Proficiency-based progression intern training to reduce critical blood sampling errors including ‘wrong blood in tube’

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Abstract

Background: Blood sampling errors including ‘wrong blood in tube’ (WBIT) may have adverse effects on clinical outcomes. WBIT errors occur when the blood sample in the tube is not that of the patient identified on the label. This study aims to determine the effect of proficiency-based progression (PBP) training in phlebotomy on the rate of blood sampling errors (including WBIT).

Methods: A non-randomised controlled trial compared the blood sampling error rate of 43 historical controls who had not undergone PBP training in 2016 to 44 PBP trained interventional groups in 2017. In 2018, the PBP training programme was implemented and the blood sampling error rate of 46 interns was compared to the 43 historical controls in 2016. Data analysis was performed using logistic regression analysis adjusting for sample timing.

Results: In 2016, 43 interns had a total blood sample error rate of 2.4%, compared to 44 interns in 2017, who had error rate of 1.2% (adjusted OR=0.50, 95% CI 0.36-0.70; <0.01). In 2018, 46 interns had an error rate of 1.9% (adjusted OR=0.89, 95% CI 0.65-1.21; p=0.46) when compared to the 2016 historical controls. There were three WBITs in 2016, three WBITs in 2017 and five WBITs in 2018.

Conclusions: The study demonstrates that PBP training in phlebotomy has the potential to reduce blood sampling errors.

Keywords

Simulation, Practical Procedures, Phlebotomy, Patient Misidentification, Wrong Blood In Tube (WBIT),
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Introduction

Errors during sampling, labelling and transport to the laboratory (pre-analytical errors) are a common problem in the laboratory and account for up to 70% of all laboratory mistakes\(^3\). Frequent errors occurring in the pre-analytical phase include: i) identification errors, ii) errors in request procedures, iii) over- or under-filling of the specimen tube, iv) empty or missing tubes, v) contradictory demographic information on the tube and the request, (vi) ‘wrong blood in tube’ (WBIT)\(^2\). The most serious error, WBIT errors, occur when the blood is taken from the wrong patient but labelled with the intended patient’s details (mis-collected) or blood is taken from the intended patient and labelled with the wrong patient’s details (mislabeled samples)\(^1\). Guidelines exist on the correct practice of phlebotomy\(^4\)-\(^7\). An observational study in 12 European countries demonstrated that compliance with phlebotomy procedures was low, with patient identification and tube labelling being the most critical steps requiring immediate action\(^8\).

Factors contributing to WBIT include incorrect patient registration\(^9\) and wrist band errors\(^9\), labelling remote from the patient\(^10\) failure to use positive patient identification\(^9\) and human errors. Human errors include slips, lapses, taking short cuts, distractions and omissions of essential steps. These ‘human factors’ are widely recognised and have been highlighted by SHOT and the National Hemovigilance office in Ireland\(^11-12\). Human factors are exacerbated by environmental issues such as fatigue, multitasking, short staffing and long shifts\(^13\).

The Testing the Utility of Collecting Blood Electronically (TUBE)\(^14-18\) found a lower incidence of WBIT in electronically labelled samples than manually labelled samples (1:3046 compared to 1:14,606, respectively). Furthermore, the sample rejection rate for samples deviating from labelling policy was 1:67 samples, with 1:26 of mislabelled samples being possible WBIT events, therefore justifying policies which do not use mislabelled samples for analysis or cross match. The benefit of electronically labelling samples has similarly been identified in other studies\(^15\).

At our university hospital, the laboratory has been monitoring and recording details of the occurrence of WBIT and other sampling errors that result in the rejection of WBIT since 2010. Newly qualified doctors (interns) were frequently unaware of the hospital’s standard operating procedures relating to ordering of blood samples from the laboratory through the electronic ordering system iSoft Clinical Manager System (iCM), and did not appreciate the critical importance of correct labelling of blood specimen bottles and laboratory forms. Much of this information was delivered either in a short induction lecture to the interns, learned in an apprenticeship style from their peers or self-taught. Efforts to reduce mislabelling errors have included educational sessions with the haemovigilance officer, educational leaflets at orientation, a zero tolerance policy for transfusion samples and educational campaigns to inform staff. These time consuming efforts, mitigate a peak in mislabelling experienced every July, but fail to reduce the ‘baseline rate’ of sampling errors. Since the introduction of an online request clinical management system (iCM) in the hospital identification errors have increased despite intensive standard training. This is a major concern. Video recordings of doctors performing phlebotomy identified practices with the potential to lead to incorrect labelling of blood specimens\(^16\) including printing labels before collecting blood and not labelling at the patient bedside. It is likely that since the introduction of the iCM system that doctors were not label at the bedside if under time pressure and labelled the tube only when they reach the label printer, therefore increasing the potential for a WBIT event.

Training and medical education can reduce the occurrence of pre-analytical errors including WBIT\(^3,17-19\) but is not sufficient to eradicate WBIT. This study proposes proficiency-based progression (PBP) simulation training as a solution to reduce pre-analytical errors including WBIT. PBP is an approach demonstrated to be more effective than traditional training models in procedural skills\(^20-22\). The study aims to compare the blood sampling error rate of interns who commenced work in Cork University Hospital (CUH) in July 2016 and did not receive PBP training in phlebotomy (historical controls), to PBP trained interventional groups who commenced work in July 2017 (intervention group 2017) and July 2018 (intervention group 2018) over three months.

Methods

Study design

This non-randomised controlled trial involved two phases, the first to develop the PBP training programme and the second to determine the effectiveness of the PBP programme to reduce blood sampling errors, primarily WBIT.

Phase 1: proficiency-based progression training programme development\(^23\). To design a new training programme, phlebotomy procedure metrics were characterised, guided by the methodological design outlined by Gallagher et al.\(^23\). We identified and defined 11 phases of the phlebotomy procedure. These 11 phases had 77-steps (metrics) for safe phlebotomy performance. The procedure characterisation focused on the correct procedure performance, patient safety and on identifying critical steps to avoid errors, including pre-analytical phase blood
specimen errors and WBIT. These phases and metrics were then presented to a multidisciplinary Delphi panel of procedure experts, who unanimously concurred that they represented a comprehensive, quantifiable depiction of the procedure. Following the Delphi panel, the metrics demonstrated construct validity (mean inter-rater reliability 0.91). An expert panel established the proficiency benchmark at a minimum observation of 69 steps, with no critical errors and no more than 13 errors in total. A list of the 11 phases and the defined critical errors are illustrated in Table 1. Table 2 lists the key metrics which mitigate WBIT.

**Phase 2: controlled trial.** The second phase of the study aimed to determine if this bespoke PBP training programme could reduce the blood sampling and labelling error rate, including WBIT. The PBP training programme was delivered to the incoming interns in July 2017 and in 2018. The blood sampling error rate was monitored over three months, and compared to interns commencing work in July 2016 (historical controls). The study examined blood samples in the haematology department, including full blood counts and coagulation profiles. WBIT events are usually identified in these sample types when there is a large discrepancy with previous results.

Qualitative analysis took place during mentorship of the interns while performing clinical duties to investigate which factors were contributing to blood sampling errors and to inform the training programme for the next phase of the study in July 2018.

**Setting and participants**
The study took place in a university teaching hospital with 800 beds. Participants were interns who commenced work in July of each year for a three-month rotation, recruited at induction training in the hospital.

**Control group.** The control group was comprised of 45 interns who were commencing work for the first-time following graduation in July 2016. The control group data had been collected prospectively as part of routine clinical practice. This group had received traditional phlebotomy training as medical students in their third medical year on two occasions and once in the

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**Table 1.** 11 phases of the validated phlebotomy metric and the 13 critical errors.

<table>
<thead>
<tr>
<th>Phase number</th>
<th>Procedure phase</th>
<th>Step Number</th>
<th>Critical Errors within phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Introduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>If Crossmatch Required</td>
<td>5</td>
<td>Completes all shaded areas of the blood transfusion form</td>
</tr>
<tr>
<td>III</td>
<td>Goes to room where equipment is kept</td>
<td>9</td>
<td>Places closed (but not locked) sharps bin on tray</td>
</tr>
<tr>
<td>IV</td>
<td>Goes to patient</td>
<td>19</td>
<td>Checks name, patient identification number on identification wristband against the written instructions (or against group and hold/crossmatch form if applicable)</td>
</tr>
<tr>
<td>V</td>
<td>Ergonomics of procedure</td>
<td>24</td>
<td>Asks the patient if there is any particularly suitable vein and if one of their arms is unsuitable for venipuncture (ensures that none of the following are present: thrombophlebitis, lymphoedema, PICC line, renal fistula or a running IV infusion /TPN/ blood transfusion)</td>
</tr>
<tr>
<td>VI</td>
<td>Prepares equipment</td>
<td>31 39</td>
<td>Positions procedures tray with sharps bin within arms’ reach Puts on gloves (gloves are snug fitting with no overhang and are intact)</td>
</tr>
<tr>
<td>VII</td>
<td>Takes blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VIII</td>
<td>Gets ready to remove needle</td>
<td>50 51</td>
<td>Release tourniquet while last blood tube is filling before removing needle from arm Once all blood tubes collected – disconnects last blood tube before removing needle</td>
</tr>
<tr>
<td>IX</td>
<td>Fixes patient up after procedure and labelling of blood tube</td>
<td>60 61</td>
<td>Writes down patient’s name and date of birth or patient identification number onto the blood tubes using a pen before leaving bedside If mobile patient label printer is available at bedside, prints label and checks it* against the wristband.</td>
</tr>
<tr>
<td>X</td>
<td>Computer</td>
<td>72 73</td>
<td>Prints off patient's labels for blood tubes after blood collection Checks name and date of birth/ patient identification number on labels against patient's details written on the blood tubes if applicable.</td>
</tr>
<tr>
<td>XI</td>
<td>Tidies up and sends bloods off</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*At the time of the study mobile label printers were not available for interns performing bloods in the hospital. They were only used by phlebotomists.
The intern in July 2017 and July 2018: proficiency-based progression training programme in phlebotomy

The interns who were commencing work in July 2017 first completed an online training module, comprising of a video of the correct process of performing bloods in the hospital. In the second component, the interns attended face-to-face training. This consisted of a short motivational introductory talk from a consultant haematologist and a laboratory scientist to outline the importance of following the correct procedure and the consequences of errors. The interns worked in groups of three, with one person acting as a patient, a second person marking according to the metric, and a third person taking bloods. A tutor was assigned to each team. Tutors included experts in phlebotomy in the hospital and comprised of phlebotomists, nurses with expertise in IV cannula education, senior lecturers from UCC experienced in providing teaching in phlebotomy skills and doctors who had participated in the metric development. A one hour session was provided before the teaching to ensure the teaching was standardised. Each person had to perform phlebotomy on model IV arms on a simulated ward to the proficiency standard of performing at least 69 steps with no more than 13 errors occurring and no critical errors allowed, to graduate from the course. The third phase of training occurred once the interns had commenced work. The interns were observed performing phlebotomy on patients on the wards to ensure they continued to achieve the proficiency benchmark in real time. The eLearning module and the simulation training on the training ward was completed before work commenced in the hospital. However, mentorship on the wards was completed in the first month following commencement of work in the hospital while data collection was ongoing. The eLearning module was made available on [www.hseland.ie](http://www.hseland.ie).

All 124 interns were trained in July 2018 and due to work in the hospital during the 2018/2019 rotation, which led to the 2018 group having fewer tutors available; the intern-to-tutor ratio was therefore much higher than in the 2017 intervention group. The ratio changed from three students per tutor in 2017 to 6–12

### Table 2. Key Metrics To Mitigate Wrong Blood in Tube.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Instruction</td>
<td>1</td>
<td>Confirms patient's name and patient ID number or patient's name and date of birth</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>If given verbal instruction repeats back to health care practitioner including patient name, patient ID number location and types of bloods to be done</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Writes down instructions including patients name, patient ID number, location and types of bloods to be done and brings written instruction to bedside</td>
</tr>
<tr>
<td>II If group and hold or cross match needed</td>
<td>4</td>
<td>Complete form using handwriting not patient label</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Completes all shaded areas of form</td>
</tr>
<tr>
<td>IV Goes to patient</td>
<td>20</td>
<td>Ask patient's name and date of birth with patient if compis mentis or with nurse if in doubt</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>Checks name, patient ID number on ID wristband against the written instructions (or against group and hold/ crossmatch form if applicable)</td>
</tr>
<tr>
<td>IX Fixes patient up after procedure and labeling of blood tube</td>
<td>60</td>
<td>Writes down patients name and date of birth or patient ID number onto the blood tubes using a pen before leaving the bedside</td>
</tr>
<tr>
<td></td>
<td>61</td>
<td>If mobile patient label printer available at bedside prints and checks against wristband (see steps for computer below)</td>
</tr>
<tr>
<td></td>
<td>62</td>
<td>In case of a group and hold OR cross match sample, completes all patients details by handwriting on the tube before leaving the patient</td>
</tr>
<tr>
<td>X Computer</td>
<td>72</td>
<td>Prints off patients labels for blood tubes after blood collection</td>
</tr>
<tr>
<td></td>
<td>73</td>
<td>Checks name and date of birth/ patient ID number on labels against patient's details written on blood tubes if applicable</td>
</tr>
</tbody>
</table>
students per tutor for some sessions in 2018. Additionally, in 2018, each intern was provided with feedback on any error that occurred in the transfusion or haematology laboratory at the end of each month.

Quantitative and qualitative data collection and analysis. Cognos was used to interrogate the laboratory information system, APEX, for pre-analytical phase blood specimen errors and WBIT. Blood samples were collected on the general wards and the emergency department but did not include outpatient samples. Of note in 2016 interns took only 6% of the bloods on the wards in the three month period analysed. The electronic ordering software ICM system records the person who prints the label placed on the tube after taking the test. A search on the ICM system provided a list of each blood test collected in the three-month period, including the healthcare practitioner who collected the test and the patient identifier number, to link to the rejected samples in APEX. By matching the searches, this provided a list of the persons who obtained the rejected samples and a list of how many blood tests were taken by the interns over three months. Descriptive statistics were performed on the type and rate of errors. WBIT was the primary outcome. Secondary outcomes were all sampling errors (including WBIT). These included over- or under-filling of the tube, clotted samples, haemolysed samples, incorrect tube type received, no specimen received, and miscellaneous errors. Logistic regression analysis was used to examine the association between the odds for rejects in the 2016 control group to the intervention groups in 2017 and 2018 using Statistical Programme for Social Sciences (SPSS V24, IBM Corporation, 2016). To adjust for potential confounding factors, the month of the test and whether the test was taken on call or during normal working hours were included in the analysis. In a post-hoc analysis, we examined the potential clustering effect by intern in the logistic regression models. A p-value <0.05 was considered significant.

A process evaluation took place during mentorship on the wards. Field notes were recorded by the investigator immediately after observing the intern collecting blood on the wards, observing ease of access to equipment, the patient, the computer, the label printer, and any interruptions which occurred. Steps of the phlebotomy metric which required assistance or that were omitted were recorded. A standard form was developed to record the field notes. A semi-structured interview was performed at the end of training comprising of two open ended questions (See Table 3). The responses were recorded by taking notes and transcribed in excel. The notes were reviewed using a theoretical domain analysis framework by two reviewers. The results of this qualitative analysis were used to inform changes to the training programme in 2018.

Results. The baseline characteristics of the 2017 pilot study and 2018 follow-on study groups are provided in Table 4. Descriptive statistics are not available for the 2016 control group as they were not working in the hospital at the time the study started. Figure 1 provides a flow chart to illustrate the recruitment of interns and the analysis of blood tests which they collected during the trial. The mean number of blood tests performed by the interns in each year is described in Table 5.

There appeared to be an increase in the primary outcome, WBIT, (although the numbers detected are very small) from 0.7 per 1,000 in 2016 (three WBITs) and 0.66 per 1,000 in 2017.

<table>
<thead>
<tr>
<th>Table 3. Topic guide for intern interviews on the wards.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topic guide for semi-structured interview at end of mentorship on the wards</strong></td>
</tr>
<tr>
<td>1. What has been your experience of phlebotomy in Cork University Hospital so far?</td>
</tr>
<tr>
<td>2. Can you give feedback on the training and any obstacles or challenges since commencing work?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 4. Baseline characteristics 2017 pilot study and 2018 follow-on study groups. *Data was not collected on historical controls but 20 of the 43 who collected bloods were male.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristics</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Median age years (interquartile range)</strong></td>
</tr>
<tr>
<td><strong>Male</strong></td>
</tr>
<tr>
<td><strong>Right-handed</strong></td>
</tr>
<tr>
<td><strong>Vision corrected</strong></td>
</tr>
<tr>
<td><strong>First language English</strong></td>
</tr>
<tr>
<td><strong>First post working as doctor</strong></td>
</tr>
</tbody>
</table>
(three WBITs), increasing to 1.3 per 1,000 in 2018 (five WBITs). The absolute numbers make an interpretation of trends difficult. Each of the instances of WBIT was identified by the laboratory, but one of the WBITs in 2018 was identified when the doctor rang the laboratory to self-report that they had mislabeled the tube. It is possible that this type of event would have been undetected in 2016, unless there was a discrepancy with previous results available in the laboratory.

There were 4,016 blood tests collected by interns in the control group who did not receive PBP phlebotomy training from July 11th, 2016, to September 10th, 2016; 96 (2.4%) of the blood samples were rejected. For the same period in 2017, 4,560 tests were taken by PBP-trained interns and 55 (1.2%) of the blood samples were rejected. In 2018, 3,724 tests were taken by PBP-trained interns and 72 (1.9%) were rejected. Table 6 describes the breakdown of errors that occurred.

Logistic regression analysis (Table 7) suggested that there was a reduction in the odds of test rejection in the 2017 pilot study when interns underwent PBP phlebotomy training, in comparison to the 2016 control group, and this difference was statistically significant (adjusted OR=0.50, 95% CI 0.36-0.70, p<0.001). The results for 2018 showed a 11% reduction in the odds of a blood sample being rejected in the PBP trained group in comparison to 2016 control group, but this was not statistically significant (adjusted OR=0.89, 95% CI 0.65-1.21, p=0.46).

During mentorship on the wards, interns were observed performing blood sampling in their usual clinical environment. Dialogue between the mentor and the interns was structured as a series of open questions during PBP training/mentorship. Of the 45 interns who attend for PBP training on the wards, observations were recorded for 40 interns. Analysis using a theoretical domain framework revealed four themes:

- **Environmental context and resources:** Written instructions given to the interns on the ward were noted to be poor with only one patient identifier provided. Time delays were

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**Table 5.** Mean number of blood tests collected by interns.

<table>
<thead>
<tr>
<th>Year</th>
<th>Average Number of blood test collected (min-max)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>91 (10-228)</td>
<td>50</td>
</tr>
<tr>
<td>2017</td>
<td>101 (2-262)</td>
<td>52</td>
</tr>
<tr>
<td>2018</td>
<td>95 (26-224)</td>
<td>44</td>
</tr>
</tbody>
</table>
commonly caused by label printers not working (seven cases) and unavailability of computers (eight cases). Essential equipment such as Azowipes®, tourniquets or blood tubes, were frequently missing (21 cases). Interns reported occasional instances of phlebotomy in patients who were not wearing an ID band.

Emotion: Nursing staff support on the wards contributed to calm and safe phlebotomy performance, while there were frequent interruptions by bleeps and time constraints contributed to stress, and multiple technical errors. Several interns expressed nervousness while somebody was watching them perform phlebotomy.

Knowledge: Interns had an average of 5.8 errors. They required prompting to ensure the steps of the metric were followed correctly.

Social influences: The interns appeared to be influenced by their senior colleagues, some of whom felt that labelling at the bedside and printing labels at the computer located away from the patient after taking bloods was time consuming and unnecessary extra work.

Discussion

This study demonstrated that interns who received PBP training in 2017 had significantly fewer samples rejected than in the
One of the limitations of the project was multidisciplinary and involved all stakeholders (including distractions such as bleeps, interruptions with requests to perform other tasks, time pressure and difficulty locating essential equipment). Due to difficulty recruiting and the large number of interns trained in July 2018, the ratio of tutors to students increased, with one tutor attempting to teach 6–12 students for some sessions. The enthusiasm around PBP training in the hospital was not as heightened in 2018, possibly due to familiarity and perceived lack of reduction in WBITs.

This study follows the methodology of previous research indicating the benefits of PBP training. It is a novel technique using technology-enhanced learning and simulation. Previous educational strategies tend to follow didactic-style teaching to improve phlebotomy technique and often rely on self-reported questionnaires to determine effect. Educational strategies have been shown to reduce but not eliminate WBIT. Bar code systems that scan the patient’s wristband demonstrate a reduction in labelling errors and improve positive patient identification practices. Many organisations, however, do not have sufficient resources to deploy these devices; the device is aimed primarily at transfusion sampling and requires proper training to be effective. Multiple interventions and feedback are likely to be more effective than single interventions, but the sustainability of improvements is not certain from previous research. WBIT rates in mislabelled samples are estimated at 1.4%, which is much higher than in correct samples, indicating that rejection of the sample due to any mislabelling event is indicative of an error-prone phlebotomy process that could have led to WBIT errors, and justifies the investigation of all blood sample errors to represent instances where there was a high risk of WBIT errors. This study demonstrates that, despite the introduction of comprehensive PBP training in phlebotomy, if the environment and process is error-prone, it is not possible to eliminate the risk of WBIT and other blood sampling errors. Healthcare organisations must adapt their systems to reduce distractions and tendency towards deviating from the correct process of phlebotomy which can lead to harm e.g. not performing positive patient identification, labelling the tube away from the bedside.

PBP training has robust evidence demonstrating a 40%–60% improvement in procedural performance. This study examines the effectiveness of the intervention for a three-month period over two years. The study gives a clear insight into the sustainability of the project. The development and design of the project was multidisciplinary and involved all stakeholders in developing a training programme that was highly relevant.

While in many cases the use of historical data is not ideal, the thorough, systematic nature of this data, which has been documented systematically since 2010, allows us to be confident that the 2016 historical control group is representative.

The study has several limitations. The study did not have a sufficient sample size in order to examine the effect of the intervention on WBITs, the primary outcome of interest. One doctor in the 2017 group did not attend the final assessment and three of the doctors in the study were discovered to not be using their own ICM login, and therefore these participants could not continue the study.

Interns may have been negatively influenced by mentors who had not undergone PBP training and this could have undermined and weakened the potential impact of PBP training. There was a concern that, although the interns were trained to proficiency, they did not always follow the process when unsupervised as it took longer to perform.

The qualitative element of the study identified factors which could potentially increase the risk of WBIT, including patients not wearing identification wristbands, difficulty accessing essential equipment, insufficient hardware and stress. This provides an insight into the environment and context within the interns are expected to perform. These human factors were persistent in all years; however, it was not possible to measure the level of these over the three years. The qualitative component of the study highlights learnings of why it may not be possible to eradicate WBIT events if the interns are expected to work within an environment that does not promotes safety. Previous research describes the need to develop “resilient” healthcare organisations that are capable of identifying and adapting to potential vulnerabilities or threats to safety without the need for an incident or accident to occur and promotes the concept of a Safety-II approach for healthcare organisations to consider as an alternative to improve the quality and safety of their systems by ensuring more things can go right. This study highlights the value in such an approach to support educational initiatives.

Given that the project was heavily promoted in the laboratory, it is possible that there was an increased awareness of WBIT, and this could have led to an increased detection rate amongst laboratory as well as ward staff. This detection bias has been described in previous studies involving WBIT, where errors increased despite the introduction of quality improvement initiatives.

PBP training in phlebotomy can reduce blood sampling errors, but must take place in an environment that clearly acknowledges the importance of the training and the quality of the training must be properly resourced. Healthcare organisations must ensure that the process of performing bloods is organised in a way that promotes safety and make it easy to perform procedures correctly e.g. ensuring bedside label printers to promote bedside labelling.

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This study was unable to demonstrate if PBP training in phlebotomy influences the incidence of WBIT due to an inadequate sample size and possible detection bias.

Main messages

- PBP training in phlebotomy can reduce blood sampling errors, but barriers to following the correct procedure on the wards must be considered and removed if possible.
- Educational interventions alone are insufficient to reduce blood sampling, including WBIT, if the environment does not allow for a safe and efficient phlebotomy process, including the availability of appropriate hardware (especially bedside label printers).
- This bespoke PBP training programme in phlebotomy can be adapted for use in other healthcare facilities to train healthcare practitioners at commencement of employment, following external validation.

Current research question

- Future studies should examine the effect of bedside label printers coupled with PBP training in phlebotomy to examine the effect on blood sampling errors including WBIT.

Data availability

The underlying data (anonymised) will be made available on request for bona fide researchers, including researchers outside of UCC. Approval for data sharing was not sought at ethics approval stage nor was it included in the information sheets and consent forms provided to participants. Also, the sample size is small, and this raises the risk of potential reidentification of participants. To request access to the data please email the corresponding author, Dr Noirin O’Herlihy-nohir@ucc.ie

Extended data

Figshare: The standard form used to collect field notes on the wards is available from https://doi.org/10.6084/m9.figshare.17242574.v1

This project contains the following data
- Standard form PBP on wards.docx

Data are available under the terms of the Creative Commons Attribution 4.0 International (CC BY 4.0).

Acknowledgements

We thank all the participating volunteers for their efforts and contributions including the laboratory at CUH and the healthcare practitioners who participated in the organisation and delivery of the PBP training programme in phlebotomy. We acknowledge Dr Patrick Kiely’s role in the development of the online eLearning programme.

Contributors

NOH collected data, performed formal analysis, investigation, data curation, writing original draft, visualization, project administration, SG revised the manuscript, PH writing review and editing, investigation, RG writing review and editing, investigation, AK formal analysis and writing review and editing, MR data curation, writing review and editing, AG conceptualization, funding and acquisition, supervision, methodology, formal analysis writing review and editing, MC conceptualization, funding and acquisition, supervision, methodology, formal analysis writing review and editing.

References

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Richard M. Kaufman
Department of Pathology, Brigham and Women's Hospital, Boston, MA, USA

General comments

The investigators report on a single-institution study of blood sample error rates from two cohorts of new interns (2017, 2018 groups) who received proficiency-based progression (PBP) training compared with a historical cohort of new interns (2016 group) who did not receive PBP training. Sample error data were obtained from the laboratory information system from a 3-month period from each study year. The primary outcome was WBIT errors, which were rare events—there were 3, 3, and 5 WBITs for the 2016 baseline and two subsequent study years, respectively. A significant reduction in rejected samples was observed for 2017/2018 relative to baseline (OR 0.5 and 0.89, respectively).

The authors are to be commended for systematically investigating the impact of their educational intervention. The main limitation of this study is the use of historical controls: this study design was practical but did not allow the investigators to prove a causal relationship between the intervention and reduction in rejected samples. Nevertheless, the data are suggestive of a beneficial effect of PBP training. This paper would be improved by providing some additional details, as suggested below.

Specific comments

Methods

- Are all blood samples at Cork University Hospital collected by interns? If not, what proportion are collected by other types of providers (e.g., nurses)?

- Were all laboratory sample types included in this study (chemistry, microbiology, etc.) or just blood bank samples? Put another way: were all the samples collected by interns tested for ABO/Rh, which would have allowed for WBIT determination? (If not, what proportion of samples were tested for ABO/Rh?)
Presumably, WBIT was defined as the ABO/Rh type of a patient not matching the historic type – this should be stated explicitly in the Methods.

Assuming the above is true, WBIT errors could only have been detected from patient samples where a historic ABO type was available. Is the proportion of patients with a historic type known for the study periods in 2016, 2017, and 2018? (A higher proportion of patients with historic types would be expected to lead to a higher number of WBIT errors detected.)

P. 4: training. Presumably, all training was completed in July, before the 3-month study period began—this should be stated explicitly in the Methods. How long did the training take for one intern?

May want to consider providing a link to the online training module.

Who were the tutors? How were they qualified and assessed?

Where were the blood samples collected? (Inpatient wards, outpatient clinics, emergency department, ORs, etc.?)

Table 1, IX – how often were mobile label printers used? Did the frequency of bedside label printing remain constant from 2016-2019? Were any of the samples collected using electronic patient identification, or were all samples collected using manual identification in all three study years? (Either way, should be stated explicitly.)

Results

P.5: “There were 4,016 blood tests performed by interns . . .” It would be more precise to say that there were “4,016 blood samples collected by interns . . .”

Table 2 would be improved by including a column for the 2016 (historical) control cohort, even if some of the data were not available. Were age and gender not obtainable for the 2016 interns?

Table 2: Were other parameters collected? For example, it would be good to know if the total number of years of training was the same for interns in the different study groups. (For example, perhaps some of the interns had previously practiced in another specialty.)

Table 2: it seems odd that a minority of interns (only 16% in 2018) reported being right-handed; 75-90% of all people are thought to be right-handed.

Is it known how many samples (mean, SD) were collected by each intern? Were there some interns who collected no samples at all?

Discussion

P.7, 1st paragraph: “This study demonstrated that interns who received PBP training in 2017 had significantly fewer samples rejected than in the control group.”

I think that this statement is well-supported by the data.

P. 7-8. “This study demonstrates that, despite the introduction of comprehensive PBP
training in phlebotomy, if the environment and process is error-prone, with the potential for shortcuts that can increase the risk of error, it is not possible to eliminate the risk of WBIT and other blood sampling errors even with optimal electronic systems.”

- I agree in principle that it is not possible to completely eliminate errors such as WBITs even with optimal electronic systems, as long individuals participating in the sample collection process have the ability to cut corners/use electronic systems improperly. But I don't think that this study demonstrates this point – “optimal electronic systems” were not studied directly here. It's also not clear to me that shortcuts were specifically documented in the data set.

**Is the work clearly and accurately presented and does it cite the current literature?**
Yes

**Is the study design appropriate and is the work technically sound?**
Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**
Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**
I cannot comment. A qualified statistician is required.

**Are all the source data underlying the results available to ensure full reproducibility?**
Partly

**Are the conclusions drawn adequately supported by the results?**
Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Transfusion medicine

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 28 Nov 2021

Noirin O’ Herlihy, University College Cork, Cork, Ireland

Dear Dr Kaufmann,

Below you will find our responses to the specific comments in turn. Text labelled ‘Reviewer’ are the comments of the reviewer. Text labelled ‘Authors’ are the responses of the authors.
Reviewer
Are all blood samples at Cork University Hospital collected by interns? If not, what proportion are collected by other types of providers (e.g., nurses)?

Author
Interns perform a minority of the bloods in hospital. The proportion of blood tests had been taken by interns alone was not provided. We have now added data to explain that in 2016, we found that interns had taken 6% of bloods on the wards. Phlebotomists, nursing staff and other doctors were performing the majority of blood tests.

Reviewer
Were all laboratory sample types included in this study (chemistry, microbiology, etc.) or just blood bank samples? Put another way: were all the samples collected by interns tested for ABO/Rh, which would have allowed for WBIT determination? (If not, what proportion of samples were tested for ABO/Rh?)

Author
This study looked at haematology blood samples only e.g. FBC, Coagulation screens. These blood tests were ordered electronically allowing for systematic tracking of laboratory errors, which had been ongoing since 2010. Blood bank samples were hand labelled and not included. We have attempted to explain this more clearly in the Methods section.

Reviewer
Presumably, WBIT was defined as the ABO/Rh type of a patient not matching the historic type – this should be stated explicitly in the Methods.

Author
We have now included in the manuscript that “WBITs are usually identified in these sample types when there is a large discrepancy with previous results”.

Reviewer
The study examined blood samples collected for the haematology department. Assuming the above is true, WBIT errors could only have been detected from patient samples where a historic ABO type was available. Is the proportion of patients with a historic type known for the study periods in 2016, 2017, and 2018? (A higher proportion of patients with historic types would be expected to lead to a higher number of WBIT errors detected.)

Author
This study examines haematology blood samples. We did not look at how many samples had previous blood tests available and therefore allowed for detection of a WBIT.

Reviewer
Presumably, all training was completed in July, before the 3-month study period began—this should be stated explicitly in the Methods. How long did the training take for one intern?

Author
We have explained ‘The eLearning module and the simulation training on the training ward was completed before work commenced in the hospital. However, mentorship on the wards was completed in the first month following commencement of work in the hospital while data collection was ongoing’.
Reviewer
May want to consider providing a link to the online training module.

Author
The online training is not available to the public as the patient in the video is recognisable and only provided consent for the video to be viewed by healthcare practitioners. It was made available on hseland.ie.

Reviewer
Who were the tutors? How were they qualified and assessed?

Author
Tutors included experts in phlebotomy in the hospital and was comprised of phlebotomists, nurses with expertise in IV cannula education, senior lecturers from UCC experienced in providing teaching in phlebotomy skills, and doctors who had participated in the metric development. A one hour session was provided before the teaching to ensure the teaching was standardised. The principles of PBP training were explained to the tutors and the metric was discussed in detail. The tutors were given time to observe and mark one person perform the procedure.

Reviewer
Where were the blood samples collected? (Inpatient wards, outpatient clinics, emergency department, ORs, etc.?)

Author
We have now explained that “Blood samples were collected on the general wards and the emergency department but did not include outpatient samples”.

Reviewer
Table 1, IX – how often were mobile label printers used? Did the frequency of bedside label printing remain constant from 2016-2019? Were any of the samples collected using electronic patient identification, or were all samples collected using manual identification in all three study years? (Either way, should be stated explicitly.)

Author
Although the metric mentions the option to use bedside label printers, in fact “at the time of the study mobile label printers were not available to interns performing bloods in the hospital. They were only used by phlebotomists” and we have now included this information in the publication.

Reviewer
P.5: “There were 4,016 blood tests performed by interns . . .” It would be more precise to say that there were “4,016 blood samples collected by interns . . .”

Author
We have changed this as suggested, thank you.

Reviewer
Table 2 would be improved by including a column for the 2016 (historical) control cohort, even if some of the data were not available. Were age and gender not obtainable for the 2016 interns?
Author
Table 2 does not include information regarding historical controls as we did not have ethical approval or consent to collect this data. However we have included a comment at the end of the table to say that “Data was not collected on historical controls but 20 of the 43 who collected bloods were male”.

Reviewer
Table 2: Were other parameters collected? For example, it would be good to know if the total number of years of training was the same for interns in the different study groups. (For example, perhaps some of the interns had previously practiced in another specialty.)

Author
Further information regarding the numbers of years in training was requested and we had asked if the interns had completed any work as a doctor before this post. This information is now included in table 2.

Reviewer
Table 2: it seems odd that a minority of interns (only 16% in 2018) reported being right-handed; 75-90% of all people are thought to be right-handed.

Author
An error was identified in Table 2, thank you. We have reanalysed the original data and the data is now correct. This did not affect the conclusions of the study.

Reviewer
Is it known how many samples (mean, SD) were collected by each intern? Were there some interns who collected no samples at all?

Author
Data on the average number of tests collected by each intern was requested and is provided in Table 5.

Reviewer
P. 7-8. “This study demonstrates that, despite the introduction of comprehensive PBP training in phlebotomy, if the environment and process is error-prone, with the potential for shortcuts that can increase the risk of error, it is not possible to eliminate the risk of WBIT and other blood sampling errors even with optimal electronic systems.”

I agree in principle that it is not possible to completely eliminate errors such as WBITs even with optimal electronic systems, as long individuals participating in the sample collection process have the ability to cut corners/use electronic systems improperly. But I don't think that this study demonstrates this point – “optimal electronic systems” were not studied directly here. It's also not clear to me that shortcuts were specifically documented in the data set.

Author
We have removed the statement regarding electronic systems in the discussion as the study does not investigate the effect of electronic systems on WBIT.

Competing Interests: The authors have no competing interests
Paula H. B. Bolton-Maggs 1
1 Serious Hazards of Transfusion Office, Manchester Blood Center, Manchester, UK
2 University of Manchester, Manchester, UK

The authors describe a novel method of practical phlebotomy training for junior medical staff and show that this was associated with a reduction in sample rejections (similar interactive and simulation training for transfusion has been introduced for final year medical students in Wales). Although not the subject of this paper, correct patient identification and sampling are particularly important in transfusion, since patients have died as a result of misidentification. However, the same standards should apply to all phlebotomy. Positive patient identification, asking the patient to say their full name and date of birth, is not included in the standards and should be.

I suggest the paper should specifically reference ‘human factors’ and the need for training in this science. The factors are there in the paper, but an additional paragraph would be of benefit.

Specific comments:

Introduction:
There is appropriate description of the errors made with pre-analytical variables. The authors cite three references relating to correct phlebotomy, but I am surprised that they do not include the British Society for Haematology guidelines, 'the administration of blood components' Robinson et al. (2017) 1, which has clear recommendations about patient identification and standards of training required for all personnel involved in transfusion.

The authors cite Kaufman et al. as reference 8. However, although the results listed from this are correct, I do not see any reference in this to ‘TUBE’. This is the BEST collaboration, (Biomedical Excellence for Safer Transfusion) and the authors are international, not just from the USA. There is other evidence that electronic processes add safety, Murphy et al. (2019) 2. These papers are particularly relevant to this article because WBIT is a particularly dangerous hazard in transfusion. It is also the focus in the results.

I am also surprised that there is no mention of human factors science as this is increasingly recognised as key in what we do.

(Note mis-spelling of haemovigilance officer in third paragraph – currently has ‘e’ where there should be an ‘a’).

It is very worrying that ‘since the introduction of an online request system...documented identification errors have increased’. There is no further discussion of this in this paper and I
would recommend further explanation. In my experience where patients are listed alphabetically it is easy to select a patient with similar or same last name. How has this been mitigated?

**Methods:**
The paper referencing the background work for this project is not open access which is unfortunate. It is clear that procedures for blood sampling through to return of results and any resulting changes in patient management are many and complex, so this is an interesting project for analysis of the steps and training to reduce the errors.

Similar work was done in Scotland by Pickup *et al.* (2017)\(^3\). Using human factors methodology they analysed 50 observations, 15 interviews and 12 months of incident data from all Scottish hospitals noting the influence of working environment, equipment, clinical context, work demands and staff resources. There are many reasons why ‘work as done’ is not ‘work as imagined’ (i.e. departures from the correct or recommended procedures).

The authors identified 11 phases and a total of 77 steps with the phases shown in Table 1. I was very surprised that under phase IV positive patient identification (i.e. asking the patient to state their name and date of birth) was not mentioned at all as this is critical to avoid ‘wrong blood in tube’. Under phase IX the description ‘fixes patient up’ could perhaps be better expressed – what exactly does it mean?

**The control group:**
We are told that these interns had received ‘traditional phlebotomy training...’. It would be helpful to know what that was, particularly what they were taught about positive patient identification and labelling at the patient’s side. These two points have been identified regularly by the Serious Hazards of Transfusion haemovigilance scheme (SHOT), where I am affiliated, as causes of error since its inception in 2006.

I do not understand what is meant by ‘ethnographic notes recorded by the investigator’

**Results:**
There was a progressive reduction in rejected samples with successive cohorts (mainly reduction in clotted and over/under filled tubes) although there was an increase in WBIT. There was a reduction in total errors from 24 per 1000 samples in 2016 to 12.1 in 2017 but 19.3 in 2018 (still a reduction compared the control group).

The observations of the interns once on the wards show the importance of environment and working conditions, and impact of senior colleagues who tended to discourage some of the correct practices. These are all ‘human factors’.

**Conclusions:**
Are mostly justified by the results. The authors show that the training had some effect in reducing errors. The reasons for the reduced effectiveness in 2018 are well described. It would be good to see further discussion of ‘lack of safety culture around mislabelling on the wards' because this is worrying and links to the lack of information about positive patient identification in the training discussed above.

The sentence ‘this study contrasts with previous research’ is unclear – do the authors mean the
contrast is in the methods used rather than the effectiveness?

The sentence at the top of page 8 is very long and would benefit from being divided into shorter multiple sentences. Short cuts are mentioned here but not elsewhere in the paper. What short-cuts were identified?

I am not sure that I agree with the statement ‘it is not possible to eliminate...errors even with optimal electronic systems’. This may be true, but the full vein-to-vein electronic systems have not been discussed or demonstrated in this project. I am convinced that they improve safety for blood transfusion and SHOT recommends they be widely adopted – a main recommendation in the Annual SHOT Report for 2017 (www.shotuk.org). Introduction of electronic processes in place of humans undoubtedly improves safety and is well recognised in the laboratory.

References

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Haematology, blood transfusion, patent safety, human factors, haemovigilance

I confirm that I have read this submission and believe that I have an appropriate level of
expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 28 Nov 2021

Noirin O’Herlihy, University College Cork, Cork, Ireland

Dear Dr Bolton-Maggs,

Thank you for reviewing our submission and for your thoughtful feedback. Below you will find our responses to the specific comments in turn. Text labelled ‘Reviewer’ are the comments of the reviewer. Text labelled ‘Authors’ are the responses of the authors.

Reviewer
Positive patient identification, asking the patient to say their full name and date of birth, is not included in the standards and should be.

Author
Thank you for drawing attention to the fact that we had not highlighted the importance of positive patient identification which is critical in the avoidance of wrong blood in tube (WBIT). This step was included in the phlebotomy metric developed. As the full metric is published in a previous publication, we have now included a table illustrating the key steps to avoid mislabelling error, including positive patient identification (See Table 2. Key Metrics To Mitigate Wrong Blood in Tube).

Reviewer
I suggest the paper should specifically reference ‘human factors’ and the need for training in this science. The factors are there in the paper, but an additional paragraph would be of benefit.

Author
Thank you for this suggestion. Human factors are now specifically included in the introduction and discussion.

Reviewer
There is appropriate description of the errors made with pre-analytical variables. The authors cite three references relating to correct phlebotomy, but I am surprised that they do not include the British Society for Haematology guidelines, ‘the administration of blood components’ Robinson et al. (2017)1, which has clear recommendations about patient identification and standards of training required for all personnel involved in transfusion.

Author

Reviewer
The authors cite Kaufman et al. as reference 8. However, although the results listed from this are correct, I do not see any reference in this to ‘TUBE’. This is the BEST collaboration, (Biomedical Excellence for Safer Transfusion) and the authors are international, not just
from the USA. There is other evidence that electronic processes add safety, Murphy et al. (2019)\textsuperscript{2}. These papers are particularly relevant to this article because WBIT is a particularly dangerous hazard in transfusion. It is also the focus in the results.

**Author**
The reference to the TUBE study has been corrected to include all the authors and now mentions the BEST collaborative. We have included the reference recommended relating to the safety of employing electronic processes during blood sample labelling. Reference: Murphy MF, Jayne Addison J, Poles D, Dhiman P, et al.: Electronic identification systems reduce the number of wrong components transfused. *Transfusion*. 59(12): 3601-3607 PubMed Abstract | Publisher Full Text.

**Reviewer**
Note mis-spelling of haemovigilance officer in third paragraph – currently has ‘e’ where there should be an ‘a’.

**Author**
This has been corrected thank you.

**Reviewer**
It is very worrying that ‘since the introduction of an online request system...documented identification errors have increased’. There is no further discussion of this in this paper and I would recommend further explanation. In my experience where patients are listed alphabetically it is easy to select a patient with similar or same last name. How has this been mitigated?

**Author**
We have tried to explain further the measures that had already been taken in the hospital to mitigate mislabelling errors and why, ‘since the introduction of an online request system...documented identification errors have increased’ (See paragraph 4 of the introduction. Page 4.)

**Reviewer**
The paper referencing the background work for this project is not open access which is unfortunate. It is clear that procedures for blood sampling through to return of results and any resulting changes in patient management are many and complex, so this is an interesting project for analysis of the steps and training to reduce the errors.

**Author**
We regret that the publication is not open access.

**Reviewer**
Similar work was done in Scotland by Pickup et al. (2017). Using human factors methodology they analysed 50 observations, 15 interviews and 12 months of incident data from all Scottish hospitals noting the influence of working environment, equipment, clinical context, work demands and staff resources. There are many reasons why ‘work as done’ is not ‘work as imagined’ (i.e. departures from the correct or recommended procedures).

**Author**
Thank you for highlighting the need to include human factor science in the discussion. We have now referenced the work in Scotland by Pickup et al. (2017). Reference: Pickup L, Atkinson S, Hollnagel E, Bowie P, Gray S, Rawlinson S, Forrester K. Blood sampling-Two sides

Reviewer
The authors identified 11 phases and a total of 77 steps with the phases shown in Table 1. I was very surprised that under phase IV positive patient identification (i.e. asking the patient to state their name and date of birth) was not mentioned at all as this is critical to avoid 'wrong blood in tube'. Under phase IX the description ‘fixes patient up’ could perhaps be better expressed – what exactly does it mean?

Author
We have now highlighted the steps to mitigate WBIT in Table 2 and this includes positive patient identification in Phase IV. We agree that Phase IV could be better described. Unfortunately as the metric has already been developed and validated it is not possible to change these descriptions at this late stage.

Reviewer
We are told that these interns had received ‘traditional phlebotomy training…’. It would be helpful to know what that was, particularly what they were taught about positive patient identification and labelling at the patient's side. These two points have been identified regularly by the Serious Hazards of Transfusion haemovigilance scheme (SHOT), where I am affiliated, as causes of error since its inception in 2006.

Author
We have highlighted what ‘traditional phlebotomy training” was comprised of i.e. the historical control group had received traditional phlebotomy training as medical students in their third medical year on two occasions and once in the final year of medical school, comprising a phlebotomy guide, training videos, and a practical training session in the clinical skills laboratory. (See page 7).

Reviewer
I do not understand what is meant by ‘ethnographic notes recorded by the investigator’

Author
We have provided an improved description of how the observational and qualitative data was collected on the wards (see end of page 8).

Reviewer
The sentence ‘this study contrasts with previous research’ is unclear – do the authors mean the contrast is in the methods used rather than the effectiveness?

Author
We have removed the statement "this study contrasts with previous research".

Reviewer
The sentence at the top of page 8 is very long and would benefit from being divided into shorter multiple sentences

Author
We have shortened the sentence at the top of page 8 as requested.

Reviewer
Short cuts are mentioned here but not elsewhere in the paper. What short-cuts were
identified?

**Author**
We removed this sentence as it mentioned ‘electronic systems’. Shortcuts identified in the study included labelling the sample away from the patient at the computer rather than hand labelling at the bedside. We have now stated the following “Healthcare organisations must ensure that the process of performing bloods is organised in a way that promotes safety and make it easy to perform procedures correctly e.g. ensuring bedside label printers to promote bedside labelling.”

**Reviewer**
I am not sure that I agree with the statement ‘it is not possible to eliminate...errors even with optimal electronic systems’. This may be true, but the full vein-to-vein electronic systems have not been discussed or demonstrated in this project. I am convinced that they improve safety for blood transfusion and SHOT recommends they be widely adopted – a main recommendation in the Annual SHOT Report for 2017 ([www.shotuk.org](http://www.shotuk.org)). Introduction of electronic processes in place of humans undoubtedly improves safety and is well recognised in the laboratory.

**Author**
We have removed the statement ‘it is not possible to eliminate...errors even with optimal electronic systems’ as this was not investigated in the study.

**Competing Interests:** The authors have no competing interests