Topic Expert Group: **Patient safety and hygiene practice**

Threat, error and success reporting: How to effectively practice error management

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Target group
Infants, parents, healthcare professionals, neonatal units, and hospitals

User group
Healthcare professionals, neonatal and paediatric units, and health services

Statement of standard
Incident reporting systems must be mandatory for all neonatal wards and have to be embedded in comprehensive safety programmes to effectively improve healthcare safety.

Rationale
To improve patient safety, it is fundamental to learn from critical incidents. (1–7) High-risk high-consequence systems, such as the nuclear industry and, more broadly recognised, the aviation industry, are commonly known to implement Critical Incident Reporting Systems (CIRS) to reduce the risk of potentially catastrophic events. (3,8,9) Hospitals are high-risk high-consequence environments as well, which makes CIRS an attractive tool to enhance patient safety. Fortunately, an increased use of CIRS in the health sector can be observed, facilitated also by several nationwide policies. (10,11) However, in healthcare systems, concerns about the effectiveness of CIRS were raised mainly owing to the isolated implementation of CIRS and a persistent lack of numerous other safety measures. (1,2,12) A standalone error reporting system without other components may not be perceived as the helpful tool it may well be. (13,14) Therefore, multiple studies are available analysing comprehensive safety bundles, which include, beneath others, the implementation of error management systems. (15) These safety bundles include the implementation of standards, checklists, compulsory regular training, deliberate employee selection, and the development of a safety culture based on just culture principles. (4,16) Also, available CIRS systems often lack basic requirements for effective incident analysis, which might lead to ineffective detection, prevention of preventable harm leading to a false impression of safety. (1,2,12)

The barriers to incident reporting are well known, also in hospital settings. (1,10,12,17) For successful work on patient safety with long-lasting effects, it is paramount to resolve these issues.

Benefits

Short-term benefits
- Reduced preventable harm (adverse events, e.g. medication errors, incompatible blood transfusions) (15,17–20)
- Improved safety culture and better identified threats for patient and employee safety (12,17,20,21)
- Provides the possibility for wards and institutions to learn from each other (12,22)
- Identifies fields with need for medical training (20,21)

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- Identifies areas where implementation of technologies supports medical teams to avoid medical errors (20)

Long-term benefits
- Optimised processed, less workload, reduced conflicts and stress for employees, reduced employee fluctuation, less sick-leave and, consequently reduced recruiting and training costs for hospitals (23–26)
- Increased satisfaction of parents and families with ongoing treatments as well with response to errors/failures that have taken place (27)
- Enhanced patient and employee safety (4)
- Improved staff well-being and safety (23,24,28)
- Reduced level and length of intensive care treatment and length of total hospital stay (29)
- Improved long-term patient outcome, therefore, higher quality of life, and, consequently, reduced costs for families and communities (24,27,30)
- Reduced costs for treatment, lawsuits and insurance costs (31)

Components of the standard

Component	Grading of evidence	Indicator of meeting the standard
For parents and family		
1. Parents and families are informed about safety programmes (e.g. existence of CIRS, how to use it, contact information). (32–34)	B (Moderate quality)	Audit report, patient information sheet
2. Parents and family members are encouraged to speak up and to participate in reporting errors, threats and successes, and are provided with information on how to do so. (32–34)	A (Moderate quality)	Audit report, parent feedback, patient information sheet
For healthcare professionals		
3. A local interdisciplinary and interprofessional safety team with special education/training in healthcare safety (safety officer), is created. Members are non-superiors, bed-side employees, and include all neonate-related medical professions (nurses, doctors, midwives, pharmacologists, psychologists). (19,35,36)	A (Moderate quality)	Minutes of team meetings
4. All employees receive basic education and recurrent training in system safety, safety culture, human factors, organisational factors and feedback. (19,37–41)	A (High quality)	Training documentation
5. There are clearly defined adverse events, which compulsorily have to be reported by employees. (10,15,42,43)	A (Moderate quality)	Audit report, healthcare

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		professional feedback
6. Employees are trained in how, when and what to report (training frequency of 6 to 12 months recommended). (15,19,37,40,41,44)	A (Moderate quality)	Healthcare professional feedback, training documentation
7. Employees are able to report threat and errors anonymously in reporting systems that are easily available and accessible. (1,10,22)	A (High quality)	Healthcare professional feedback
8. Employees are invited to participate in the investigation process and receive feedback following their reports for follow-up. (1,10,22,40,41)	A (High quality)	Healthcare professional feedback
9. All employees receive regular feedback on long-term safety improvements and key performance indicators. (1,10,22,35,40,41)	A (High quality)	Healthcare professional feedback
For neonatal unit		
10. A local interdisciplinary and interprofessional safety team with special education/training in healthcare safety is in place.	B (High quality)	Healthcare professional feedback, minutes of team meetings, training documentation
11. The members of the local safety team are selected deliberately according to their personal knowledge, skills and attitude, non-technical competencies and level of experience in the according medical field.	B (High quality)	Healthcare professional feedback
12. The local safety team is provided with sufficient time and resources within normal working hours to perform safety work. Time for safety work is made available exclusively, not in addition to usual bed-side care and other already existing duties.	B (High quality)	Healthcare professional feedback
13. Management commitment is given in written form that reports of threats, errors and adverse events, will never lead to any consequences and impact on personal or professional levels according to just culture principles. (39,45)	A (High quality)	Healthcare professional feedback

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For hospital		
14. The hospital provides easy access to a system for incident reporting. (10,20,46)	A (High quality)	Audit report
15. The reporting system is operated by specifically educated and trained safety officers with a background in the according medical field and is hosted externally. (22,37)	A (Moderate quality)	Audit report
16. Sufficient time and financial resources are provided for education and training of all employees in healthcare safety issues. (22,40)	B (High quality)	Healthcare professional feedback
17. Full-time jobs are created for specifically trained employees to focus exclusively on healthcare safety (systemic investigations, implementation and follow-up). (19)	B (Moderate quality)	Audit report
18. Regular reports on safety key performance indicators (KPI) have to be provided to hospital management by local safety teams. (40)	A (Moderate quality)	Audit report
For health service		
19. Healthcare safety is embedded in current educational curricula for all occupational groups in the healthcare system. (47)	B (High quality)	Training documentation
20. Certified education and training programmes for healthcare safety are available ("Safety Officer"). (48)	B (High quality)	Healthcare professional feedback, training documentation

Where to go – further development of care

Further development	Grading of evidence
For parents and family	
• Parents and family members are part of healthcare safety programmes and participate in investigations following safety reports.	B (Moderate quality)
For healthcare professionals	
N/A	
For neonatal unit	
N/A	
For hospital	
• Install full-time Safety Officers in all patient-treating wards.	B (Moderate quality)

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• Create networks for neonatal healthcare safety to allow different institutions to learn from each other.	B (Moderate quality)
• Enable and commit all employees to participate in basic education and recurrent training in healthcare safety.	B (Moderate quality)
For health service	
• Create and install new professions such as Safety Officer with appropriate education and training possibilities.	B (Moderate quality)
• Make safety teams and a safety officer mandatory in all patient-treating wards. The Safety Officer must be active in his medical field for at least 20% of his working time or have an adequate professional experience for 10 years or more.	B (Moderate quality)
• Make anonymous, voluntary reporting systems mandatory for all patient treating wards.	B (Moderate quality)

Getting started

Initial steps

For parents and family
- Parents are routinely informed about the importance of safety culture and are encouraged to speak up for threats, errors and success.
- Parents are provided with access to the anonymous reporting system to anonymously report threats, errors and success.

For healthcare professionals
- Complete courses, educational programmes or academic studies in healthcare safety.
- Inform yourself about ongoing healthcare safety programmes in your institution.
- Educate yourself with practical-related high-quality manuscripts (1,12,22,45), and recommended literature (see Description).

For neonatal unit
- Install a local safety team.
- Educate and train your local safety team in healthcare safety by providing courses or send them to educational programmes or academic studies.
- Provide all healthcare professionals with anonymous, easy-access possibilities to report threats, errors and success (e.g. electronic or as a start analogue letterboxes).
- Organise regular local education for all healthcare workers in your ward to inform them about the potential and benefit of safety work.
- Collect ideas, worries and threats from employees, prioritise and delegate safety issues to small teams and start first safety initiatives.

For hospital
- Organise regular local education for all healthcare workers in order to inform about the potential and benefit of safety work.
- Offer to organise and compensate for external education in healthcare safety.
- Encourage your employees to participate in healthcare safety projects and demand for improvement reports.

For health service
- Evaluate safety programmes in medical institutions and make them mandatory for all patient-treating wards.
- Install certified educational programmes in healthcare safety.

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Description

After numerous catastrophic events in the last century, the aviation industry was forced to improve flight safety. In a decade-long process of systematic investigations of accidents and incidents, a bundle of measures was implemented step by step. These measures included deliberate employee selection, standardisation of processes, the obligatory use of checklists, mandatory training and regular checking and – above all – the development and support of a safety culture based on just culture principles. As the last step in this process critical incident reporting systems (CIRS) were implemented in order to continuously improve and to identify new issues to increase aviation safety. (3,8) Similar measures were undertaken in other risk areas, e.g. the nuclear industry. (9)

Healthcare shares the high-risk, high-consequence characteristics of the aforementioned industries. Yet, CIRS has only recently begun to attract the medical field, commencing its integration to hospitals after the widely recognised publication "To err is human". (7) To date, an increasing number of medical institutions, partly pushed by nationwide incentives (10,11), adapted CIRS to report errors and to improve the care and safety of patients.

It must be emphasised, however, that the implementation of CIRS in other high-risk areas was implemented as a last step, only after a whole bundle of safety measures had been established. In many medical institutions, however, CIRS is operated as the first or often isolated measure to increase patient safety. (1,16) CIRS on its own, without the existence of the underlying basis for it (how to report, how to respond, etc.) is not sufficient (13,14,49) and thus inadequate to contribute to a successful improvement of patient safety in the long run. (1,2,12)

Requirements for a functioning CIRS
In general, for the effective processing of reports, several requirements need to be met that are listed in the components of the standard and are described here and in figure 1 in more detail:

1) Concerning the user (healthcare workers):
Since healthcare safety so far is still underrepresented in most educational curricula, medical employees only rarely have education or training in healthcare safety; often there is a lack of knowledge on how to identify safety issues or to implement changes. It has been shown that a lack of information of the healthcare workers on what and how to report seems to be an important barrier that hinders employees from reporting incidents. (1,10,12,35,39,50) Regular training on what and how to report, therefore, seems to be the fundamental basis of a functioning CIRS. While the exact interval for recurrent training is unclear, training effects likely deteriorate after 12 months of the intervention. (44) Recurrent training intervals of 6-12 months, similar to the aviation industry, therefore, are advisable.

What to report:
Regarding the results of most reporting systems in the medical field, the focus still seems to be on the number of reports ("the more the better"). (1,22,35) However, it is the investigative process that should be the core measure of CIRS as well as the strategies to implement the required changes. (1,34,38,46) Therefore, it is not effective to report every single incident or threat. (1,35) Instead, employees need to be informed (through education and training) on how to deliberately decide, which incident implies the potential to learn/to improve safety, and which incident does not. (1,22,35) Furthermore, all employees need to understand which adverse events are mandatory to report (see below).

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How to report:
Employees require education and training on how to describe an incident and what language to use. (51) This facilitates the reporting and also the investigative process can be done as easy and as effectively as possible.

Voluntary or mandatory?
Unlike in aviation, reporting in medicine happens on a voluntary basis. Voluntary (and anonymous) reporting is reasonable when it comes to delicate issues preferably handled confidentially and which might not be reported otherwise. However, it cannot be accepted that the decision, whether to report an incident with preventable patient harm, relies on the willingness of certain individuals which commonly results in underreporting of critical issues. (1,19,20,39) Therefore, trigger tools should be used (43), i.e. adverse events with an obligation to report have to be clearly defined and brought to the knowledge of all employees. (1,22,35,43) The purpose of the compulsory part of the reporting system is to monitor the frequency of events and to track undesired outcomes. (22) The basic prerequisite is that notifiable events are being reported in practice. A decrease in reporting can mean both an improvement in this area, as well as a lack of safety culture and compliance. (13,14,49) However, a functioning mandatory reporting and visualisation of adverse events might be helpful in creating the pressure on decision-makers to provide sufficient resources for healthcare safety issues.
Hence, an effective reporting system on the one hand enables voluntary reports of threats, errors and success, and on the other hand includes the mandatory report of clearly defined adverse events.

2) Concerning the CIRS-analysts:
Since the investigative process is the core of every reporting system, analysts require not only knowledge in the certain medical field (e.g. neonatology) but also need appropriate knowledge, skills and attitude, basic education and recurrent training and deep understanding of healthcare safety. (22) This includes, amongst others, knowledge about safety and just culture, human factors, organisational factors, principles of safety I and safety II, root-cause analyses and change management.

3) Concerning the reporting system:
The following qualities are essential for a well-designed reporting system in order to enable effective reporting and processing (1,17,22,39):

- Anonymity, including no mentioning of the specific ward or medical field, if not voluntarily provided. Only the guarantee that a certain incident report cannot be followed back to a certain person will enable barrier-free reporting.
- Despite reporting anonymously, analysts need to have the possibility to ask additional questions or clarify certain aspects of the incident. Therefore, a communication tool is required between user and analysts, preserving anonymity.
- Preferably use external analysis (other institution or external CIRS provider) to ensure anonymity and to reach greater experience by choosing professional providers.
- Reports or proposed solutions must not be provided to superiors directly, but to the local safety team only (with education and training on how to respond). This is to avoid hierarchic problems and to ensure that reports/solutions are analysed and dealt with special care. The local safety team can further discuss implementation strategies and next steps to take.
- Reporting must not be limited to reports of errors, but also includes threats and success. Since focus lies on learning to improve safety, solutions that have proved to be successful are of great value.

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- Reporting must be accomplished easily and fast with clear questions to describe the incident as appropriate as possible.

4) Concerning the local safety team:
It is important to emphasise that healthcare safety is a very extensive and complex field and a local safety team with education and regular training in healthcare safety is paramount for success of CIRS. A randomly chosen person for safety issues without specific knowledge (sometimes involuntarily nominated by superiors, working alone and without appropriate resources) will not be able to effectively resolve safety issues.

The local safety team serves as a link between CIRS-analysts and users (healthcare workers) when it comes to the implementation of proposed solutions and adaptation on certain local conditions. CIRS-analysts provide the information of the reported incidents, results of the root-cause analysis (or complete them together with the local team) and - if possible - provide solutions for the reported safety issue. The local safety team then discusses the proposed solutions on feasibility considering the certain conditions of the ward and induces possible ways on how to implement the necessary changes.

5) Evaluation and monitoring
The process of reporting, investigation and change has to be continuously monitored and evaluated. Evaluation can be done best by the users themselves, working bed-side and, therefore, experiencing impact of changes first-hand. However, sufficient (financial and personal) resources for monitoring must be provided and reports must be demanded on regular intervals by the management.

Financial aspects of CIRS:
Establishing and maintaining a successful and effective CIRS with all of the above-mentioned components (CIRS system, personnel, education and training, etc.) requires major financial resources. Such high initial costs combined with non-existing legal obligations appear to be a deterrent and may be the reason why CIRS is often not fully implemented. However, sustainable planning is required and a comprehensive CIRS system can be seen as a financial investment in risk-reduction. (52) It is estimated that on average one adverse event in an acute patient exceeds 13,900 € within one year and, therefore, is doubling the normal healthcare expenses per patient; the estimated accumulated costs of adverse events per annum in Danish Hospitals alone is 3.1 billion €. (51) Also, approximately 15% of the total hospital expenditures in OECD countries can be attributed to adverse incidents, approximately half of which is considered avoidable patient harm. (31) Furthermore, the calculated costs thereof are immense: 606 billion dollars, equalling 1% of the economic output of all OECD members combined, are spent on avoidable safety lapses. (31) Quality improvement strategies such as the implementation of a comprehensive and functioning incident reporting system, therefore, seem to far outweigh the costs of implementation and maintenance.

CIRS is not a measuring tool
It is important to notice that CIRS is neither effective for benchmarking, measuring patient safety, nor for analysing improvements over time. (12,22) Some reports might reflect on low occurrence of errors, but as discussed above it might as well point to a low willingness to report, insufficient safety culture and non-reporting. (13,14,49) Therefore, to reiterate, the core of CIRS must not be reporting but the focus must be on effective, long-lasting solutions to improve healthcare safety.

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Cultural aspects and just culture

In order to establish a functional and meaningful incident report system, certain interwoven culture-related aspects have to be taken into account. A common safety culture must be developed (4,39,45,53), in which failure/error or adverse events do not lead to shame or blame of the reporting healthcare professionals. Instead, employees must feel psychologically safe to report without fear. Thus, the first question after an event must not be "Who did this" but "How could this happen?". Errors, for example, that occur due to system-immanent conditions must not be at the expense of individual employees.

Following just culture principles, an analysis must classify for each failure whether it was caused by human error (unintended outcome, often system-immanent, could have happened to anyone), due to risky behaviour (risky, but deliberate decision, made e.g. under pressure), recklessness (knowing that the action is not safe) or on purpose. (45,53,54) Depending on each individual case, failure that occurred because of intentional non-compliance, due to recklessness or risky behaviour must not be tolerated and employees must be aware of both the differences and the consequences of these actions.
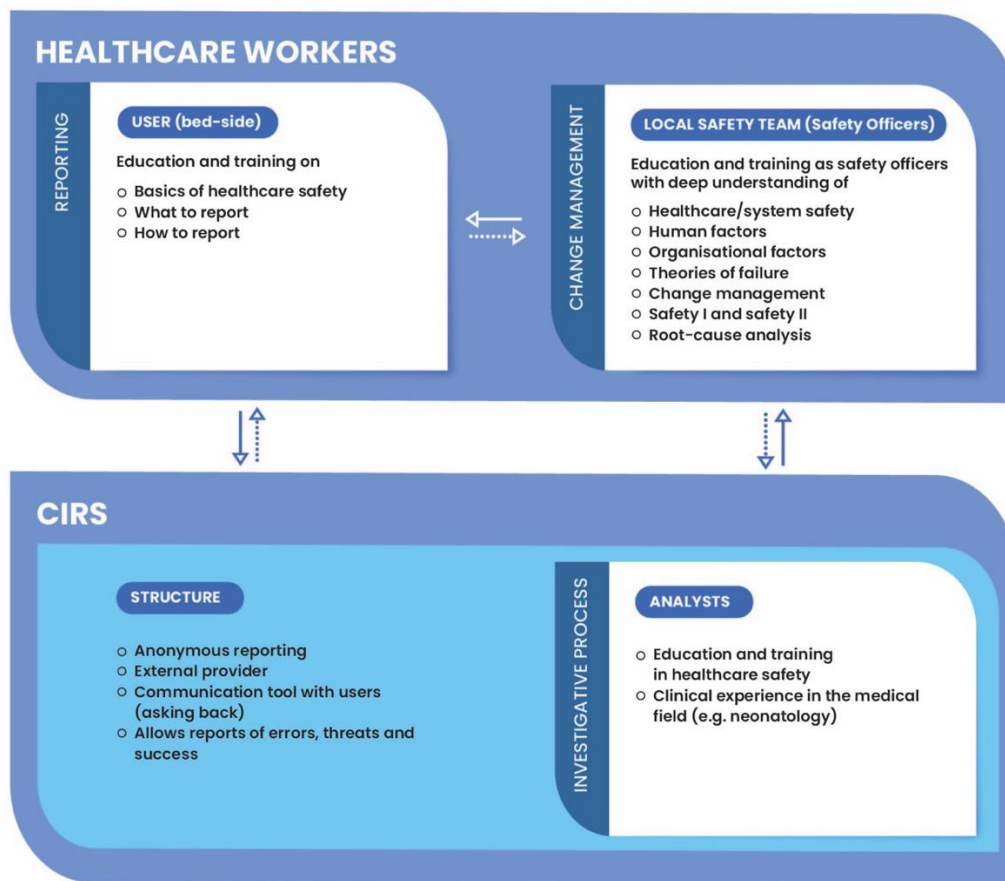

Figure1 Components and required preconditions of critical incident reporting systems (CIRS).

Recommended literature

- Suzanne Woodward: Implementing Patient Safety: Addressing Culture, Conditions and Values to Help People Work Safely; Productivity Press; ISBN-13 978-0815376859

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- Sidney Dekker: The Safety Anarchist: Relying on Human Expertise and Innovation, Reducing Bureaucracy and Compliance; Routledge, ISBN-13: 978-1138300460
- Institute of Medicine: To Err Is Human, Building a Safer Health System National Academy Press, ISBN 0-309-06837-1
- Why Hospitals Should Fly, The ultimate Flight Plan to Patient Safety and Quality Care; Second River Healthcare Press, ISBN 10:0-9743860-5-7
- Michael Leonard, Allan Frankel Achieving Safe and Reliable Healthcare – Strategies and Solutions; Health Administration Press ISBN 1-56793-277-4
- Edited by Christopher P. Nemeth: Improving Healthcare Team Communication, Building on Lessons from Aviation and Aerospace; Ashgate, ISBN 978-0-7546-7025-4
- Atul Gawande: The Checklist Manifesto, How to get things right; Metropolitan Books, ISBN 987-0-8050-9174-8
- Peter Pronovost, Eric Vohr: Safe patients, smart hospitals: how one doctor's checklist can help us change health care from the inside out; Verlag Hudson Street Press, 2010; ISBN 159463064X
- Suzanne Gordon, Patrick Mendenhall, Bonnie Blair O'Connor, Chesley Sullenberger: Beyond the Checklist: What Else Health Care Can Learn from Aviation Teamwork and Safety (The Culture and Politics of Health Care Work); ILR Press, ISBN-13: 978-080147829
- Robert M. Wachter: Understanding Patient Safety; McGraw Hill, ISBN 978-0-07-176578-7
- Robert M. Wachter, Kaveh G. Shojania: Internal Bleeding, The truth behind America's terrifying epidemic of medical mistakes; Rugged Land, LCC, ISBN 1-59071-0738
- Michael R. Cohen: Medication Errors; Jones and Bartlett Publishers ISBN 0-917330-89-7
- Joe Graedon, Teresa Graedon: Top Screwups Doctors Make and How to Avoid Them; Three Rivers Press
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