Feasibility of confirming drugs administered during anaesthesia

A qualitative study in pilot NHS sites, England and Wales

October 2010

A collaborative project of the National Patient Safety Agency (NPSA), Royal College of Anaesthetists (RCoA) and Association of Anaesthetists of Great Britain and Ireland (AAGBI)
Appendix 1: Investigators, contributors and participants
About this report

The purpose of this report is to present the conduct and results of a qualitative study undertaken to assess the feasibility of introducing the practice of confirmation of drugs administered during anaesthesia in pilot NHS sites in England and Wales. The results of this study have also been published, as a research paper, in the British Journal of Anaesthesia. The primary audience of this report is all members of the theatre team, particularly anaesthetists, operating department practitioners (ODPs) and theatre practitioners.

Section 1 of the report explains the basis for the collaborative project called ‘Improvement through Partnership’, and the role of the Expert Consultative Group overseeing the project. We also present the reasons why drug errors in anaesthesia was chosen by the group as one of the areas of priority, and what methods of preventing these errors were considered. Finally, in this section, we present the aims of the present study.

Section 2 presents the details of the methodology used for the study, including the details of sampling, selection of pilot sites and methods of data collection, handling and analysis. Section 3 presents the results of the study. In Sections 4 and 5, the results are discussed in the context of current practices, attitudes and existing culture around drug administration in anaesthesia, and the possible implications of any proposed change in practice in terms of feasibility. Finally, the conclusions of the study are presented and recommendations made regarding the introduction of the practice of confirming drugs administered during anaesthesia in National Health Service (NHS) settings.

The report also aims to highlight practical issues related to the practice of confirming drugs administered during anaesthesia by exploring the perceived benefits, barriers and practicalities of the two different methods of drug confirmation that were studied. We believe that this information will be a valuable resource for healthcare managers, professionals and clinicians who are looking for ways to reduce drug errors and improve patient safety during anaesthesia. In particular, the report will inform the development of future strategies of introducing the practice of confirming drug administration during anaesthesia.

Executive summary

Drug errors are among the top five reported patient safety incidents occurring during anaesthesia. Confirmation of drugs with a second person at the time of preparation and administration has been recommended to help prevent drug errors outside anaesthesia practice. However, this is not routinely practised during anaesthesia in the UK or elsewhere in the world. In the present study, we aimed to assess the feasibility of introducing second-person confirmation or electronic barcode confirmation of drugs administered during anaesthesia in National Health Service (NHS) settings in the UK.

The study involved seven NHS pilot sites. Over a three-month period, five of these NHS pilot sites implemented second-person confirmation, and the remaining two sites implemented barcode electronic confirmation of drugs, given during anaesthesia. In total, 36 consultant anaesthetists and three trainees, 15 operating department practitioners (ODPs) and seven anaesthetic nurses participated. Another group of professionals (anaesthetists, ODPs and nurse practitioners), not from the participating sites, was invited to provide independent observations. Each site was also visited by one of the study investigators for observations.

The data were obtained from different sources. Four focus groups (two with participants from pilot sites and two with observers) were held at the end of the study. The discussions were taped, transcribed and qualitatively analysed. The other sources of data were the observers’ notes and the investigators’ reflective diaries. These data were used to triangulate the focus group data. The final data were coded line by line. The codes were then synthesised into themes, which were then grouped into categories and subcategories.
Confirmation of drugs administered during anaesthesia by either of the studied methods was perceived to contribute to the prevention of drug errors. Second-person confirmation was not always feasible due to lack of continued availability of a second person. This method also met with some resistance from staff at a few pilot sites. For this method to be carried out properly, there should be no distraction or time pressure. In contrast, electronic confirmation was always feasible, as it did not require the presence of a second person. The anaesthetists preferred this method as it was intuitive to their current working practice. However, some practical issues emerged, related to introduction of new technology and an initial learning curve.

Introduction of the two-person confirmation method in the NHS will require serious consideration of the implications for resources and the impact of the method on existing working practices in anaesthesia. The electronic confirmation method is more feasible, but there will still be some capital resources and the technological aspects related to its integration into the operating theatre environment will require detailed consideration.

Section 1: Introduction to the project

_Improvement through partnership_

In order to enhance clinical engagement to improve patient safety in anaesthesia, in September 2007 a two-year project was started by the National Patient Safety Agency (NPSA) in partnership with the Royal College of Anaesthetists (RCoA). Details of the project are available on the NPSA website: [www.npsa.nhs.uk/nrls/improvingpatientsafety/anaesthesia-and-surgery/anaesthesiapartnership](http://www.npsa.nhs.uk/nrls/improvingpatientsafety/anaesthesia-and-surgery/anaesthesiapartnership).

A multidisciplinary expert consultative group was set up to provide strategic direction to the project. The following three priority areas were agreed for the project:

- Developing a dedicated way for anaesthetic staff to report patient safety incidents.
- Investigating two methods of double checking anaesthetic drugs given by injection.
- Evaluating the effectiveness of direct communication through professional networks. A known patient safety issue (retained throat packs) will be used in the evaluation.

_The Expert Consultative Group_

The Expert Consultative Group comprised independent experts in the area of patient safety, and members representing the NPSA, the RCoA, the Association of Anaesthetists of Great Britain and Ireland (AAGBI), the College of Operating Department Practitioners and the Association of Perioperative Practice. On reaching a consensus on the areas of priority for the project ‘Improvement through Partnership’, the group considered, in detail, the anaesthesia related patient safety incidents reported to NPSA and what was achievable within the time-frame of the study. It was important that the selected areas of priority and the objectives were deliverable and visible in order to consolidate a longer-term partnership among the representative national organisations and for wider engagement with clinicians.

_Drug errors in anaesthesia_

Drug errors are among the patient safety incidents most frequently reported to NPSA. The reported incidence in the literature varies widely, ranging from 1:131 to 1:5,475 anaesthetics, and these errors remain a cause of serious harm to the patients. The wide
range of reported incidents should be viewed in the context of the well-known under-reporting of adverse events, and the large variations that exist worldwide in the practice of collecting and analysing reports. Also, the wide range of the reported incidents can be perceived as being due to a lack of consensus regarding the magnitude of the problem. However, the Expert Consultative Group was in clear agreement that any preventable harm to the patient during anaesthesia, no matter how minor or how infrequent, is unacceptable.

The group reviewed the NPSA patient safety incident data, which showed that the majority of the reported incidents occurred during ‘administration’ of the drugs. Further analysis of the incidents suggested that these could have been prevented by a ‘double-checking’ measure. However, double checking, or more appropriately confirming the drugs, during anaesthesia is not routine practice in the UK or elsewhere in the world. Also the practice of anaesthesia is unique in the sense that usually the drugs are prescribed, prepared and given by the same individual in a relatively short period of time, and often under pressing circumstances. Therefore, introducing methods of confirming the drugs during anaesthesia, in particular methods that are based on experiences outside anaesthesia practice, may not be all that straightforward.

**Methods of confirming drugs during anaesthesia**

Ideally, all intravenous drug administration should be checked by two qualified practitioners – this is the recommendation in the White Paper *Building a safer NHS for patients*. This recommendation is supported by many studies in the literature, which suggest that practice of double checking can reduce many drug errors. Jensen and colleagues reviewed drug errors during anaesthesia and the strategies that could have prevented these. They concluded that double checking could have prevented 58% of the errors reviewed, making it the most effective single measure in their review.

Despite many calls for confirming the drugs administered during anaesthesia, very little information is available on the methods that have been used to do this, and been evaluated, in the past. The expert group identified two methods that had the potential for use in anaesthetic practice. These were two-person verbal confirmation and electronic confirmation using barcode technology.

The two-person verbal confirmation of drugs has been strongly recommended by Toft, who has extensively studied and reported on drug errors in NHS practice, in particular, those related to administration of vincristine and heparin. Toft has recommended use of an ‘explicit appropriately configured verbal double checking protocol’, in which the expectation is that if one person misses an error the other will detect it. If done correctly, the protocol would reduce drug preparation and administration errors. We could not find any example of use of this kind of protocol in the literature related to anaesthetic practice. Because of the lack of experience in the use of similar protocols in anaesthesia, and this protocol’s potential in preventing many errors, the group decided to develop and evaluate the feasibility of introducing a protocol of second-person double confirmation of drugs administered during anaesthesia.

Merry and colleagues developed an integrated drug administration and automated anaesthesia record system. This electronic system was designed with the aim of reducing the opportunity for error in drug administration and record keeping. The system can be mounted on existing anaesthesia machines, and connected serially to the electronic output of most monitoring devices currently in use. The system produces a real-time output of anaesthetic record. All the events during anaesthesia (e.g. intravenous cannulation, tracheal intubation), including drug administration, can be automatically uploaded and recorded in the system by using barcoded labels. With regards to drug administration, each time the barcoded syringe is scanned, the system produces an auditory and a visual response, which confirms the name and the dose of the drug, and subsequently enters it into the anaesthetic record. Therefore, the confirmation of drug administration using this system is ‘rapid,
accurate and not subject to human suggestibility’. Although the system has been in use in some hospitals in New Zealand, its use in the UK has not been described so far. Because of its potential in reducing drug errors, the group agreed on evaluating the feasibility of using this technology-based system in NHS settings.

**Aims of the project**

We aimed to perform a qualitative study to explore the feasibility of introducing a practice of confirmation of drugs given during anaesthesia, using two different methods, that is second-person confirmation or electronic confirmation, in seven NHS pilot sites within England and Wales over a three-month period during 2008.

**Section 2: Methodology of the feasibility study**

It was decided to use qualitative methodology that included convenience sampling driven by a purpose and multiple sources of data collection.

**Pilot sites and participants**

The patient safety meetings organised by the RCoA provided an opportunity to advertise for volunteers willing to participate in the study. From among those who volunteered, pragmatic and purposive sampling was used to select anaesthetists from different NHS hospitals; these pilot sites were geographically spread across England and Wales, and represented a range of secondary and tertiary referral centres. In total, anaesthetists from seven NHS trusts were selected. Of these seven sites, two were selected for evaluation of the technology-based system (integrated drug administration and automated anaesthesia record system utilising barcode technology). The other five sites evaluated the use of the two-person confirmation protocol.

The study was approved by a multi-domain ethics committee and local NHS research governance at all sites. The lead participant at each site identified other anaesthetists at the site who were also willing to participate. Prior to taking part in the study, a letter of invitation was sent to each participant along with an information sheet and a consent form. The participants included 36 consultant anaesthetists, three trainee anaesthetists, 15 operating department practitioners (ODPs) and 7 anaesthetic nurses.

**Second-person confirmation**

The NPSA’s Human Factors Team designed a flowchart (flowchart 1; Figure 1) with the aim of standardising the process of confirming the drug to be drawn up into the syringe. This flowchart was used at all the seven participating sites. A second flowchart showing the standardised process of drug administration (flowchart 2; Figure 2) was designed for use at the five sites that were selected for second-person confirmation. The use of flowchart 1 during drawing up of anaesthetic drugs, and flowchart 2 during administration, was integrated into clinical practice at the participating sites for a period of three months.
Figure 1: Flowchart for use during drug preparation.

Double-checking process for drug preparation
Repeat for each drug

ANAESTHETIST

START
1.1 Select drug ampoule and show to 2nd checker

LISTEN

1.3 If as intended, draw into syringe

NO

Diluted drug?

YES

1.4a Select diluent and show to 2nd checker

LISTEN

1.4c If as expected, dilute drug

1.5 Select syringe label (if diluted, record dilution on label). Apply to syringe and show to 2nd checker

LISTEN

1.7 If as expected place in tray

END
1.8 Record and sign by anaesthetist and 2nd checker that double-check has been completed for all drugs

SECOND PERSON CHECKER
(Registered Practitioner)

1.2 Read aloud
drug name, dose and expiry date from ampoule

OBSERVE

1.4b Read aloud
diluent name, dose and expiry date from ampoule

OBSERVE

1.6 Read drug aloud
dosage and dilution) from syringe label

OBSERVE
Figure 2: Flowchart for use during drug administration.

Electronic barcode confirmation

The system designed specifically for use within anaesthesia by Merry and colleagues with the aims of reducing drug errors and maintaining automated electronic records was installed in the two sites selected for evaluation of the electronic confirmation method. The participants used flowchart 1 (see Figure 1) for drawing up the drugs, and the electronic system for confirming the drugs at the time of administration. A specific label was placed on the syringe after drawing up of the drug. This label contained a barcode that identified the drug in the syringe. A computer-assisted barcode reader was used to ‘confirm’ drugs prior to administration. The use of flowchart 1 during drawing up of the anaesthetic drugs and the electronic barcoding system during administration was integrated into clinical practice at the participating sites for a period of three months.

Independent observers

Four anaesthetists, four theatre nurses and three ODPs, all from NHS hospital trusts not identified as pilot sites for the study, were invited to be independent observers of the study. Hence, the observers had no first-hand experience of either of the two methods that were evaluated. The names of the observers were suggested by the RCoA, the College of Operating Department Practitioners and the Association for Perioperative Practice.

The observers were randomly allocated to the pilot sites to observe the two-person confirmation and the electronic barcode confirmation. During the study period of three
months, each observer visited two pilot sites, and observed both the methods of drug confirmation during anaesthesia.

In addition to the independent observers, two members of the study team also visited all the pilot sites during the study period to monitor the conduct of the study and to allow comparisons and internal validity checks on the collected data.

**Data collection**

Data were collected from several sources.

**Reflective diaries**

The participants were asked to keep reflective diaries (Figure 3) during the study period. The diaries were provided by the study team at the induction visit, and were therefore standard across all sites. The diaries were meant to be completed after every surgical session for the first two to three weeks of the study. Each entry had five components that prompted the participants to reflect on the setting, drug preparation, time, feasibility and other areas of their experience with the assigned methodology. The prompts within the diary were only meant to serve as a guide, and were by no means prescriptive.

**Figure 3:** The reflective diary used in the study

<table>
<thead>
<tr>
<th>Reflective diary</th>
<th>Date: __________ Time: __________</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description of today’s list</strong></td>
<td></td>
</tr>
<tr>
<td>Number of patients on list __________</td>
<td>Start and end time of list __________</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td></td>
</tr>
<tr>
<td>➢ Type of theatre – including type and length of surgery, number of patients per list/day</td>
<td></td>
</tr>
<tr>
<td>➢ Brief description of anaesthetic room – including drug storage, working space</td>
<td></td>
</tr>
<tr>
<td><strong>Drug preparation</strong></td>
<td></td>
</tr>
<tr>
<td>➢ When were the drugs prepared – in advance for the whole pathway or just induction phase?</td>
<td></td>
</tr>
<tr>
<td>➢ Were any drugs prepared for the next patient?</td>
<td></td>
</tr>
<tr>
<td><strong>Time</strong></td>
<td></td>
</tr>
<tr>
<td>➢ Did the double check cause any delay in giving drugs? How and why?</td>
<td></td>
</tr>
<tr>
<td>➢ Which part of the anaesthetic was delayed – induction, maintenance or reversal?</td>
<td></td>
</tr>
<tr>
<td>➢ Were there any delays to the list due to the double-checking procedure?</td>
<td></td>
</tr>
<tr>
<td>➢ If yes, could they have been avoided with an amendment to the double-checking procedure?</td>
<td></td>
</tr>
<tr>
<td><strong>Feasibility</strong></td>
<td></td>
</tr>
<tr>
<td>➢ Were there any problems in using the double-checking procedure? Please describe.</td>
<td></td>
</tr>
<tr>
<td>➢ What parts of the double-checking protocol did you find most difficult to adhere to?</td>
<td></td>
</tr>
<tr>
<td>➢ Was a member of staff available to carry out the double check? If not, describe what happened.</td>
<td></td>
</tr>
<tr>
<td>➢ Feedback and criticisms by staff – all grades</td>
<td></td>
</tr>
<tr>
<td>➢ Potential impact on patient? Is the double checking effective in preventing errors or near misses? Can you think of any error or near miss you have experienced or witnessed where the double-checking protocol could have prevented it from occurring?</td>
<td></td>
</tr>
<tr>
<td>➢ If there were any emergencies, did you manage to use the double check?</td>
<td></td>
</tr>
<tr>
<td><strong>Other comments</strong></td>
<td></td>
</tr>
</tbody>
</table>

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Observers’ notes

To promote consistency, all observers were given instructions and a schedule by the investigators (Table 1). They were also asked to transcribe their notes immediately after the observation.

Table 1: Instructions given to observers.

<table>
<thead>
<tr>
<th>Key themes</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>Brief description of anaesthetic room Include drug storage, working space</td>
</tr>
<tr>
<td>Staff and teams</td>
<td>Is the team well established? Do they know each other? Work regularly together? Consider the skill mix – who is apparently ‘in charge’? Does being ‘in charge’ vary by clinical activity?</td>
</tr>
<tr>
<td>Leadership</td>
<td>Role of ODP Level of autonomy</td>
</tr>
<tr>
<td>Drug preparation</td>
<td>Document as much detail as possible Record all verbal and non-verbal exchanges</td>
</tr>
<tr>
<td>When are drugs prepared?</td>
<td>In advance for the whole pathway or just for the induction phase? Are any drugs prepared for the next patient?</td>
</tr>
<tr>
<td>Double checking</td>
<td>How easy is it to use? Describe any problems</td>
</tr>
<tr>
<td>The protocol</td>
<td>Do staff adhere to the protocol (follow the flowchart)? If not, which steps are difficult to follow and why?</td>
</tr>
<tr>
<td>Labelling syringes</td>
<td>When and how?</td>
</tr>
<tr>
<td>Second checker</td>
<td>Which staff are used?</td>
</tr>
<tr>
<td>Bolus or infusions</td>
<td>Record how drugs are administered Certain syringes for certain drugs? Labels placed differently, depending on the drug? Drugs kept apart in theatre? If so, which drugs are separated?</td>
</tr>
<tr>
<td>Anaesthetist’s own system to prevent drug error</td>
<td></td>
</tr>
<tr>
<td>Drug administration</td>
<td>Are drugs double checked? Do staff adhere to the protocol (follow the flowcharts)? Any problems with double checking before administration?</td>
</tr>
<tr>
<td>Second checker</td>
<td>Which staff are used?</td>
</tr>
<tr>
<td>Key themes</td>
<td>Observations</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Movement</strong></td>
<td></td>
</tr>
<tr>
<td>Impact on double checking</td>
<td>Document movement of un-scrubbed team in and out of theatre/anaesthetic room. What is the purpose of movement? If not clear make a note of this.</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td></td>
</tr>
<tr>
<td>Double checking</td>
<td>Is double checking discussed beforehand?</td>
</tr>
<tr>
<td></td>
<td>How is the checker assigned?</td>
</tr>
<tr>
<td></td>
<td>How is it discussed?</td>
</tr>
<tr>
<td>Task orientated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are instructions/information specific?</td>
</tr>
<tr>
<td></td>
<td>Is communication addressed to a specific person?</td>
</tr>
<tr>
<td></td>
<td>Is it timely?</td>
</tr>
<tr>
<td></td>
<td>Are instructions/information acknowledged?</td>
</tr>
<tr>
<td>Non-task communication</td>
<td>Record when non-task communication takes place</td>
</tr>
<tr>
<td>Non-verbal communication</td>
<td>Record when non-verbal communication takes place</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td></td>
</tr>
<tr>
<td>Impact on drug administration</td>
<td>Noise or activity that might be a distraction to staff administering drugs</td>
</tr>
<tr>
<td><strong>Time</strong></td>
<td></td>
</tr>
<tr>
<td>Does the double check/workstation cause any delay in giving drugs?</td>
<td>How and why?</td>
</tr>
<tr>
<td>Which part of the anaesthesia is delayed?</td>
<td>Induction, maintenance or reversal?</td>
</tr>
<tr>
<td>Is the list delayed?</td>
<td></td>
</tr>
<tr>
<td><strong>Feasibility of use</strong></td>
<td></td>
</tr>
<tr>
<td>Are staff available to carry out the double check/use the workstation?</td>
<td>If not, describe what happens</td>
</tr>
<tr>
<td>Criticisms by staff</td>
<td>All grades</td>
</tr>
<tr>
<td>Impact on patient</td>
<td></td>
</tr>
<tr>
<td>If there are any emergencies, how is the double check followed?</td>
<td></td>
</tr>
</tbody>
</table>

**Focus groups**

At the end of the three-month study period, the participants and the observers were invited to attend focus groups. Two of the focus groups were attended by the participants and these were held within two weeks of the end of the study. The other two focus groups were attended by the observers and were held within two weeks of the end of the observations. The composition of the focus groups is shown in Table 2.
Table 2: Details of the focus groups

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Occupation</th>
<th>Method of confirmation observed or used</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focus group 1: observers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Consultant anaesthetist</td>
<td>Both</td>
</tr>
<tr>
<td>2</td>
<td>ODP</td>
<td>Both</td>
</tr>
<tr>
<td>3</td>
<td>Nurse</td>
<td>Both</td>
</tr>
<tr>
<td><strong>Focus group 2: observers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Nurse</td>
<td>Both</td>
</tr>
<tr>
<td>2</td>
<td>Consultant Anaesthetist</td>
<td>Both</td>
</tr>
<tr>
<td>3</td>
<td>Consultant Anaesthetist</td>
<td>Both</td>
</tr>
<tr>
<td><strong>Focus group 3: participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>ODP</td>
<td>Electronic</td>
</tr>
<tr>
<td>2</td>
<td>Consultant Anaesthetist</td>
<td>Two person</td>
</tr>
<tr>
<td>3</td>
<td>Consultant Anaesthetist</td>
<td>Two person</td>
</tr>
<tr>
<td>4</td>
<td>Nurse</td>
<td>Two person</td>
</tr>
<tr>
<td>5</td>
<td>Consultant Anaesthetist</td>
<td>Electronic</td>
</tr>
<tr>
<td>6</td>
<td>ODP</td>
<td>Two person</td>
</tr>
<tr>
<td>7</td>
<td>ODP</td>
<td>Two person</td>
</tr>
<tr>
<td><strong>Focus group 4: participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Consultant Anaesthetist</td>
<td>Two person</td>
</tr>
<tr>
<td>2</td>
<td>Nurse</td>
<td>Two person</td>
</tr>
<tr>
<td>3</td>
<td>Consultant Anaesthetist</td>
<td>Electronic</td>
</tr>
<tr>
<td>4</td>
<td>Nurse</td>
<td>Electronic</td>
</tr>
</tbody>
</table>

All the participants and observers who took part in the focus groups were assured of anonymity and confidentiality, and informed written consent was obtained. Two of the investigators were present in all the focus groups, one of whom moderated the groups and the other took notes. In order to maintain consistency in focus groups, we utilised the SWOT format to focus on the strengths, weaknesses, opportunities and threats of the two methods of confirming drug administration. Pre-defined open-ended questions and prompts were used across all focus groups, and a digital recorder was used to continuously record all discussions. The recordings were then transcribed by one of the researchers within seven to 10 days of completing each focus group. Subsequently, the finished transcripts were checked against the recordings by an independent researcher for accuracy and integrity; further comments, if any, were added at this stage.

**Data handling**

The data from the three sources were handled in the following manner: the reflective diaries were used to check outliers, if any, emerging from the observers’ notes. Outlying themes were also explored in the focus groups to build a comprehensive picture of the issues. In this way, by corroborating data from different sources, we aimed to provide triangulation, check outliers and enhance validity. In addition, one of the investigators also maintained a research diary – this was used as a ‘memo’ during analysis.
Data analysis

In this qualitative study, the data were used as guide to generate detailed descriptions and categories,\(^2\), which, in turn, explained the phenomenon under investigation.\(^3\) The main thrust of data analysis was to determine meaning and understanding, and not counting to events or prove hypotheses. Also the processes of analyses were iterative rather than sequential.\(^2\)

The methodology of line-by-line coding of the transcripts has been described by Charmaz.\(^2\),\(^5\),\(^6\) Using this method, one of the researchers (RE) read the transcripts twice and then coded the data. From the codes, concepts were developed, which were then condensed into themes and categories within and across the transcripts.\(^2\) Then a second researcher (RM) independently read through the transcripts and coded them as described above. Both the investigators then met, went through the codes, and concurred or revised the thematic categories.

At the beginning of analysis, the line-by-line coding generated over 150 codes. The codes were then synthesised and focused into two main categories, which could be subdivided into three subcategories. In addition, one extra category on a wider cultural issue was also identified. Memos were written to define each thematic category – this ensured consistency between the two researchers who analysed the data, and also allowed the researchers to elaborate on a category, specify its properties, define any relationships between the categories, and identify gaps in the data collected.\(^2\)

During the process of analysis, the transcripts were repeatedly read to compare categories, and to look for ‘negative’ or contradictory themes. This allowed the investigators to further explore such themes during the study period through collecting additional purposive data, so that a point of data saturation could be reached where no new themes could be seen to be emerging.

Section 3: Results of the feasibility study

The analysis, and focused categorisation of the emerging themes from the data, led to two main categories which were the same as the methods undertaken for evaluation. These were second-person confirmation and the electronic barcoding system. Based on the data, the themes in each of these categories could be subcategorised in terms of: benefits, disadvantages and practical issues. In addition, several emerging themes were categorised as perception of drug errors and wider cultural issues related to patient safety. Hence, the data were finally categorised as follows:

1. Second-person confirmation
   a. benefits;
   b. disadvantages;
   c. practical issues.

2. Electronic barcoding system
   a. benefits;
   b. disadvantages;
   c. practical issues.

Second-person confirmation

Benefits

Very importantly, the participants, in their experience, concurred with the opinion that second-person confirmation can potentially enhance patient safety. However, for it to be effective, the process of confirmation has to be carried out properly without distraction. In addition, time has to be allocated for it to be carried out properly. The participants felt that introduction of second-person confirmation had increased awareness of drug errors and other safety issues both among them and in their departments.

The following quotes emphasise the stated benefits of second-person confirmation.

‘As a concept I have no doubt that it is a robust [system] and if rigorously applied fairly fail-safe method of getting the right drug into the right syringe’ (Anaesthetist 1).

‘Providing it is done properly, it’s ensuring what is in the syringe and the label match so it does confirm the content of the syringe’ (Anaesthetist 4).

‘If it was adhered to rigidly and you were allowed the time taken to do it properly then it was just a matter of two minds confirming to each other the chosen drug is the one intended’ (Nurse 2).

‘I think it has heightened awareness among users, they felt they were much more aware and spending time just checking ampoules, expiry dates’ (Anaesthetist Observer 1).

‘The double-checking project has raised awareness and is being used for other procedures’ (Nurse Observer 3).

‘You don’t need any expensive electronic equipment; all we need are the two people’ (Anaesthetist 2).

Disadvantages

The participants highlighted several disadvantages of the process of second-person confirmation. It was often abandoned during an emergency when the drugs were required urgently – presumably, this is also the time when the risk of administration of the wrong drug or the risk of misadministration may increase.

One of the strong themes that emerged was that to wait for somebody to be available to confirm the drug was not intuitive in anaesthetic practice, or even in the best interests of the patient. Indeed it had often frustrated the anaesthetists and impacted on the working pattern of some of the participants, and in practice, they started to modify the protocol. They started to check more than one drug at a time, or sometimes administered inhalational agents instead of intravenous drugs when no one was available to confirm. Many participants felt that the process was perceived to delay the running of the theatre lists, and in order to avoid this, they had started to modify the confirmation flowcharts, which reduced the drug confirmation protocol to a mere lip service.

The following quotes emphasise the disadvantages of the second person confirmation.
‘In an emergency situation it goes straight out of the window, to be honest’ (ODP 2).

‘errors happen when the system is stressed, whatever the system is, and if there’s an emergency that’s when you want a system that can work and because the system is ignored when the emergency was happening it makes it worthless in a lot of ways’ (Anaesthetist Observer 4).

‘I think the thing to do in an emergency is not to compromise the double checking but to call for more help’ (Anaesthetist Observer 2).

‘I was giving my drugs when my ODA was there rather than when I wanted to give the drugs’ (Anaesthetist 5).

‘I found it really didn’t work when you are giving a drug in the middle of an operation, maybe a repeat dose of muscle relaxant and the ODP was not around’ (Anaesthetist 2).

‘I felt that additional propofol was indicated in a patient but the perceived hassle of double checking was a disincentive and the patient was bagged with an inhalation agent’ (Anaesthetist Observer 2).

‘If someone’s busy reading out what’s on the label, you’re busy getting an ampoule out and likewise your nurse is not watching, you drawing it up into a syringe, you could be drawing something else up’ (Anaesthetist 5).

‘My experience of the process was not just that it was time consuming, but that it also became menial and frustrating, and in any process like that I try to make it as efficient as possible. I found I was speeding up the process, so instead of checking one drug to its completion and finishing that, I would be checking more than one drug at once’ (Anaesthetist 1).

Practical issues

In the implementation of the second-person confirmation, the main practical difficulty, as per the participants’ experience, was continued availability of a second person. This was a common problem across all pilot sites. In addition, as indicated by independent observers, in some instances, ODPs drew up the drugs for induction of anaesthesia in order to minimise the time between cases in theatre lists. In these instances the availability of a second person was a major issue.

In addition, the varied attitude to second-person confirmation among the teams at the different pilot sites affected the uptake of the confirmation protocol. In general nurses and ODPs did not see it to be obstructive to their clinical practice. However, on some occasions the second-person check was perceived as nuisance and was not carried out. There was variation among the participants regarding their perception on whether or not the double-confirmation of drugs delayed the running of theatre lists. Also, some participants expressed reluctance to perform confirmation in front of the patient.

The following quotes highlight the practical issues surrounding the use of the second-person confirmation system.

‘Some members of staff were refusing to be involved’ (Anaesthetist Observer 4).
‘within the same patient there were other people checking the drugs as the procedure went on, so they started off with the ODP and they would latch onto whoever they could find’ (Anaesthetist Observer 4).

‘As a nurse it is routine, we always double check whatever we are giving’ (Nurse 1).

‘If the sequence of events starts at the non-anaesthetic end it is easier to do the double checking’ (Anaesthetist Observer 2).

‘this [double check] was perceived as a nuisance and an imposition on the ODP’ (Anaesthetist Observer 1).

‘I don’t think double checking takes that long to do it properly …. I would just like the patient to not be there, for us to say we are ready now to focus on the patient’ (Anaesthetist 4).

‘The patient hadn’t arrived and it was easier to concentrate and double check without the patient’ (Nurse 1).

‘It’s resources and time; if that allotment arrives … then it could be made to work’ (Anaesthetist 1).

‘I think there is a misconception about the time it adds on, because how often do we go into theatre and we are waiting for the surgeon’ (Anaesthetist 4).

‘If you can double check (blood) in a bleeding aneurysm, why can’t you double check drugs in other situations?’ (Anaesthetist Observer 4).

**Electronic barcoding system**

**Benefits**

Overall, the participants liked this system. It was found to be user-friendly and effective in confirming the drug administration. The main benefit was that it did not require presence of second person and therefore the confirmation of drug administration was almost always feasible. This was seen to enhance patient safety.

The automated electronic record that the technology-based system produced was seen to provide additional benefits, such as enhancing patient safety further due to the ability to view the anaesthetic record in advance in areas such as the recovery unit. Also the quality and accuracy of the anaesthetic record produced by the system was seen by the participants and the observers as an important safety feature and great incentive to use the system. The electronic system was seen to allow the participants more time to concentrate on the patient.

The following quotes highlight the benefits of the electronic barcoding confirmation system.

“unblinking, untiring eye” on the drug, you never need to find someone else to do it [double check’. (Anaesthetist 3).

‘if your ODP’s disappeared you don’t need to have to keep calling them back to check the drugs” (ODP 2).

‘Obviously the electronic [system] would make it easier in theatre during the case because you didn’t have to have your second person, you’d have your machine with you’ (ODP 3).
‘The scanning system was simple and effective to use and a good clear tool, both audibly and visually’ (Nurse Observer 1).

‘the nurses had looked at the chart and they had the whole picture of what had happened with that patient before they had even entered there and I thought that was really good and if I was in recovery I would love that’ (Nurse Observer 2).

‘There was a more complete record of the patient journey through theatre’ (Nurse Observer 1).

‘I can see if you were scanning prior to administration it will reduce the potential for giving the wrong drug undoubtedly’ (Anaesthetist 4).

‘You could go through various individual safety features that you use, different labels, different syringes, different trays, but the ultimate one has to be barcoding’ (Anaesthetist Observer 2).

‘The ability for the consultant to keep track of what has happened when they are away from theatre; I think that is a great incentive…’ (Anaesthetist Observer 2).

‘the bait of good record keeping is an important key to changing the culture’ (Anaesthetist Observer 2).

‘It’s an accurate record of what’s going on and it’s my record’ (Anaesthetist 4).

‘More time to spend concentrating on the patient rather than head down in the notes’ (Study Team Observer 1).

Disadvantages

The observers and participants noted that the electronic barcoding system could become a distraction at the beginning of the learning curve. Also, they considered the permissive design of the system to be a disadvantage. The fact that the drugs could be given without having to swipe them through the barcode reader, or multiple drugs could be scanned prior to administration, defeated the purpose of confirmation. It was felt that this could be overcome by locating the scanner close to the intravenous drug administration port.

The following quotes highlight the disadvantages of the electronic barcoding confirmation system.

‘Initially using the system … you’re concentrating more on the system than on you patient’ (Anaesthetist 4).

‘so much attention was being paid to getting the electronic record started and that people were focusing more on that than on the patient’ (Anaesthetist Observer 4).

‘There is potential for the system to be a distraction from other matters of patient/anaesthetic care’ (Anaesthetist Observer 1).

‘the system is permissive in that it allows you to do anything you like; some people might view this as a weakness in that it doesn’t prohibit you from doing the wrong thing’(Anaesthetist 3).
‘If you had barcoded a drug that said cyanide for example, it would say cyanide and you could carry on’ (Anaesthetist 3).

‘The main concern was that if there was an [medical] alert and the anaesthetist wanted to scan penicillin, it would still allow him to do it’ (Nurse Observer 2).

‘There are ways round the system, because you can scan all the drugs for induction and have them sitting on the side, so there’s still a potential for picking up the wrong syringe’ (Anaesthetist 4).

‘The accuracy of the resulting documentation is totally dependent on the syringe being scanned and the dose that has been administered being entered correctly by hand. There is still room for user error’ (ODP Observer 1).

**Practical issues**

The system was installed in the anaesthetic room and the theatre. Having to move patients from anaesthetic room to the theatre created some practical problems. The system in the anaesthetic room was ‘parked’ prior to moving the patient, once in the operating theatre the second system was initiated and the patient data retrieved. This step of retrieving data had the potential to retrieve records of some other patient.

In addition, there were some other initial teething problems. These were related to the physical placement of the system, some drugs not being in the database of the system, and hospital monitoring devices and IT facilities having to integrate with the system. These issues started to resolve as the participants became more familiar with the system.

The following quotes highlight the practical issues surrounding the use of the electronic barcoding confirmation system.

‘Another theatre can retrieve your anaesthetic record if they are moving their patient from the anaesthetic room to the theatre at the same time as you and they chose the wrong patient’ (Consultant Anaesthetist, Study Team Observer 1).

‘Occasionally we’ll lose data from the monitoring that’s going into the servers and it will just stop collecting data’ (Anaesthetist 4).

‘Sometimes the scanning of the drugs are a bit tricky if there’s a crease in the label … it just takes a few attempts of the scanning so that can be a bit time consuming’ (Nurse 1).

‘In this pressured situation, the scanner would not accept the drug; however, the consultant anaesthetist did persist and it was accepted. This took an additional 15 seconds’ (Nurse Observer 3).

‘The drug was not on the drop down menu and the system wouldn’t allow the anaesthetist to input the name manually, anaesthetist unable to enter the drug into the anaesthetic record’ (Study Team Observer 1).

‘The arm holding the system is sited on the wrong side of the anaesthetic machine, this would have been better sited away from the patient, as too crowded near the patient’ Consultant Anaesthetist (Study Team Observer 1).
‘One of the issues that I saw was the remoteness of the scanner from the cannula, if it was right by the cannula then you are likely to scan it, but if it’s a few feet away you may scan it, you might put it [syringe] down and pick up something else’ (Anaesthetist Observer 4).

**Perception of drug errors and wider cultural issues**

Many participants and observers agreed that drug errors happened in clinical practice and there was perception that anaesthesia is safe, drugs errors are rare and not of much significance, and most of the times one could ‘get out of trouble’. This was the view of all professional groups, not just confined to the anaesthetists. There was a feeling that drug errors, when they occur, are ‘sanitised’.

It was highlighted that, in the current climate, theatre efficiency took priority, making it difficult to introduce new initiatives that may be perceived to slow down the running of the lists. Among the professionals, nurses thought that confirming drug administration was a good idea. However, ODPs had mixed views. One ODP commented that, at the beginning, anaesthetists and ODPs reacted differently to second-person confirmation; anaesthetists ‘didn’t want to do it’ whereas the ODPs did ‘a lot of this anyway’.

Among the participants, the views on the practice of second-person confirmation ranged from ‘it must be done’ to ‘complete waste of time’. One of the participants felt that second-person confirmation made them feel as if their capability was being questioned. Those who used the electronic system were in favour of using it, and, in general, the anaesthetists preferred the electronic system as it did not break the ‘rhythm of the work’.

It was a clearly emerging theme that introduction of confirmation of drug administration during anaesthesia would require cultural change in thinking and practice. In order to facilitate it, it will be important to raise awareness regarding drug errors among anaesthetists, ODPs and nurses, and prove that confirmation of drug administration reduces it. Of the two methods, the electronic system was more likely to be adopted because it made fewer demands on the change in current anaesthetic practice.

The following quotes emphasise the different attitudes among the professionals regarding confirmation of drug administration.

‘We’re all used to double checking anyway. As a nurse it’s routine, we always double check what ever we are giving’

‘It’s not really an issue to double check’

‘I feel that double checking of drugs should always take place’

‘What are you bothering doing that for? It’s just a waste of time’

‘Are you questioning my capability?’

‘Just another hassle for us to take on board’

‘There is just one pointless initiative after another – it can distort clinical priorities’

‘Does everybody have to make a mistake before being convinced?’
‘Double checking is known to work, so why can’t we have a directive to say this is the way it should be done?’

‘All of a sudden the responsibility for the preparation and administration of drugs becomes shared between two people’

‘We are in a culture where theatre efficiency is the be all and end all, I think to the detriment of patient safety’

‘Sanitising error, because that’s what we do, we sanitise it and accept it and it really doesn’t matter, it happens but it really doesn’t matter, and we’re all guilty of that and it’s overcoming that’

‘How do you change a culture though, I’m really not sure, you’d have to prove I think that there really is a reduction in error in some way’

Section 4: Comments and discussion

Key results

The main results of this study are listed below.

- Both the methods that were studied, that is, the two-person and electronic confirmation, were perceived by the participants to have potential to improve patient safety by minimising drug errors during anaesthesia.

- Regarding the second-person confirmation method:
  - it relied on the availability of the second person at all the times of drug administration – this was recognised as a major barrier to its feasibility;
  - it was perceived to be time-consuming and prone to human manipulations;
  - it had potential to alter anaesthetic practice and the choice of anaesthetic – some anaesthetists started to modify their technique to suit the practice of availability of the second person;
  - its implementation met with some resistance from the staff.

- Regarding the electronic confirmation method:
  - being independent of the presence of the second person, it was always available for use;
  - it was found to be reliable and easy to use;
  - it was a preferred option by the anaesthetists as it was perceived to fit in with their current practice;
  - it required a period of training for the staff;
  - it required installation of new technology in the anaesthetic room and operating theatre environment, and some initial teething problems had to be overcome.

- Attitudes to drug errors are highly variable among professionals. Some of these could be potential barriers to implementing practice of confirming drug administration. These include:
  - perception among some professionals that drug errors were not a big problem;
  - perception that confirming drug preparation and administration will hamper theatre efficiency;
feeling that the practice, particularly that of second-person confirmation, can be de-professionalising for anaesthetists.

Results in the context of preventing drug errors

Evidence-based medicine is the cornerstone for implementing changes in modern healthcare systems. Traditionally, randomised controlled trials have been considered to provide the highest strength of evidence. However, this approach has limitations in the area of patient safety. Randomised controlled trials in this area, particularly with blinding and hard end points quantifying actual harm to patients, are usually not feasible. This is because the outcomes of interest (that is, adverse events), although catastrophic and unacceptable in the clinical context, are usually rare in the context of research. The overall mortality rate related to anaesthesia is probably about 1 in 50,000 in the developed world. To show a 50 per cent reduction in this rate would require a randomised controlled trial of over four million anaesthetics (with a power of 80 per cent and p = 0.05). A study this large is simply not feasible. It is therefore not surprising that attempts to demonstrate objectively and definitively the benefits of many safety measures through randomised controlled trials have not been successful.

Owing to the limitations of traditional research methodology, much of the evidence of drug errors during anaesthesia comes from incident reporting. Also, recommendations regarding the methods to prevent these drug errors are based on retrospective reviews and opinion. Among the reported incidents during anaesthesia, drug errors are one of the top five themes. Among the recommended methods of preventing these errors, double checking of drugs, although common and routinely done elsewhere in healthcare, is not practised routinely during anaesthesia. Our study was not designed to quantify the drug errors during anaesthesia or to evaluate whether confirming drugs would reduce their incidence. Rather, we aimed to evaluate the feasibility of implementing currently available methods of confirming drug administration in healthcare in the particular situation of during anaesthesia. In this context, it is important that many of our participants felt that confirmation of drugs administered during anaesthesia, if performed correctly, would prevent errors.

Feasibility of confirming drug administration during anaesthesia

In the present study, we evaluated the feasibility of two methods – second-person confirmation and electronic barcode confirmation.

It is recognised that verbal double checking does not always prevent drug errors. This may be because during the process, when two people are responsible for the same task, they both rely on the other to be rigorous, resulting in neither giving the task their full attention. The process of involuntary automaticity has also been described as reducing the real value of the double-checking process. Involuntary automaticity relates to repeated use of identical checking procedures unintentionally leading to a ritualistic chant of the checklist items with the risk of ‘the literal meaning of the message being ignored’.

In the present study, the protocols and flowcharts for two-person confirmation were developed by the experts in human factors. These ensured active engagement of the second person in the process. However, our participants found these protocols difficult to adhere to because the presence of a second person could not always be guaranteed. This was particularly so in emergencies and when there was a perceived shortage of time. Circumstances were described in which one participant tried to speed up the process by simultaneously confirming more than one drug at once, which defeated the whole purpose of
drug confirmation. Some anaesthetists also showed reluctance in using second-person confirmation, which could have been due to the cultural change that it required. Hence our study highlights the resource (time and personnel) and culture implications of introducing second-person confirmation during anaesthesia, which would need to be addressed for successful implementation of this method.

With regards to the electronic confirmation method, the system that we used draws anaesthetists’ attention through audible and visual information articulated when the syringe is passed over the barcode reader immediately prior to administering the drug. This provides a ‘computerised check’, which is prompt, definitive and not prone to human susceptibility. Among the two sites that used this methodology, the electronic system was accepted into clinical practice readily at one site and after a few organisational teething problems at the other. The participants saw the electronic anaesthetic record as one of the driving incentives in its adoption. We also found that training and education of all members of staff in the use and purpose of the system was of paramount importance in its adoption. However, overall the electronic system appeared to be more feasible and less challenging culturally than the two-person confirmation method. It is recognised, however, that there would also be some capital costs associated with the introduction of this system.

Using the electronic system the anaesthetist can scan multiple drugs at the same time. This, in a strict sense, bypasses confirmation at the time of administration, and thus is one of the perceived disadvantages of this system. The risk of this happening could be reduced by locating the scanner close to the intravenous port.

Successful implementation of electronic confirmation of drug administration will require addressing the many logistical issues that were raised in this study. These issues include integration with existing technologies and IT in operating theatres, possibility of technological failure and use of space utilisation. The introduction of any new technology can occasionally introduce unforeseen hazards that then appear over a period of time. Therefore, a further, detailed expert technical hazard assessment exercise will need to be conducted before the introduction of such a system in the NHS environment.

**Cultural issues**

Our study has shown that the perception of significance of drug errors varies among anaesthetists, and this may affect their attitude towards use of measures to prevent them. In particular, in our study, there was some reluctance among participants who were allocated to the second-person confirmation method.

For a safety measure to be successful acceptance by the professionals is essential. This can be achieved by a deep understanding of the cultural issues, active engagement of the professionals and taking into consideration any resource issues that may have a positive or negative impact on the implementation. Our study did not aim to explore in depth the cultural issues and attitudes of anaesthetists and other professional groups towards drug errors and the methods of preventing them. Further studies are required to explore these issues to help understand how best to address the barriers that can prevent universal adoption of methods to prevent drug errors.
Section 5: Conclusions and recommendations

From the results of present study we have drawn the following conclusions:

- Both second-person confirmation and electronic barcode confirmation are perceived to be effective methods in preventing drug errors during anaesthesia.
- The electronic confirmation method, on the other hand, is more feasible as it does not rely on the presence of a second person at the time of drug administration.
- It may be adopted more readily by the anaesthetists as it is more aligned with their current working practice.
- When considering the electronic barcode confirmation method, technological aspects related to its integration into the operating theatre environment will require careful attention.
- The introduction of the second-person drug confirmation in anaesthesia practice, can, at times, be difficult to achieve due to resource issues such as availability of adequate staff and time allocation.
- The process of second-person confirmation can be prone to human manipulation. Also, it can alter the behaviour and practice of anaesthetists, and some anaesthetists may be reluctant to adopt it.

Based on the above, we make the following recommendations:

- Anaesthetists, and other professional groups, should give serious consideration to implementing methods of confirming the drugs administered during anaesthesia.
- When second-person confirmation is considered as the method for implementation, adequate resources in terms of time and personnel should be ensured.
- The second-person confirmation method should only be considered after active engagement with clinicians regarding its impact on existing working practices of the anaesthetists and resolution of anxieties, if any.
- Implementation of either of the methods should be accompanied by adequate training of the staff.
- Implementation of confirming drug administration during anaesthesia should be accompanied by a constant drive to improve the patient safety culture in the operating theatres. This includes education in methods to improve patient safety, training in human factors and team working, reporting and learning from incidents and participation in safety improvement initiatives.
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