurse looking after them before departure from the ward. Since nurses often know their patients, a formal identity check may not be carried out. However, it was felt that there was some potential here for the generation of errors in terms of the handover of patients.

Of the other four subtasks, step 3 (inscription) carries the risk that digits and letters may be confused by careless handwriting, and also that data pre-entered before the patient is present may not be correct. Step 4 (verification of identity) may fail if 'leading questions' are asked and the patient acquiesces even if the information is wrong. Step 5 (application) seldom presents any safety problems.

Step 7 (reapplication) is most likely to present a hazard if the wristband is simply not reapplied once it is removed or becomes illegible.

Discussion

Our task analysis has demonstrated the complexity and possible risk of error of the application and use of wristbands to confirm the identity of hospital inpatients. There is a contrast between official policy and informal usage and there is also variability in the use of wristbands across different groups of staff and different activities within hospitals. In addition, there are a number of potential hazards which do not seem to have been documented previously.

Although there is an abundant literature on patient safety, there is very little empirical work on identity checking. In

Table 3 Task analysis of wristband application and use

Task	Subtask	Potential error	Comments
1 Decision to apply wristband	1.1 Decision to apply wristband in elective patients	Some patients have no wristband applied at all	It is standard UK practice for patients to have a wristband applied [37] a. Decision to apply is usually made when decision made to admit to hospital or refer to another clinical team. However, the patient may already have been in the accident and emergency department for some time, with the attendant risk of mismatching during this period b. Many patients are admitted via assessment units. Does the position here differ? c. One possibility would be for wristbands to be applied before arrival at hospital, e.g. applied by ambulance personnel. Has theoretical appeal but may not be always easy or possible to elicit correct details in some situations There are no standards for size, material, tensile strength or robustness of fixing mechanism
	1.2 Decision to apply wristband in emergency patients	Some patients have no wristband applied at all	
2 Preparation of wristband	2.1 Take blank wristband from store		a. It is necessary to check with patient and case notes for known allergies. Not labelling creates a risk of inadvertent administration of drug to which patient is allergic b. It must also be established that these are true allergies as there is otherwise a danger of perpetuating a false 'allergy' in patient's record c. If patient has multiple allergies, should all be recorded on the wristband? If there are constraints of space, should two allergy bands be used?
	2.2 Decide if separate allergy band is necessary	a. Not labelling a patient as allergic when allergy is present b. Patients may be labelled as allergic when reaction is part of expected pharmacological profile of drug, e.g. diarrhoea with antibiotics	
3 Inscription	3.1 Prepare for writing	a. Ink washes off over time b. Similar letters and similar numbers, e.g. 5s and 8s or 4s and 9s written indistinguishably	There are no standards for type of pen or colour of ink. Also no standards for writing size (if handwritten) or font (if printed) nor capitals/lowercase. Adhesive patient 'addressograph' labels have also been used Recommended standard is first name, last name, date of birth and hospital number. Patient may have abbreviated form of name(s), nicknames or be known by a name other than that given
	3.2 Decide on which details to be entered on wristband	Incomplete data might increase risk of misidentification	

	3.3 Enter patient's details on wristband	Pre-entering data creates the risk of loss, fixing to wrong patient's notes or of being applied to wrong patient: for instance, details entered before admission to hospital by ward clerk	Entering data is best done at the bedside during the nurse's admission clerking
4 Initial verification of identity	4.1 Positive identification of patient's name and date of birth with patient	Patient responds incorrectly to leading questions such as 'Are you XX?' or 'Is your date of birth XX/XX/XX?'	Ask questions such as: 'Can you confirm your date of birth?' or 'What is your name?'. Procedure cannot be applied to patients who have learning disabilities, cannot understand English or who are unconscious. Increased risk of error in those who have very similar names to others. In these circumstances, an alternative is to check with patient's carers, parents or other responsible adult. Patient's details should be checked against computerized patient data system, and other documentation—operating list or pre-admission questionnaire completed by patient. NHS/hospital number should be verified against case notes and other documentation
	4.2 Verify other information on wristband		Useful safeguard but patient will not be familiar with his/her NHS/hospital number and cannot therefore be involved in checking that
	4.3 Show wristband to patient for approval before application		Wrist usual; can also be applied to ankle
5 Application to patient	5.1 Choose site for application		One usual for adults; two usual for neonates
6 Utilization	5.2 Choose number of bands to apply		
	6.1 Staff check wristband on first meeting patient		
	6.2 Staff check wristband at start of every nursing shift, e.g. as part of nursing handover procedure	Nurses rely on personal knowledge but mistake identity	'Getting to know patient' is a useful defence against misidentification. It is also part of professional identity of nurses to 'know patients' personally
	6.3 Staff check wristband on every occasion patient leaves a ward, goes for an investigation or procedure	Often performed when leaving for procedure. Less often undertaken when patient returns from procedure	There are closely specified procedures for surgery and other invasive investigations (usually those where specific written consent required). Most diagnostic departments, e.g. radiology have identification protocols but the role of wristband checking as part of these not formally investigated in this study. Other departments may be less assiduous in checking identity
	6.4 Staff check wristband at every point where care is handed over to another member of staff		Handovers of care often informal and relatively unstructured. This may also be true of checking patient identity

(continued)

Table 3 Continued

Task	Subtask	Potential error	Comments
	6.5 Staff check wristband before taking blood or any other specimen	Wristband not checked	This is usually well specified in local policies Phlebotomists were felt in our interviews to check more reliably than, for instance, junior doctors. Is this a training issue? Or do those who perform a limited range and number of tasks tend to do them more accurately?
	6.6 Staff check wristband before transfusing blood	Wristband not checked	There are closely specified national policies, e.g. <i>Right Patient, Right Blood</i> issued by UK NPSA (National Patient Safety Agency)
	6.7 Staff check wristband before administering drugs or intravenous fluids	Wristband not checked	We found local policies based on national guidance. However, staff did not always check wristbands if they are administering drugs to a patient they feel they know well, or to whom they have already given drugs earlier in the same shift
7 Re-application to patient	7.1 Re-production of wristband when previous one has become illegible or has been removed or dislodged	Wristband not reapplied	Wristbands must be readily available throughout the hospital, or at the very least, in the areas where they are most likely to be removed
	7.2 Re-verify patient's identity	Risk of misidentification if wristbands removed from more than one patient at a time Risk of perpetuating error if original details on wristband incorrect	This should proceed as under 4.1 and 4.2 above If old wristband still available (e.g. if removed to allow venous cannulation), old details should be checked and not simply copied onto new wristband

theory, checks represent an ‘absorption mechanism’ [49] and as such are essential components of system reliability. They are also processes and therefore should be adequately designed by eliciting their goals, inputs, outputs, resources and methods [50]. Our study represents an attempt to provide some data by which this design might be improved. We used a systematic task analysis to itemize the subtasks associated with wristband application and use and a variant of the SHERPA technique to critically analyse potential errors and the points at which they might occur. A previous survey of 712 hospitals revealed a median total wristband identification error rate of 2.2%, though in 10% of participating hospitals, error rates of 10.9% or greater were found [51]. Absent wristbands represented 49.5% of errors; multiple wristbands with different information, 8.3%; wristbands with incomplete data, 7.5%; erroneous data, 8.6%; illegible data, 5.7%; and patients wearing wristbands with another patient’s identifying information, 0.5% [50]. A more recent study of 217 institutions found an error rate of 2.57%, with missing wristbands accounting for 71.6% of the errors [52].

Compared with such numerical data, our ethnographic approach has both strengths and drawbacks. On the one hand, it offers the prospect of understanding the phenomenon under study—in this case, bedside identity checking—within its social context and of capturing how it is shaped by participants’ prior beliefs and work practices. Policies aimed at changing practitioner behaviour to improve safety are less likely to succeed if they do not take existing practices into account. On the other hand, ethnography sacrifices a large sample size for a more detailed picture of a smaller number of cases [40]. There is also the risk of bias and misinterpretation of the data, though we aimed to reduce this by ensuring our research team was made up of people with a range of backgrounds and perspectives. Finally, for convenience we sampled wards and staff in one hospital trust, albeit on two of its geographically dispersed constituent three sites.

Notwithstanding this, our findings raise a number of issues relating to the use of wristbands in particular, but which reflect more broadly on patient safety in hospital. First, wristband checks were performed inconsistently across different clinical activities, with blood transfusion, surgery and the administration of drugs generally triggering greater use of wristbands to confirm patient identity than other tasks. This appeared to go against the recommendations of a Safer Practice Notice from the UK National Patient Safety Agency (NPSA), issued some time prior to our study. Previous work has reviewed the barriers to the implementation of simple safety strategies [53]. Of particular relevance here are limits imposed by organizations to limit staff/worker discretion in their actions, the need for simplification and the need for senior leadership to sponsor safety strategies.

Second, we suggest that ‘non-clinical’ staff, such as porters and ward clerks, clearly have a greater role in maintaining safety, through ensuring correct identification of patient identity, than may have been previously realized. Whilst systems of work are set up such that errors made by such staff are usually identified and rectified by professionally trained individuals, this cannot on first principles be as safe as awareness and training amongst all staff on the importance of

verification of patient identity. The importance of such staff is underlined by a survey of hospitals where it was the policy that phlebotomists would not draw blood until wristband errors were corrected; the error rate was lower than in hospitals without such a policy [52].

Thirdly, the possible conflict between official policy and patient’s dignity should be highlighted. Wearing wristbands in itself does not seem to offend patients in the UK as it now seems a well established and usually uncontroversial practice. A paper from Switzerland, where it was not usual for hospital patients to wear wristbands, provides some additional support for this view. Over 1100 teaching hospital patients were asked firstly whether hospitals should introduce a compulsory identification bracelet and secondly whether each individual patient would wear it. Positive responses were received from 83.9 and 90.2% of patients, respectively [54]. However, nurses in our interviews took pride in the fact that they ‘knew their patients’ and were concerned that repeated checking of names and identities might affront patients’ dignity.

Recommendations for practice

After our fieldwork was completed, in July 2007, the UK NPSA issued further guidance on the standardization of wristbands [55]. The World Health Organization has recently issued a ‘Patient Safety Solutions’ notice on patient identification [56]. This provides simple advice on protocols for checking, and on education and training, and reviews the potential barriers and risks for unintended consequences.

Both authorities recommend that from admission, the patient should wear a wristband bearing identifiers such as name and hospital number. The information may be handwritten or typewritten or, in a high-technology setting, bar coded or be contained within a chip or radio tag. In some areas, an additional red wristband is applied if the patient has a history of drug allergy. Further, clinicians may rely entirely on the wristband details rather than checking notes. The NPSA has been working to ensure safer patient identification by greater compliance with wristband wearing in acute settings. It also recognizes the need for other solutions for some patient groups such as neonates, those with skin allergies and those with learning disabilities.

The information contained in such guidance should be more widely disseminated, and policies should be updated to reflect the areas of difficulty we have identified (application to emergency patients and advance preparation of wristbands for elective patients). In addition, consideration should be given to widening the ‘indications’ for the routine formal checking of identity to include the first meeting with the patient, transfers around the hospital and during clinical handover.

Finally, the role of ‘non-clinical’ staff in maintaining safety through correct identification of patients should be more widely acknowledged.

Author contribution

A.F.S. co-ordinated the study, analysed and interpreted the data and wrote the paper, J.W. collected data, helped analyse it

and write the paper. K.C. collected data, organized enrolment, helped analyse and interpret data and helped write the paper. D.F.-S. helped design the study, interpret the data and critically revised the paper. A.F.S. is guarantor. (i) The study was given a favourable ethical opinion by Cumbria and Lancashire A Research Ethics Committee (ref. 06/Q1308/74). Informed written consent was obtained from the staff studied. (ii) This work was supported by the UK Patient Safety Research Portfolio (NPSA 001). The study sponsor had no role in the design, collection, analysis or interpretation of the data or in the writing or decision to submit the paper.

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