

# BMJ Open Quality Current status of medical device malfunction reporting: using end user experience to identify current problems

Arkeliana Tase , Melody Z Ni, Peter W Buckle, George B Hanna

**To cite:** Tase A, Ni MZ, Buckle PW, *et al.* Current status of medical device malfunction reporting: using end user experience to identify current problems. *BMJ Open Quality* 2022;11:e001849. doi:10.1136/bmjopen-2022-001849

Received 15 February 2022  
Accepted 15 May 2022

## ABSTRACT

**Introduction** The current under-reporting of medical device malfunctions, difficulties with the current system and absence of continuous good-quality data has removed the possibility for constant data interrogation and trend recognition to identify evolving issues. This research used end user experiences aiming to understand causes for the lack of data and knowledge on device performance and associated patient risks. This approach was used to identify existing barriers and methods for improvement.

**Methods** This is a qualitative study involving semistructured interviews and surveys with clinicians (15 interviews, 39 surveys) and manufacturers (13 interview participants, 5 surveys). Multiple sources of recruiting were used. Data collected were thematically analysed. Interview results were used to design the surveys. Standards for Reporting Qualitative Research was used.

**Results** Medical device use is based on personal experience rather than evidence which is scarce. Multiple barriers to reporting were identified alongside patient safety and system related aspects. Furthermore, the acceptable level of error was variable as were effects on working practice. Many workarounds have been developed to overcome problems and have become normalised in daily work. These factors were found to have a limiting impact on improvements and learning. Greater system transparency, feedback on submitted reports, a more efficient system of reporting and better communication with manufacturers were reported as some of the required improvements.

**Conclusions** This study has identified numerous complex issues affecting reporting of medical device performance and their subsequent effect on patient safety and clinical staff. The focus on incidents has created many limitations to learning and development. The rich experience of end users should be appropriately used to identify system weaknesses and seek improvement methods. Better communication methods should be developed between healthcare and MedTech (Medical Technologies) industry.

## INTRODUCTION

The medical device (MD) market has over 500 000 products belonging to 10 000 generic groups.<sup>1 2</sup> Currently, there are 4140 MD companies in UK (99% of which are small to medium enterprises) with a combined turnover of £27.6 billion.<sup>3</sup> MDs are implicated in a significant number of adverse events.<sup>4</sup> The last publicly available report from Medicines

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Currently there are concerns about systems in place for acquiring data on medical device (MD) performance.

### WHAT THIS STUDY ADDS

⇒ The study takes an end user approach to identify the root of the problems leading to system deficiencies and lack of data on device performance. It improves knowledge an understanding on the existing system. The study also explores improvement methods as per device end users and manufacturers of devices.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The study findings can be used in further research on improving the system of MD performance reporting and improving data gathering.

and Healthcare products Regulatory Agency (MHRA) in 2013, reported 14819 adverse event reports including 4955 serious injuries and 309 deaths.<sup>5</sup> Lack of reports on ‘near misses’ leads to lack of data for event analysis.<sup>6 7</sup> Lalani *et al* reviewed the Manufacturer and user Facility Device experience database managed by Food and Drug Administration over a 20-year period and identified 290 141 reports stating serious injury or death.<sup>8</sup> Another report stated 1.7 million injuries and 80 000 deaths possibly linked to MDs between 2008 and 2017.<sup>9</sup>

MDs are diverse, and their increased complexity has brought a high risk for error.

Between 2005 and 2012 John Hopkins Hospital (USA) incurred US\$75.3 million in settlement costs and legal fees in relation to MDs.<sup>10</sup> It is recognised that poor usability is a common cause of device-associated errors. Being able to evaluate and predict patient safety in relation to device use is a critical step in error reduction by either redesign or staff training.<sup>11–13</sup>

Currently, manufacturers report directly to the MHRA on any safety concerns raised to them. End users of MDs (clinical teams, patients) officially report concerns through



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

Surgery and Cancer, Imperial College, London, UK

**Correspondence to**  
Dr Arkeliana Tase;  
a.tase@imperial.ac.uk

the incident reporting system (Datix) which feeds into national data managed by National Reporting and Learning System (NRLS). NRLS is recognised to have many deficiencies.<sup>14 15</sup> The biggest criticism of NRLS is that its approach to data is 'wide and shallow', hence not allowing for in-depth analysis.<sup>14</sup> Considerable work has been carried out with a resulting Patient safety Incident Management System<sup>15</sup> currently under development. Literature by National Health System (NHS) Improvement shows this to be an improvement in comparison to NRLS. The question whether this incident reporting system can overcome the complexity of the existing problems with MDs, however, remains a valid one.

The recently published Cumberlege report<sup>16</sup> brought further evidence to the lack of knowledge on informed decision making for both clinicians and patients on surgical procedures, devices and medications. Concerns were raised over the safety of the system in relation to the use of new MDs and techniques. Substantial revision of the reporting system was recommended to create a more transparent and user friendly system.<sup>16</sup>

In the current regulatory framework, the acceptable level of risk related to a device is determined by device manufacturers. They; however, have little control on how devices are used. Many assumptions are made on critical aspects such as training and equipment maintenance.<sup>17 18</sup> The lack of adequate communication between healthcare and MedTech (Medical Technology industry) and lack of device-related data is recognised to have a negative effect on learning, device improvement and event prevention.<sup>18</sup>

Current challenges include under-reporting and poor quality of reported data through Datix.<sup>19</sup> This is affected by local organisational factors such as education and training of staff on both device use and reporting of events, recognition of patient safety events associated with device use and ability of the organisation to implement positive changes.<sup>19</sup> To address these challenges, we should take a system's approach. This study will (1) explore end user experiences on the root problems with the existing reporting system and (2) their views on improvement methods addressing lack of data with the final aim of improving patient safety. This study has taken a bottom-up approach to the problem identifying deficiencies in the current incident reporting system leading to lack of data on MD safety reporting. The term system throughout this paper refers to the incident reporting system unless otherwise specified.

## METHODS

The study concentrates on the reporting methods and system(s) used in operating theatres. A high proportion of surgical devices are intermediate and high risk devices<sup>20</sup> and used in a complex environment.

This is a qualitative study. It used semistructured interviews and surveys for data collection. First, a thorough literature review was carried out using Medline, Embase and PubMed. NHS Improvement publications were

reviewed as was published literature on existing implant registries. The interview protocol was developed based on findings from the literature review and pilot study. The protocol was reviewed by members of the National institute for Health Research London IVD (In-Vitro diagnostics group) at Imperial College London prior to the interviews.

## Patient and public involvement

The patient and public involvement group working with the London IVD group at Imperial College London was involved in the initial design of the study. The end users in this case were clinicians and manufacturers of MDs. No direct patient involvement took part in this study.

## Stakeholder studies

Key stakeholder identification and recruitment was completed using a mixed methods approach utilising convenience and snowball sampling. To avoid sample bias, all surgeons (registrar and consultant level) and operating theatre nurses were included. Recruitment was carried out via email, social media (LinkedIn, Twitter), Association of British Healthcare Industry newsletter and surgical trainee groups (x2). The same methods were used for recruitment of device manufacturers. One hundred email invites were sent to clinicians and 161 invites (email and LinkedIn) to manufacturers. Following stakeholder analysis,<sup>21</sup> semistructured interviews were carried out followed by surveys. The clinicians that responded and took part in the study were from seven different trusts in UK.

Participants were encouraged to consider all MDs used in operating theatres in general but were free to discuss any particular type of device if this helped them to explain their experiences or give examples.

Participants were sent the study information sheet, study requirements and consent form prior to the interview. All participants were consented prior to the interviews. The consent form was incorporated at the start of the survey.

Data were collected on the following aspects:

### Clinical staff

1. Knowledge on reporting methods.
2. Understanding reasons for reporting/non-reporting.
3. Reporting system effectiveness.
4. Barriers to reporting.
5. Improvement methods.

### Manufacturers

- ▶ Methods and quality of reports received from healthcare.
- ▶ Methods and challenges in post market analysis.
- ▶ Methods of receiving/giving feedback.

Literature<sup>22-24</sup> on thematic analysis of qualitative data was researched to ensure a rigorous process. Interviews were transcribed verbatim by the first author, to increase familiarity with the data. Data were reviewed by a second reviewer to reduce bias in data analysis. Codes

**Table 1** Number of stakeholders invited and taking part in the study (\*invites sent via email and LinkedIn)

| Clinicians   |                             | Manufacturers      |                            |
|--|-----------------------------|--------------------|----------------------------|
| No of invites sent   | No taking part              | No of invites sent | No taking part             |
| 100  | 15 interviews<br>38 Surveys | 161                | 13 interviews<br>5 surveys |
| Study also advertised in LinkedIn, Twitter, ABHI, NIHR London IVD website, East of England trainee group                   |                             |                    |                            |
| ABHI, Association of British Healthcare Industry; IVD, in vitro diagnostics; NIHR, National Institute for Health Research. |                             |                    |                            |

were created to create meaningful grouping and identify similarities and differences in the data. Thematic analysis was carried out. Six main themes were set for each stakeholder interview based on the aims and objectives of the study. Emerging themes were explored from the interview manuscripts and studied further in the surveys. In vivo coding was incorporated. The same methods were utilised for analysis of the survey data. The five qualities for good interpretation as presented by Yin *et al*<sup>24</sup> were used at the data interpretation stage. Standards for Reporting Qualitative Research<sup>25</sup> was used to structure and report the results of this study.

## RESULTS

Semistructured interviews were completed with 15 clinicians and 13 manufacturers. Surveys were completed by 38 clinicians and 5 manufacturers (table 1). Interviews lasted between 35 and 60 min each. The interviewed clinicians worked in seven different trusts in UK. Manufacturers represented a combination of medium and large international corporations.

### Commonly reported challenges

#### Knowledge gaps

Personal choice and experience in using similar devices were the most common reasons for device use (46.8%). Clinical evidence was the reason for use in only 28.7% of participants.

There was a general confusion on the best methods to report. Most participants were aware of the Datix (for incident reporting) and direct contact with manufacturers which often occurred in parallel. None of the interviewed clinicians and only 24% of those completing the survey were aware of the Yellow Card as a method of reporting directly to MHRA. The Yellow Card is the MHRA's official method of receiving reports of any events related to MDs, drugs and vaccines. Some clinicians also believe that discussing equipment concerns while completing the WHO checklist at the start of a procedure is a method of reporting which is not the case. None of participants were aware of the national levels of reporting/under-reporting for MDs.

There is generally bias in the decision-making process with regard to which devices to report and where by all

stakeholders. In the absence of evidence, the decisions are made on a personal basis.

### Likelihood of reporting

The likelihood of submitting a formal report was only 27%. 43% stated they are not likely to submit a report (30% passive responses). This was due to lack of effectiveness of all (formal and informal) reporting methods (82% of participants), no quality improvements noted following reporting (63.6%) and Datix regarded as poor to extremely poor (91% of participants). Despite this, Datix was considered appropriate by 48% of participants as the only official method of reporting. The remaining participants considered it appropriate only if a patient related incident had occurred (39.4%), never appropriate (3%) and 9% were unsure.

Consultant surgeons stated that the final responsibility rests with them. However, reporting is often delegated to nursing staff or theatre manager. The reason for this was usually lack of time. Nurses acknowledge the doctor's time limitations, however they would like help with the process. At times devices are not reported due to them also being busy or forgetting to carry out the task. Some of the events are further delegated to a third party (often theatre manager). Hence, the information reaching the manufacturer becomes minimal as shown by the manufacturer interviews. This process fails when the theatre manager is away with the device either not reported or poorly reported with delay.

Report to the theatre manager who will report to her manager

The consultant takes the fall at the end of the day but responsibility is often delegated to a senior nurse or sister in theatres.

### Repeated problems

The most common complaint from staff was that reported equipment would return to use with no improvement. (quote below) The reasons for this were unknown with associated patient risks. In a few cases, this was thought to be due to lack of training of junior nursing staff sending the equipment for cleaning rather than repair.

Despite escalation, it came back in the kit. This was a new device that was placed in the trays. The consultant was not happy as it was different from the one he would normally use. The device would not apply the clips properly and despite multiple reporting it still appeared in the trays

### Device use out of 'life cycle'

At times, equipment is used beyond its 'end-of-life cycle' due to inability to replace them. Devices are used outside their use range leading to wearing out and suboptimal performance. This relates to the lack of maintenance contracts. It results in inability to maintain or repair equipment with increase in purchasing costs. Lack of alternative equipment leads to reuse of the same devices

with pre-existing knowledge they may not function as required. Equipment tracking is absent with lack of awareness on the amount of equipment present in the department.

We spend so much time buying things but not to repair them and they end up on someone's desk and is just replaced and not reported.

If all equipments have a maintenance contract it would help. I have been saying that this needs to be in place but at present we just keep replacing them.

### Patient safety aspects

#### Acceptable level of device error

The concept of 'acceptable level of error' is well known to high-risk industries. In healthcare, however, this level of error is not standardised. This (among other reasons) has led to development of workarounds. Hence, the use of these devices is at times considered expensive (due to need for multiple devices used for the same procedure) rather than unsafe.

To reduce the device related risk, clinicians ask for standardised training on device use for the surgical team. The level of training received is generally poor and inconsistent. Majority of training is manufacturer lead (60.6%) for specific devices with only 12% always receiving training and only 9% being trust lead. Clinicians are often faced with unfamiliar devices during a procedure creating new challenges.

#### Device malfunction as a patient safety concern

Clinicians stated the need to discuss major device events in clinical governance. The aim of this was to improve learning, staff education and patient safety. This was resonated in the questionnaire by 91% of participants.

Despite the low likelihood of reporting, 88% of clinicians stated that MD events should be considered as incidents or near misses due to potential for harm. However, it is accepted that this does not always happen. Often only serious events are reported.

If no patient harm observed may not be treated as urgent

Theoretically yes, they are incidents/near misses, practically depends on the problem

I think all potential equipment failure or inadequate equipment performance can lead to patient harm for example an energy device not working and intraoperatively you have a bleed or a scope failing in the middle of a difficult procedure so every equipment failure has the potential to cause harm and should be treated as such

For a small group of clinicians, device events were considered simply as a malfunctioning technology with no relation to patient outcome (unless a patient incident was observed).

### System-related aspects

#### Lack of process transparency

Datix is considered non-efficient with lack of transparency on the information submitted, documentation kept and lack of feedback. Little or no improvement is often seen following submission of a report. At times there is lack of understanding on the importance of reporting and retaining a log.

#### Lack of feedback

Lack of feedback removes the opportunity for learning from the event. Seventy-three per cent of the participants had never received feedback on submitted reports despite it being very important (48%). When feedback was received, it was not useful to improve practice. For one of the participants, reports had previously been being dismissed by management leading to frustration and lack of belief in possibility for improvement.

Senior nurses stated that sometimes they would receive feedback from manufacturers (when directly reporting to them) via email. In the absence of an authorised process to capture this feedback, these reports they were kept within their accounts and not shared regularly with the team.

Feedback would be very helpful as at least we would know what went wrong and I suppose the other question is 'did we do something to the instrument to make it faulty or was it just faulty anyway?'

It is good to know what comes of your efforts. It is about incident reporting as a whole, you fill this form and it disappears and you never hear back on your submission and not even a broader feedback with other submissions from other sources.

The feedback is very important, but we don't receive it, we just assume that the machine is being fixed and we carry on.

#### Barriers to reporting

The reported barriers to reporting were grouped into six subgroups: (1) workload, (2) knowledge and training, (3) understanding the function/importance of event reporting, (4) reporting system factors, (5) organisational factors and (6) other.

While clinicians initially stated that nothing apart from lack of time would stop them from reporting, on further discussion several other factors became evident. **Box 1** shows a breakdown of all the barriers reported in this study.

#### Manufacturer challenges

Device manufacturers report that the quality of information they receive is variable and most often poor. Very often the malfunctioning device is not returned to them for assessment. When the device is returned, it often only has a note saying 'faulty'. This is not helpful in assessing the event and make useful changes to device design or provide required training. Essential information about

## Box 1 Barriers to reporting medical device events in healthcare

### Barriers to reporting

#### Workload

⇒ Lack of available time (inducing shift patterns).

#### Knowledge and training

- ⇒ Not knowing who to contact.
- ⇒ Not knowing how to report.
- ⇒ Lack of training.
- ⇒ Inability to recognise the cause of the problem, that is, device/human error/process error.

#### Understanding the function and importance of event reporting

- ⇒ Information being passed to a second or third party before reporting occurs.
- ⇒ Belief that the event will not occur again.
- ⇒ Medical device malfunctions not considered as patient related events.
- ⇒ Individual acceptable level of error.
- ⇒ Direct (in person) reporting to manufacturer representative leads to absence of internal reporting.

#### Reporting system

- ⇒ Existing methods—time-consuming.
- ⇒ Lack of transparency on submitted reports.
- ⇒ Belief that reporting will not bring about a positive change.
- ⇒ Datix
  - ⇒ Has 'blame' attached to it.
  - ⇒ Not appropriate for medical device reporting.
  - ⇒ Takes too long to complete.
  - ⇒ Too difficult to complete.
- ⇒ Lack of feedback.

#### Organisational factors

- ⇒ Management unable to recognise importance of reporting.
- ⇒ Dismissal of submitted reports.
- ⇒ Poor IT system.

#### Other

- ⇒ Worry about consequences of reporting.

the device (its identification) and circumstances of use are often missing as are the details of the person submitting the report. This does not allow tracing and further information gathering.

When an event is reported (to the manufacturer) through MHRA, this occurs through a number of formal steps. By the time it reaches the manufacturer, tracking of the original report is unfeasible. In these cases, the manufacturer is unable provide feedback until the investigation is completed.

Manufacturers only receive a proportion of the feedback on their devices and often this is of poor quality. Hence, they find it difficult to always assess device function to the best of their abilities. A standardised process is used to analyse device malfunction or failure, however, this is dependent on the data available. This safety assessment is

## Box 2 Challenges faced by manufacturers on information gathering

### Challenges faced in effective assessment of medical device malfunctions

#### Clinical studies

- ⇒ Cost implications of clinical studies.
- ⇒ Randomised controlled trials rare due to cost implications.
- ⇒ Difficult process in gaining ethical approval for clinical studies.
- ⇒ No adequate resources in place for clinical data gathering.

#### Lack of good-quality data

- ⇒ Registry information anonymous—difficult to distinguish data from that of competitors.
- ⇒ Reports do not include risk factors.
- ⇒ Analysis of registry data may be biased.
- ⇒ Insufficient information on reports.
- ⇒ Missing basic information on device being reported for example, batch number.
- ⇒ Missing time, date, circumstances of use.
- ⇒ Unknown reporting hospital trust.
- ⇒ Devices not returned for assessment (especially single use devices).
- ⇒ No knowledge on frequency of use or repair history.
- ⇒ Event analysis—at times incomplete as dependent on the data available.

#### Feedback

- ⇒ Difficulties in receiving direct feedback from clinicians.
- ⇒ Gaining both positive and negative feedback by clinical users.

#### Process related

- ⇒ No information on reporting person thus unable to follow up.
- ⇒ Products going through National Health System supply chain—no knowledge on end users to contact.
- ⇒ Inefficient system of reporting.
- ⇒ Concern of assigning blame.
- ⇒ -Contact with healthcare managers—at times more interested in cost than the product.

often based on published literature and internal bench studies when other sources are absent.

Their feedback from healthcare consists mostly of complaints with varying levels of clinical information. Manufacturers have a set process for providing written feedback to the person or trust making a report.

Many challenges were reported in gathering clinical data with large associated costs (both financial and personnel). Manufacturers producing devices recorded in existing implant registries, are using this data in their postmarket analysis (although recognise their limitations). The sales representatives are often the point of contact between clinicians and manufacturers. They were reported as the most effective method of communication between clinicians and manufacturers.

The importance of the information received is dependent on the type of device under investigation. For low-risk devices (class I) with low risk of patient injury, the lack of information is overcome by their high volume and trend analysis. Higher risk devices often are used in lower volumes and the same is not possible. [Box 2](#) shows

the challenges reported by manufacturers in information gathering process. Below are some of the comments made by the manufacturers.

The problem is true of lacking clinical data in general, we also produce implants for the dental market which is a “black box”. We have no idea what is happening in that. We wished there is some ways of covering other markets. We have no idea how the implants are performing.

I think the lack of information is widespread and not many people have the time or interested in reporting. Sometimes the theatre manager would find a device on their desk with no other information then tries to tell us.

Biomedical Engineering teams don't tend to say whether it was used on a procedure, on the patient, they just tell us—needs repairing or replacement and nothing more. Usually, the information is very short.

### Methods for improvement

Clinicians want greater transparency on the submitted information and effective feedback on the actions taken by the manufacturer and the healthcare trust. They want to know if the problems they are facing are recurrent and faced by others. This would affect safe practice. While at present, it may not be possible to detect the cause of the error, most appreciate that malfunctions may relate to both device design and associated human factors. They stated that an effective reporting system would be an online, dedicated to MDs that takes minimal amount of time to complete. A standardised training is required for clinical staff on safe use of devices. Manufacturers would like better communication methods with healthcare and useful clinical feedback on device performance.

Need to have something to be able to see what other trusts are facing problems with and to see whether problems are linked to a particular device or just to a specific batch.

For me personally, I would be interested to know if other trusts are facing the same problems with the devices I am having problems with as it would make me decide whether it is just the devices I am using or whether this is a more wider problem. It would certainly make me more cautious about using the device if I know its causing problems elsewhere.

## DISCUSSION

### Key findings

This study has brought to attention the main reasons behind poor levels of device performance data threatening their safe use. In its absence, their adoption occurs on an individual basis rather than clinical evidence. Devices are not automatically subject to a clinical trial (due to their nature). They are tested for mechanical and electrical safety prior to use in patients.<sup>26</sup>

Staff training on device use is poor and highly variable. Many difficulties are faced by trusts in this respect.<sup>27</sup> Clinicians want to be able to make an informed decision on the devices they use. Hence, there is a need for better data to guide their use. End user experience is invaluable and clinical staff should be an active part of the process. When this occurs, the organisation is likely to promote experiences that enrich knowledge and increase the skills of their staff.<sup>28</sup>

### Acceptable level of error and workarounds

Existing problems have led to development of workarounds and changes to working practice. Workarounds arise from the need to offer solutions by overcoming a mismatch between the device function and its performance.<sup>29</sup> This mismatch introduces system vulnerabilities with considerations on whether the right tool is being used for a particular procedure.<sup>29</sup> To maintain a safe environment for patient care, building of resilience is a protective factor towards these system vulnerabilities. Resilience is the maintenance of positive adjustments, maintaining functions and bouncing back in challenging conditions.<sup>30–32</sup> This is often achieved through reliance on the whole surgical team.

Senior management is often not aware of the developed workarounds while staff when aware of device limitations, do not question an inefficient interaction and unremarkable errors which are not considered serious enough to report.<sup>33</sup> Workarounds often become normalised despite the introduction of system vulnerabilities.<sup>34</sup> Work is being done<sup>35</sup> to apply principles of resilience engineering such as safety-II approach to healthcare with the aim of ensuring successful outcomes by recognition and learning of good practice and functional adaptations to variations in work conditions.<sup>36</sup>

The acceptable level of risk for a device is assigned by the manufacturer. This does not take under consideration the ‘actual’ environment and context of use including patient and use variability and multiple devices which may lack compatibility.<sup>18</sup> Local risk management processes are not known to the manufacturer.<sup>18</sup> Hence, these risk levels should be carefully considered by healthcare trusts based on local circumstances. For these risk levels to be identified, good communication channels are required between manufacturers and end users.<sup>18</sup>

Good reporting is essential in allowing the organisation to learn about its vulnerabilities. When this data are used as a learning tool, it can improve processes and minimise or prevent future problems. A good reporting system should adequately inform manufacturers on the performance of their devices.<sup>37</sup> The ideal method of capturing safety events is thought to be a web-based electronic reporting system that is simple to complete and incentivises voluntary reporting.<sup>38 39</sup>

### Requirements for improvement of reporting system and data quality

Effective utilisation of end user experiences is an effective method of initiating change. The adoption of evidence

### Box 3 Main requirements for improvement

1. Adoption of evidence-based practice in device use.
2. Improve system transparency and feedback.
3. Develop systems that promote learning and knowledge sharing.
4. Utilisation of end user experience and knowledge for quality improvement.
5. Identifying both successes and failures to improve quality.
6. Evaluate performance rather than only failures.
7. Gain knowledge on workarounds and adaptations utilised.
8. Concentrate on incident prevention.
9. Improve data sources for clinicians to allow evidence-based practice.
10. Standardised training programme for clinical teams.

based practice is essential to create a patient safety environment.<sup>40</sup>

Currently, our patient safety efforts focus on identifying incidents and errors. This is a reactive approach with limited benefits.<sup>36</sup> A broader approach addressing the balance between failures and success is useful in improving quality in healthcare.<sup>36</sup> Data evaluating performance rather can lead to positive changes and be utilised to learn about useful workarounds and adaptations at the ‘sharp end’<sup>36</sup> (see box 3 for a summary of main requirements).

The rate of reported incidents is known to be very low<sup>41 42</sup> with data containing numerous biases.<sup>43</sup> They are at times used to measure safety performance, a function it was never intended to fulfil.<sup>44</sup> The focus on the incident data has led to many problems with incident reporting. More focus should be given to develop systems that allow learning and sharing of knowledge that can achieve greater prevention of patient incidents.<sup>45</sup>

### CONCLUSIONS

This study has taken a bottom-up approach to identify factors that lead to poor reporting of MD malfunctions and failures. The issues are numerous and complex contributing to the difficulties faced by clinical staff. This has an impact on the level of intelligent information transfer to clinicians and manufacturers and raises patient safety concerns. The focus on incidents has created many limitations in learning and development and performance data for evidence-based decisions. Having an appropriate performance reporting system that allows interaction with end users and management for data interrogation, can lead to informed decision making and assist in preventing patient related incidents.

Significant changes and thinking outside the box are required to overcome the discussed problems. The rich end user experience should be used appropriately with their involvement at all stages.

### STUDY LIMITATIONS

This is a medium size study. Being qualitative in nature, it brought large amount of data for analysis. Surgical devices

have a large impact on the care of surgical patient and the outcomes of surgery with findings thought to be transferable to other high-risk areas of healthcare. Further work should be carried out involving different groups of clinicians and devices. A small number of manufacturers completed the survey while saturation was reached during the semi-structured interviews. Further feedback from manufacturers is an area that could be developed further in future research.

**Contributors** AT carried out this research as part of a PhD Research programme and is the guarantor for the study. She developed the methodology with assistance from PWB and MZN, conducted the study and analysed the results. She wrote the original draft of this paper which was reviewed and amended by the other authors prior to submission. PWB and MZN provided regular input into the research methodology and data analysis of the study. They were involved in the review (internal and external) of this article. GBH was the overall supervisor for the research and the senior author for this article.

**Funding** The research was supported by the English National institute for Health Research (NIHR) MedTech and In vitro diagnostics Co-operative (MICs) program.

**Disclaimer** The views expressed are those of the author(s) and not necessarily those of the National Health Service, the NIHR or the Department of Health.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Ethics approval** Ethical approval for this study was granted by the Joint Research Compliance Office (JRCO) at Imperial College London. Ref: 19IC5455. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** All data relevant to the study are included in the article or uploaded as online supplemental information. Not applicable.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

### ORCID ID

Arkeliana Tase <http://orcid.org/0000-0003-1369-8543>

### REFERENCES

- 1 Campbell G. Statistics in the world of medical devices: the contrast with pharmaceuticals. *J Biopharm Stat* 2008;18:4–19.
- 2 Chapman AM, Taylor CA, Girling AJ. Are the UK systems of innovation and evaluation of medical devices compatible? the role of NICE's medical technologies evaluation programme (MTEP). *Appl Health Econ Health Policy* 2014;12:347–57.
- 3 ABHI. HealthTech for life, 2021. Available: <https://www.abhi.org.uk> [Accessed 12 May 2021].
- 4 AAMI-FDA. *Infusing patient safety: priority issues from the AAMI/FDA infusion device Summit*, 2010.
- 5 MHRA. *Medical devices -adverse incidents reported to MHRA 2011 -2013*. MHRA.gov.uk, 2013.
- 6 SUV T. *Wearable doctors: transforming the way we track manage and improve your health*, 2017.
- 7 ICST. *Safer interactive medical device design: insights from the CHI+MED project*. London, Great Britain: MOBIHEALTH, 2015.
- 8 Lalani C, Kunwar EM, Kinard M, et al. Reporting of death in US food and drug administration medical device adverse event reports in categories other than death. *JAMA Intern Med* 2021;181:1217–23.
- 9 International Consortium of Investigative Journalists. *The implant files*, 2020.
- 10 Doyle PA, Gurses AP, Pronovost PJ. Mastering medical devices for safe use. *Am J Med Qual* 2017;32:100–2.

- 11 Zhang J, Patel VL, Johnson TR. Advances in Patient Safety Evaluating and Predicting Patient Safety for Medical Devices with Integral Information Technology. In: Henriksen K, Battles JB, Marks ES, eds. *Advances in patient safety: from research to implementation (volume 2: concepts and methodology)*. Rockville (MD: Agency for Healthcare Research and Quality (US), 2005.
- 12 Alert SE. New alert promotes medical device alarm safety in hospitals. In: *Joint Commission perspectives*, 2013.
- 13 Organizations JCoAoH. *Comprehensive accreditation manual: CAMH for hospitals: the official Handbook: joint Commission on accreditation of healthcare organizations*, 2009.
- 14 Mayer EFK, Callahan R, Darzi A. *National reporting and learning system research and development*. Imperial College London and Imperial College Healthcare Trust, NIHR Patient Safety Translational Research Centre, 2019.
- 15 Improvement N. *The development of the patient safety incident management system (DPSIMS): project completes its alpha phase*. NHS, 2018.
- 16 Cumberlege J, Chantler CWS. *First do no harm – the report of the independent medicines and medical devices safety review*. Crown copyright, 2020.
- 17 Sidebottom CRH, Schmidt M. The role of risk management in the new IEC 60601-1. *J Med Dev Reg* 2006;8–17.
- 18 Suján MA, Koornneef F, Chozos N, et al. Safety cases for medical devices and health information technology: involving health-care organisations in the assurance of safety. *Health Informatics J* 2013;19:165–82.
- 19 Tase A, Buckle P, Ni MZ, et al. Medical device error and failure reporting: learning from the CAR industry. *J Patient Saf Risk Manag* 2021;26:135–41.
- 20 Commission E. *European medical device directive 93/42/EEC. classification of medical devices*, 2010: 1–51.
- 21 Improvement N. *Stakeholder analysis*. NHSi, 2018.
- 22 Nowell LS, Norris JM, White DE. Thematic analysis: Striving to meet the Trustworthiness criteria. *Int J Qual Methods* 2017:807–15.
- 23 Castleberry A, Nolen A. Thematic analysis of qualitative research data: is it as easy as it sounds? *Curr Pharm Teach Learn* 2018;10:807–15.
- 24 Yin RK. *Qualitative research from start to Finish: new York*. NY: The Guilford Press, 2011.
- 25 O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014;89:1245–51.
- 26 Commons Ho. *Fifth Report. Regulation of medical implants in the UK and EU*. (HCSTC) HoCSaTC, 2012.
- 27 Keselman A, Patel VL, Johnson TR, et al. Institutional decision-making to select patient care devices: identifying venues to promote patient safety. *J Biomed Inform* 2003;36:31–44.
- 28 Berru e M, Thiveaud D. Medical Devices Vigilance, «Mat eriovigilance», as an Actor of the Hospital Safety Culture. *Adv Intell Syst Comput* 2019:955–60.
- 29 Blandford A, Furniss D, Vincent C. Patient safety and interactive medical devices: Realigning work as imagined and work as done. *Clin Risk* 2014;20:107–10.
- 30 Weick K E SKM, Obstfeld D. Organising for high Reliability: Process of Collective Mindfulness. In: *Research in organisational behaviour*. Greenwich, CT: JAI Press, 1999: 81–124.
- 31 Bunderson JS, Sutcliffe KM. Comparing alternative conceptualizations of functional diversity in management teams: process and performance effects. *Acad Manag J* 2002;45:875–93.
- 32 Masten AS, Reed M. *Resilience in development Oxford*. UK: Oxford University Press, 2002: 74–88.
- 33 OBHC. Workarounds: Straddling or widening gaps in the safe delivery of healthcare. *Proceedings of the 7th International Conference in Organisational Behaviour in Health Care (OBHC)*; 11–14 April, Birmingham, UK, 2010.
- 34 Nemeth CP, Brown J, Crandall B, et al. The mixed blessings of smart infusion devices and health care it. *Mil Med* 2014;179:4–10.
- 35 Hollnagel E, Wears RL, Braithwaite J. *From Safety-I to Safety-II: a white paper. The resilient health care net: published simultaneously by the University of Southern Denmark, University of Florida, USA, and Australia*. Macquarie University, 2015.
- 36 Kelly N, Blake S, Plunkett A. Learning from excellence in healthcare: a new approach to incident reporting. *Arch Dis Child* 2016;101:788–91.
- 37 Kai S, Lipschultz A. Patient safety and healthcare technology management. *Biomed Instrum Technol* 2015;49:60–5.
- 38 Grant MJC, Larsen GY. Effect of an anonymous reporting system on near-miss and harmful medical error reporting in a pediatric intensive care unit. *J Nurs Care Qual* 2007;22:213–21.
- 39 Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ* 2000;320:759–63.
- 40 Gaffey AD. Embracing change to make health care safer. *J Healthc Risk Manag* 2016;36:6.
- 41 Vincent C. *Incident reporting and patient safety*. British Medical Journal Publishing Group, 2007.
- 42 Craig A OMP C. The need for greater reporting of medical device incidents. *EMJ Innov* 2019;54:71–95.
- 43 Noble DJ, Panesar SS, Pronovost PJ. A public health approach to patient safety reporting systems is urgently needed. *J Patient Saf* 2011;7:109–12.
- 44 Billings C. *Lessons learned from incident reporting in aviation. A tale of two stories: contrasting view of patient safety*. Boston, MA: National Health Care Safety Council of the National Patient Safety Foundation, 1998.
- 45 Macrae C. The problem with incident reporting. *BMJ Qual Saf* 2016;25:71–5.