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QUALITY AND PATIENT SAFETY

National critical incident reporting systems relevant to anaesthesia: a European survey

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Editor's key points

- Reliable incident reporting and dissemination of learning improves patient safety.
- Establishing a 'no blame' safety culture and ensuring legal protection will encourage greater incident reporting.
- Standardizing definitions, benchmarking, and closing the patient safety loop are important steps in this process.

Background. Critical incident reporting is a key tool in the promotion of patient safety in anaesthesia.

Methods. We surveyed representatives of national incident reporting systems in six European countries, inviting information on scope and organization, and intelligence on factors determining success and failure.

Results. Some systems are government-run and nationally conceived; others started out as small, specialty-focused initiatives, which have since acquired a national reach. However, both national co-ordination and specialty enthusiasts seem to be necessary for an optimally functioning system. The role of reporting culture, definitional issues, and dissemination is discussed.

Conclusions. We make recommendations for others intending to start new systems and speculate on the prospects for sharing patient safety lessons relevant to anaesthesia at European level.

Keywords: anaesthesia; clinical audit; critical incident technique; incident reporting, hospital; patient safety

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Critical incident reporting is a key component of patient safety.[1 2] Experience from risk management in other industries suggests that safety can be improved by learning from accidents and near misses. Optimal management of errors requires organizations to learn from the threats to safety, identify the underlying causes, and seek out opportunities for change.[3] Commonly, this involves the introduction of incident reporting systems (IRSs) which enable front-line staff to communicate their safety concerns and experiences of error to those responsible for safety and quality. These incident reports then provide organizations with the information needed to make proactive remedial changes to practice. Furthermore, there is often a great deal to learn from important individual reports.

Four key components must be optimized for IRSs to achieve their potential:[1] *Data input* must be encouraged with a non-punitive culture; the *data* themselves are best gathered by free text to allow as much detail as possible; *data analysis* needs time and expertise to turn the report into a 'lesson'; and *feedback* is essential not only to change practice but also to encourage further reporting. Reporting systems have been organized at a variety of levels: within individual departments of anaesthesia, within individual hospitals, at regional level, and at national level. While immediate analysis and feedback are essential at local level, wide dissemination of safety lessons can improve patient care on a larger scale. However, many countries do not yet have national systems for reporting

incidents arising from anaesthesia and critical care, and there is also no European platform for sharing the lessons from those countries that do. In this study, our aim was to compare the different IRSs operating in these European countries with a view to gathering intelligence which might help others establish new systems.

In addition, we aimed to bring together those who might in future collaborate to share the lessons learnt from incidents at European level.

Methods

A standardized questionnaire was sent out to representatives of nationally organized IRSs, which include reporting about anaesthesia in six European countries. The questionnaire invited free text responses on more than 30 questions grouped under seven headings (Table 1). We asked how and when systems started operating, how they were funded and publicized, and how they linked into local and other national systems. We also asked for data on the number of incidents and the processes of analyses and feedback, before inviting recommendations to those considering establishing similar systems in other European countries. We sent this questionnaire to representatives in Denmark, Finland, Germany, Spain, Switzerland, and the UK, as we were aware from preliminary work that these countries had national systems for incident reporting. Responses were analysed within the themes set out in the data collection tool and, specifically, advice for setting up new systems was extracted separately.

Results

The results of the enquiry are summarized and compared in Table 2. Detailed intelligence about each national system is presented below, in alphabetical order.

Denmark

The Danish National Board of Health raised the need for a patient safety IRS in 1997, but did not receive any support until after the publication of *To Err is Human* by the US Institute of Medicine in 1999.[4] A report from the Danish Institute for Health Services[5] showed that patient safety was similar to the situations in Australia, the UK, and New Zealand, where incident reporting was already developing. However, the electronic reporting systems were not quite suited to the Danish context and it was necessary to design a new one. Patient safety laws were passed in 2003, meaning that incidents are reported to the national patient safety reporting system in both public and private practice. In 2010, this was extended to include pharmacies, pre-hospital care, and the municipal health service. The online system was launched nationally in 2004, includes all incidents in all specialities, and is funded by the national budget (~€1 000 000 per year). Each hospital is required to have at least one safety representative in each department and between one and three patient safety managers. At regional level there is a patient safety unit with between five and ten managers. Nationally at the central authority (the Danish National Agency for Patients' Rights and Complaints or *Patientombuddet*), four full-time employees (two medical doctors, one nurse, and one pharmacist) are running the system and are disseminating learning nationwide. Anyone can report incidents using the system—including members of the public from 2011—although the public does not have access to the reports.

It is an extensive system in all hospitals with 140 285 cases (2004–2011) and in its second incarnation 156 000 cases (2010 until June 2012), a total of 296 285 reports.

Currently the system receives more than 150 000 reports in a year. After de-identification and local processing, the incidents are analysed at national level by the Danish National Agency for Patients' Rights and Complaints, which is responsible for disseminating learning nationwide. This is done using alerts, monthly newsletters, themed reports, annual reports, and by arranging 'awareness' days on specific themes. No regular/systematic analysis of the database is carried out. However, based on alerts from, for example, safety managers and safety representatives and special focus areas, specific analyses are carried out. Built-in search terms trigger an alarm in incidents of particular concern. Any publications using the database as a source are required to report their research findings to the central authority.

Since 2004, the central authority has issued 30 warnings about procedures/workflows posing a risk to patient safety and 18 major theme reports. The Danish system shares its findings internationally via the Global Patient Safety Alerts within the World Health Organization.[6]

In 2006, the system was formally evaluated: it was found to be well implemented and used but many healthcare professionals felt a lack of time to report and a lack of knowledge about what to report, and it was concluded that the system was not being used as effectively as it could be. The poor individual feedback to the reporter and the long lag time to follow-up with safety intervention were also highlighted. This led to changes in the law in 2010, which has since improved incident reporting in Denmark.

Finland

The IRS in Finland, HaiPro, was also developed after the publication of *To Err is Human* in 1999.[4] It started as a pilot project in one hospital—Helsinki University Hospital—in 2005, where 210 incidents were reported in a 4-month period. The system was gradually rolled out across the country in 2007 and now covers ~90–95% of hospitals in Finland and all specialties. Each hospital district pays for its own HaiPro. Although HaiPro is a national system, the reporting and resulting actions after the incidents take place at local level. Reporting is anonymous.

HaiPro is an online system aiming to capture all incidents and near misses with patient care, medications, and equipment anonymously within a 'no blame' culture. It is funded by the hospitals using it. By December 2012, more than 200 000 incidents from all specialities and all sections of healthcare, over the whole country, had been reported by clinical staff. Only in a few instances, has the report been filled out by a patient, assisted by a member of the nursing staff. Currently, the data

Table 1 Data collection prompts

History and development
How did the idea for a national (anaesthetic) reporting system start?
When did it start?
How did you publicize the system when it was starting up?
Did it start small and grow or did you aim for a national launch?
Current status
Does the system cover critical/intensive care? Emergency medicine? Perioperative care?
Do you have funding for the system? Where does it come from? How much is it per year?
How have funding arrangements changed since you started the system?
What form does the reporting system take (paper based, online, both, other)
Do you have a definition for users of the system of what is reportable? Or what is excluded?
What percentage of hospitals in your country is now taking part?
How many incidents are now in the database?
How do you manage the balance between confidentiality and identifiability?
Relationships with other systems
How does the system link to other local or national reporting systems (for instance, for reporting drug-related problems)?
Are these systems competing in some way or co-operative?
In the case of local departments of anaesthesia or hospitals, are incidents discussed/responded to locally as well as being submitted nationally?
Is there any sort of filtering/quality control locally before incidents are submitted to the national system?
Patient and public involvement
Is the general public and/or patient representatives, involved in any way in the running of the system?
Can members of the public/patients report incidents?
Are they involved in analysis or feedback?
Access and analysis
Are the incidents in the database analysed in any way?
Are the materials publicly accessible?
Can the database be searched by others—anaesthetic society members, the general public, researchers?
Feedback, outputs, impacts, pros, and cons
How do you feed back the learning from reported incidents to anaesthetists (e.g. rapid-response alerts about especially dangerous incidents, summaries on society websites, emails to members, newsletters, peer-reviewed publications, etc.)?
Have any publications resulted from the database?
What practical impacts/'success stories' have you had (media coverage, enquiries from other specialties, evidence of change of practice, feedback from colleagues, downloads of documents/website hits, etc.)?
Has your system been formally evaluated in any way?
General
What problems/difficulties have you had?
What advice would you give to anyone planning to set up a system from the beginning?
Is there anything else you would like to add, or anything else you would like the article to say about your system?

are analysed only within the hospital where they are reported, and the impact remains local, although this is currently being reviewed so that the educational value of such a system can be improved. The incident reports in HaiPro are fed back at monthly meetings in the anaesthesia units; they are not published anywhere. The official number of HaiPro reports in 2012 from the Helsinki University Hospital district, employing ~20 000 healthcare professionals, was 10 121. The number reported from the department of anaesthesiology and the intensive care unit was 951 (9.3%). Overall, the most common categorical reason for reporting incidents was errors or near misses in medication and various types of i.v. fluid therapy. These made up 42% of all reports filed by staff working in anaesthesiology, intensive care, and surgical units. The second most common reason was failure in communication and leadership (25%).

Feedback on the system is very positive. Initially, it was mainly the nursing staff that were using the system, but after several initiatives and patient safety projects (including the initiation of a national patient safety strategy for 2009–2013), doctors are now engaging with the system more. This strategy, elaborated by the Ministry for Social Affairs and Health, aimed to embed patient safety into the structures and practices in healthcare through involving patients, proper resourcing, and encouraging reporting of, and learning from, problems. Finland has had some difficulties with connecting and linking individual databases from different hospitals in the past, which is what led to HaiPro being conceived as it stands.

Table 2 Comparison of key characteristics of European IRSs; see text under individual countries for definitions of abbreviations

	UK	Spain	Germany	Denmark	Finland	Switzerland
When did it start?	2008	2009	2006 specialty specific; integrated into the national system in 2009	2004	2005	1998 2006—online joint system established
Associated organizations	RCoA, AAGBI, NPSA	Spanish Ministry of Health	DAGI, BDA, BÄK, KBV and ÄZQ			SSAR/SGAR, Patient Safety Foundation in Switzerland
Funding	UK NHS	Government grants and industry support	Individual hospitals	Danish Government	Individual hospitals	SSAR/SGAR, PSF, hospitals, and cantons
Other incident report systems	Overall system run by NRLS	New national IRSs—at pilot stage Adverse drug events	CIRSmedical.de—nationwide anonymous IRS—now fully integrated		Encompasses all incidents—not anaesthesia specific	Encompasses all incidents—not anaesthesia specific
Aims to capture	All anaesthetic-related incidents	All anaesthetic-related incidents	All incidents	All incidents	All incidents	All incidents including near misses
'Roll-out' strategy	3-month pilot of 12 hospitals before national roll-out	Pilot in 16 hospitals then rolled out to others slowly	All hospitals wanting to be part of the system have to send a representative to a training day	Nationwide	Pilot in one hospital, then rolled out to others	Pilot in 24 hospitals, currently in 43 hospitals
Coverage	National	70 of 800 hospitals currently	National—but only 64 hospitals paying for the service currently	National	90–95% of hospitals	15% of hospitals currently
Who can report?	Healthcare professionals	Healthcare professionals	Healthcare professionals—but the general public can read the de-identified incidents online	Anyone	Healthcare professionals—but patients can ask them to fill out a report	Healthcare professionals
Are the incidents analysed?	By consultant anaesthetists if submitted by e-Form	By anaesthetists—locally	Depends on hospital—2 different packages—none, or analysis by multidisciplinary team	Yes; depth depends on level of analysis (local/regional/national)	Local hospital analysis	Local hospital analysis
Feedback strategy	Quarterly summary unless high impact incident	Individual—unique number Local—email alerts National—rapid-response emails, summaries, and newsletter	'Case of the month'—interesting case Special—frequently reported incidents	Via weekly mortality reports from the national data Different areas of focus identified at local level	Monthly local departmental meetings	Via Quick-Alerts—published in specialist journals and PSF website
Number of incidents reported	1004 in 4 yr	More than 2800 in 3 yr	2700 in 6 yr	296 285 cases in 8 yr (now ~10 000 reports yearly)	More than 100 000 in 7 yr	More than 3000 reports in 8 yr
Any difficulties?	(i) Not all information required by individual trusts to investigate incidents is collected so some additional work is required by risk management (ii) The government body responsible for inception and development has been closed	(i) Lack of funding—unable to use national staff for formal evaluation of incidents (ii) Slow—but steady—introduction across the country (iii) Spanish law does not protect reporters—has been tackled	Initial concern over confidentiality and fear of sanctions—high levels of confidentiality and server security has addressed this	Formal evaluation led to identification of problems with knowledge of what to report, and finding time to fill out the report This was addressed via a change to the law in 2010	(i) Nursing staff engage more than physicians—being addressed by several initiatives (ii) HaiPro developed because of difficulty connecting individual hospitals IRSs	(i) Funding became an issue as the system grew—further funding channels identified (ii) Not currently in all hospitals nationwide

In any case, as each hospital and healthcare centre already has, or will have its own HaiPro officer (usually a clinical staff nurse), it will be possible to receive more detailed and speciality-related aggregated summaries of incidents in the next few years.

Germany

The German Society for Anaesthesiology and Intensive Care [*Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin* (DGAI)] and the Association of German Anaesthetists [*Berufsverband Deutscher Anästhesisten* (BDA)] endorsed the nationwide implementation of a web-based specialty-specific reporting and learning system, the Patient Safety Optimisation System (PaSOS), which was developed by the Patient Safety Centre in Tübingen (TüPASS) in 2006.[7] This system was felt to be practical and user friendly and was repeatedly publicized in the journal of the DGAI and BDA.

In 2006, the Federal Medical Council [*Bundesärztekammer* (BÄK)] and the national Association of Statutory Health Insurance Physicians [*Kassenärztliche Bundesvereinigung* (KBV)] commissioned the German Agency for Quality in Medicine [*Ärztliches Zentrum für Qualität in der Medizin* (ÄZQ)] to develop a parallel system. In addition, they asked the Agency to manage and develop the web-based reporting system 'CIRSmedical.de' into a national interdisciplinary reporting and learning network—an anonymous national database of incidents.[8 9] The executive committees of the BDA and DGAI decided in 2009 to integrate PaSOS into 'CIRSmedical.de', leading to one nationwide specialty-specific IRS after 2 yr of them running in parallel. At present, the IRS for anaesthesia and critical care, 'CIRS-AINS', is a subsystem of 'CIRSmedical.de'.

The system can be used in two ways: as a free access reporting system—without the need to register—and as an internal reporting system accessible only to members of specific anaesthesia departments. In the latter case, identification is granted via an individual Internet portal (IP) address and password and hospitals pay a monthly fee. At the moment, 79 hospitals use the system and have reported more than 3000 cases from 2006 to March 2013. The report form is a combination of check boxes and free text boxes which cover all areas of practice relevant to anaesthesia—perioperative care, intensive care, pain management and, pre-hospital emergency medicine. The only compulsory field is the nature of the incident.

The database can be searched using free text terms to find incidents of interest.[8] At least one member of staff from each hospital must have attended a 1-day training course before the hospital is able to use the system. Financing of the system is shared by BDA/DGAI and by users: BDA and DGAI provided financing for software development and for any updates, whereas running costs are funded by individual hospitals. The subscription fee is based on the number of physicians in the department and on what services the hospital wants from the system, and varies from 12€ to 510€ per month. The hospital is issued with a 'starter kit'—a series of PDFs—which includes pre-written letters to nursing and medical directors encouraging incident reporting and ensuring the absence of sanctions. In February 2013, the German government passed a law (the so-called 'Patientenrechtegesetz') which, for the first time in German history, grants legal protection of healthcare professionals who submit data into local or national reporting systems.

These reports are analysed by the German Agency for Quality in Medicine (ÄZQ) in Berlin and a staffed office of DGAI and BDA in Nuremberg. ÄZQ provides the server (a high-security server in Switzerland), keeps contact with the software developer, manages the website, and gets in contact with industry where necessary. DGAI and BDA contact participants, anonymize reports, and distribute the reports to a member of an interdisciplinary team of experts who will provide analysis. Depending on the package paid for this may be a basic summary, or may be a thorough analysis by anaesthetists, an interdisciplinary team of experts and a legal team. The incidents are then published on two websites, which can be accessed by anyone with an Internet connection. They are also published in the journal *Anästhesiologie and Intensivmedizin*, in PDF format via the website as 'Case of the Month' and as an extended analysis of frequently reported cases. The frequently reported cases—'CIRS-AINS special cases'—are made accessible to all physicians in Germany via publication in the German Journal for Evidence and Quality in Healthcare [*Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen* (ZEFQ)].[10 11] While critical incident reporting system (CIRS)-AINS as an internal reporting system is accessible only to members of specific anaesthesia departments, unrestricted reading by the public is allowed for the free access reporting system. In principle, all cases from the internal reporting system are transferred in full to the free access system unless the respective department vetoes its publication. The reports are cleansed of features that could provide clues to identifying departments or hospitals.

Spain

January 2009 saw the introduction of the 'Sistema Español de Notificación en Seguridad en Anestesia y Reanimación' (SENSAR), which had developed from the University Hospital Fundación Alcorcón Anaesthesia Department Incident Reporting System (IRS),[12] a hospital web-based Microsoft Access database™ that started in 1999. The pilot of the online web-based SENSAR started in two hospitals in 2008 and then was expanded to 16 hospitals that founded the SENSAR society. The Spanish Society of Anaesthesia (*Sociedad Española de Anestesiología y Reanimación*) and the Patient Safety Agency of the Spanish Ministry of Health endorsed the system. Since February 2009, the number of hospitals involved has grown and the system is now used in 70 of 800 Spanish hospitals. It covers all areas of anaesthesia from preoperative through to postoperative care and pain management, and has collected more than 2800 incidents since 2009. It is funded by government grants and industry support.

SENSAR is confidential and anonymous – each anaesthetic department is supplied with a generic user name and password—the database does not track via IP address or other

identifying markers as Spanish law does not protect the reporter. For this reason, incidents cannot be traced back for further analysis. Local analysis of the incidents by anaesthetists from the same department follows a common methodology[13] and departments can search the database for similar incidents. The members' section of the SENSAR website distributes alerts, guidelines, and discussion of incidents along with more general patient safety information.

Feedback is given in three different ways:

(1) Individual unique incident report numbers are issued to the reporter, who can then use this to look at the analysis and recommendations.
(2) Local safety committees provide local email alerts to the anaesthetists in the department.
(3) National rapid-response emails, SENSAR website summaries, newsletters, peer-reviewed publications, and conference meetings.

Multiple publications have come from SENSAR including the Spanish *Guidelines for Labelling of Injectable Drugs used in Anaesthesia*[14] and a special patient safety educational issue of the national anaesthesia journal, *Revista Española de Anestesiologia y Reanimación*.[15]

The Spanish Ministry of Health has recently launched a national general IRS that has just finished its pilot stage, and there is a national adverse drug reaction reporting system that has existed for 15 yr. SENSAR is looking at the compatibility between all these systems for the future. The main success of SENSAR is that it has brought patient safety to the minds of anaesthetists in Spain. Budget restrictions have prevented a dedicated national staff being employed by the system, although the slow and steady introduction across the country of SENSAR may change this in the future. National and regional meetings are being planned to support the departments new to SENSAR, and those falling behind, through the experience of the most successful ones.

Switzerland

Switzerland's Foundation for Patient Safety in Anaesthesia (*Stiftung für Patientensicherheit in der Anästhesie*) at the Swiss Society for Anaesthesiology and Reanimation [*Société suisse d'anesthésiologie et de reanimation/Schweizerische Gesellschaft für Anästhesiologie* (SSAR/SGAR)] has been maintaining a national CIRS since 1998,[16] based on the local development of a system at the University of Basel using Internet technology (CIRS) as long ago as 1997.

Progress at national level was hampered by the need to have the same electronic reporting system locally available in order to participate at the national system, as more and more hospitals developed their own reporting system locally. The Patient Safety Foundation in Switzerland, a nationwide organization, stepped in and offered a partnership with the SSAR/SGAR to develop a national IRS that allowed data input from various local reporting schemes. Together they developed Critical Incident Reporting and Reacting NETwork (CIRRNET) in 2006.[17] The project is mainly funded by the Patient Safety Foundation, with support from SSAR/SGAR, participant institutions, and the Swiss cantons.

The pilot project involved 24 hospitals with anaesthetic departments; this was expanded in 2009 to all medical departments (not just anaesthesia departments) of the hospitals involved. Currently, 43 hospitals (~15% of Swiss hospitals) are part of CIRRNET. Risk managers at local level decide which incident reports are uploaded—encrypted and anonymous—online to the national database. These local systems in the majority of cases are connected electronically to the national database. In addition, individual cases can be reported manually, in French, German or English. The system is complemented by a national group of selected experts in anaesthesiology, which acts as a review board for the published national recommendations ('*Quick-Alerts*'). In addition, a steering committee of representatives from the SSAR/SGAR and the Patient Safety Foundation oversees the incoming cases in order to detect clusters or important single cases that would form the basis for the alerts. As of September 2012, the database contains >3000 incident reports. Since the start of CIRRNET, 29 *Quick-Alerts* have been published via national and international mailing lists to Germany and Austria and in specialist journals. Various national groups and societies comment on the alerts before publication, to involve as much expertise as possible. The *Quick-Alerts* can be downloaded from the Patient Safety Foundation's webpage.

The UK

There has been a national healthcare-wide IRS [the National Reporting and Learning System (NRLS)] in the UK since 2006. The NRLS has been collating patient safety incidents from public hospitals in England and Wales (though reporting is mandatory only for deaths and severe harm) and is funded by the National Health Service (NHS). In response to senior anaesthetists' opinions that specialty-specific feedback and incident reporting would help to enhance reporting, the National Patient Safety Agency (NPSA) in conjunction with the Royal College of Anaesthetists (RCoA) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) developed the 'Anaesthetic e-Form'. A 3-month pilot in 12 hospitals was carried out in 2008 by the Safe Anaesthesia Liaison Group (SALG); its success led to the introduction of the system to the whole of England and Wales in 2009. Workshops were held around the country to publicize the new system. The e-Form aims to capture all incidents related to anaesthesia and, therefore, collects a breadth of information. It allows all members of healthcare staff to report any problems encountered and is not limited only to critical incidents, leading to information sharing about problems that may not be immediately obvious to individual hospitals.

By the end of June 2012, 1004 reports had been logged on the system. These have been reviewed by consultant anaesthetists from SALG; they are then de-identified and shared nationally in a quarterly summary. If an incident is reported via the e-Form, the risk management department in the relevant hospital is automatically notified; however, if an incident is

reported via the generic NRLS, it will not be copied into the e-Form data. Thus, the e-Form mechanism contains only a proportion of anaesthetic incidents, but reports are generally highly relevant and of good quality. There is also a rapid-response system if serious incidents occur. Lessons learnt from the system are thus available to support individual reflection and departmental education.[18–21] The system complements other national NHS reporting systems for equipment and drug reactions (through the Medicines and Healthcare Products Regulatory Agency, the latter via the long-standing 'yellow card' system) and for reactions to blood products. Users of the e-Forms are directed to use these reporting systems as well if relevant to the incident reported. We suspect that the use of several systems leads to some duplication, but also to some failures to report some incidents at all.

Discussion

We have detailed IRSs from six European countries. Some are exclusive to anaesthesia, while others aim to cover the whole of healthcare. We will discuss some of the resulting themes in the following paragraphs.

Incident reporting had its origins in military aviation,[22] but was adopted into safety-critical industries in the second half of the 20th century. Anaesthesiology was the first specialty to make use of the technique in clinical care and, although the few randomized trials to investigate the effect of incident reporting in healthcare generally have not suggested great benefit,[23] it has been well received in our specialty.[24] The narrative element makes incident reports accessible and memorable,[25] and the potential for improving the safety and quality of care seems self-evident. Reporting can be organized at local,[26 27] regional,[28] and national levels.[2] The systems described demonstrate that for a system to function effectively, the different levels need to complement each other. Initial reporting, incident handling and analysis,[29] and dealing with immediate implications must all happen at local level. However, national involvement can complement this in a number of ways—for instance, by establishing a framework to encourage local reporting or by linking departments together to share lessons learnt. It also enables wider surveillance of problems, allowing clusters of reports relating to specific problems to be identified, and also identifying rare but serious events where local action might be insufficient.

An important aspect of reporting is the safety culture within which the system operates.

Industrial reporting systems promote a 'no blame' culture, where reporting is valued and individuals are disciplined if they do not report relevant safety problems, rather than if they do. If healthcare insurers, providers, or both, offer a no-fault system for compensation, this would also be expected to help reporting. However, there is still the perception in healthcare that acknowledgement of problems might lead to disciplinary action from an employer or the threat of legal action from an affected patient. This is a major barrier to reporting.[30 31] A further issue is whether incident data are disclosable in legal cases. The situation varies in the different countries surveyed. In the UK, it differs depending on the level of reporting considered. At local level, NHS organizations are obliged to reveal information on untoward incidents to the patient concerned under a newly introduced 'duty of candour'. This would include incident data, although if the incident is made known to the patient, the report is unlikely to contain any more detail. At national level, NRLS incidents are anonymized and confidential and not available. This is also the case in Denmark. Likewise, in Switzerland, data are anonymized and it is not possible to trace reports back to individual clinicians.

The introduction of an incident reporting scheme could in itself help to change the culture for the better as, if it is run properly with appropriate engagement and support from senior hospital management, it demonstrates that the 'no blame' approach is real and not an impossible fantasy. Some have suggested that couching the requirement to report incidents in terms of a professional ethical responsibility is effective[32] and indeed, a continual striving for improvement is one of the hallmarks of excellence in anaesthesia.[33–35] The right culture can also be promoted through practical measures, such as the de-identification of reporters, protecting reporters and 'whistle-blowers' from unwarranted reprisals, and providing meaningful feedback. Likewise, national laws also play their part in incident reporting. In Spain and in Switzerland, it appears to be necessary to anonymize any nationally shared incidents as there is no law to protect the person or hospital reporting, whereas in Denmark the law encourages healthcare staff to report incidents. However, as noted above, from this year, healthcare professionals in Germany are protected by law if they report incidents.

Government-run systems are more likely to have greater funding but also more likely to involve patients and the public in reporting of incidents, analysis of incidents, or both. It would be wrong, however, to suggest that specialty-specific and government-run systems are exclusive. It is clear from the experience in many countries that they work best when they work together. Thus specialty-specific systems have looked to government to help promote and fund their activities, while those running national schemes have realized that proper engagement with clinical specialties brings its rewards. Finally, national initiatives are necessary to ensure that where there are multiple reporting systems, important safety messages are not lost. For instance, in Finland, Switzerland, and the UK, there are additional arrangements for reporting problems with medical equipment, problems with medications, and the hazards of blood transfusion.

The issue of what to report—that is, how a reportable incident is defined—is important. If there is too loose a definition, many events that have no value find their way into the system, and on the other hand, if there is too strict a criterion for reporting, there is a danger that useful lessons will not be learnt. While anaesthetists may have their own, often unspoken, operational definitions of what is reportable,[36 37] it can help to have an 'official' definition. Thus, the Spanish system uses the latest World Health Organization definition ('an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient')[38] and the UK National Reporting and Learning

Service is similar ('any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care'). This is often glossed over but decisions on definition can affect the balance between the quantity and quality of incidents within the system. In addition, everyday experience, in the UK at least, suggests that it is common for staff to use the IRS to vent frustrations with inadequate systems; their concerns may be valid, but such reports can distort the data.

There are judgements to be made, too, at a higher level in the system; here, the composition and expertise of expert groups who undertake the filtering and identification of material to be shared, is crucial. A prior decision on what level of 'evidence' might need to be met before alerts are issued might be helpful. There is always a balance to be struck between disseminating early warnings of possible threats and waiting for better evidence.

Taxonomies for classification must be decided; if incidents can be classified according to useful analytical categories when they are received, it makes further analysis more straightforward. At least two generic analytical taxonomies are currently available.[39 40]

Feedback on reported incidents is also vital.[41] Without it, staff feel that reporting is futile, and this acts to discourage reporting still further. It is no surprise, then, that the most successful systems have given careful thought to multiple methods of dissemination. Finally, attention to the various mechanisms of reporting is important; there are many possible means through which clinicians can report—paper-based, on-line, smart phone, etc.—and we do not know which methods work best, either singly or in combination.

There are alternatives to incident reporting as it exists. The analysis of routinely collected data[42] can help improve the safety and quality of care; some countries, for instance Hungary,[43] Germany,[44] and Denmark,[45] have large-scale anaesthesia databases already, but these are established for a different purpose and are complementary to incident reporting. They do, however, have some limitations, such as the need for data cleaning and the absence of explanatory text, making interpretation more difficult. Further, incident reports may suffer from bias and one alternative is to observe actual practice for remediable problems.[46 47] However, although this can be revealing and would certainly get round the problem of underreporting, it would be highly labour-intensive and might be seen as both intrusive and threatening by staff. Finally, we should bear in mind that, although the 'critical incidents' we aim to gather and analyse in medicine are negative events, Flanagan's original work with the trainers of aircraft pilots invited them to describe desirable traits as well as potentially dangerous behaviour.[22] So perhaps we should aim to encourage the promotion of enhancements to safety as much as aspects that threaten it.

Besides all the advantages that incident reporting has at local level, the national or large-scale collection of critical incidents also has its potential. The main advantage at national level lies in the learning aspects. Additionally, certain clusters of similar events that only rarely happen in one place might perhaps show more readily visible patterns on a larger scale. Alerting a larger number of anaesthetists to a problem can potentially prevent it from recurring in other places. The disadvantage of a national reporting system often lies in the isolation between the reporter and the incident reporting administrator. Because of its often anonymous or de-identified approach, questions from the administrator back to the reporter are often not possible, hindering the clarification of certain details, perhaps not initially reported.[48] Another aspect of IRSs (either locally or nationally) is the importance of individual cases.

Table 3 Recommendations for starting a new IRS

Preliminaries
• Do not start the system before explaining the blame-free systems approach of the reporting system to potential reporters
• Start small, gain experience, and only then roll-out the system for wider use
• Do not start without secure financial and staff resources (if possible)
• Define the scope of the project early
• Prepare a 'starter kit' for reporters and safety officers
• Establish whether potentially overlapping systems already exist and decide how they will interact with the new system
System features
• Define or adapt the taxonomy to use in the analysis clearly
• Create multiple solutions for data input into the national incident database
• Keep the reporting form concise and clear
Feedback and analysis
• Regularly scan the database for clusters of similar situations or individual important cases
• Schedule feedback to reporters and use all possible means (local meetings, email alerts, bulletins, paper contributions, etc.) to provide it
• Set up an advisory board of experts to judge the relevance of the submitted incidents and invite this advisory board to edit the published recommendations
Dissemination
• Build local or regional networks to expand system and provide feedback and continuous education to safety officers in a cascade mode
• When writing recommendations, involve the important experts on the relevant topic
• If medical devices are involved, contact the manufacturer and try to publish recommendations jointly with that company

Individual cases have a powerful narrative element which makes them memorable, but it must also be remembered that, if a severe problem is reported, one case is enough to trigger some action; large case series are not needed.

What advice can be offered to those considering setting up a new system? In general, where systems have arisen within the specialty, they have been pioneered by enthusiasts, and grown gradually from small beginnings. Nationally designed systems are usually established by governments and may or may not have involvement from individual clinical specialties from the outset (though are more likely to show meaningful results if they do). Involving potential users is vital.[49] National expert groups that serve as review boards or steering committees are important for these national systems, because they guarantee the quality of the content of any recommendations issued. Additional recommendations from respondents on starting a new specialty-specific reporting system are given in Table 3.

Finally, one possibility is to transcend national boundaries and work at European level to spread the national recommendations more widely. Clearly, this would not be an international reporting system, but would be conceived more as a platform to share the safety lessons reported through national systems more widely throughout Europe. This would be in line with the aims of the Helsinki Declaration for Patient Safety in Anaesthesiology[50] and indeed is one of the activities occupying the joint European Society of Anaesthesiology/European Board of Anaesthesiology Patient Safety Task Force. Further work is needed to determine what sort of incidents, national recommendations, or both should be shared and how this would be achieved in practice, but given that there is a clear willingness to improve patient safety still further in anaesthesiology in Europe, this seems to hold great promise for the future.

Authors' contributions

S.R.: data co-ordination and writing the first draft of the article. D.A.: study design, data collection and analysis, and critical revision. O.F.: data collection and analysis, first draft of the paper, and critical revision. J.I.G-A.: data collection and analysis, first draft of the paper, and critical revision. J.H.: data collection and analysis, first draft of the paper, and critical revision. O.L.: data collection and analysis, first draft of the paper, and critical revision. K.L.M.: data collection and analysis, first draft of the paper, and critical revision. T.R.: data collection and analysis, first draft of the paper, and critical revision. P.H.R.: data collection and analysis, first draft of the paper, and critical revision. A.S.: data collection and analysis, first draft of the paper, and critical revision. M.S.P.: data collection and analysis, first draft of the paper, and critical revision. S.S.: study design, data collection and analysis, and critical revision. A.F.S.: conception of the idea for study, study design, critical revision, and guarantor for the work.

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