Danish Society
for
Patient Safety

We are striving to improve patient safety and to create a health service in which patients are able to see and feel to a greater extent that the service is there for them.

patientsikkerhed.dk

Optimisation of the Danish incident reporting system

Recommendations by a working group appointed by the Board of the Danish Society for Patient Safety

PS!

Published by:
The Danish Society for Patient Safety
(Dansk Selskab for Patientsikkerhed)
c/o Hvidovre Hospital
P610 Kettegård Alle 30
DK-2650 Hvidovre Denmark

March 2016

Layout: Herrmann & Fischer A/S

Danish Society
for
Patient Safety

More lessons learned – less bureaucracy

In 2003, Denmark became the first country in the world to pass an Act on patient safety. An important element of the legislation was the establishment of a reporting system for patient safety incidents. The Danish Society for Patient Safety – in joint association with the organisations behind the Society – was the primary initiative taker behind the original reporting system, and it is now natural and important for us to contribute to the necessary revision and renewal of the system.

All the way back in 2002, the Society drew up the set of recommendations that came to form the basis of the reporting system, a system that became mandatory for health care staff in hospitals from 2004 onwards and then, in 2010, for those in the primary care sector (municipalities, pharmacies and medical practices). Since 2011, patients and their relatives have also had the opportunity to report patient safety incidents.

The purpose of the reporting system was – and is – to support patient safety. Our starting point was – and is – that it is human to err. We can never completely eliminate human error, but we can learn from our experiences and, on this basis, find new preventive solutions. It is our duty to do so.

After more than ten years, we can state that the reporting system has, without doubt, contributed to both patient safety and to a culture that focuses to a greater degree on the wishes and needs of the patient. At the same time, however, we recognise that the system is in need of revision. Health care professionals find that some of the procedures involved in reporting are cumbersome and bureaucratic, contributing neither to learning nor to improved safety for patients. Adjustments and modernisation are required. There is also a need for us to act to a greater extent on the important knowledge that we gather through the reporting system.

At the meeting of the Board of Directors of the Danish Society for Patient Safety on 23 November 2015, it was decided that a working group consisting of the Danish Disabled People's Organisations, the Association of Danish Pharmacies, the Danish Medical Organisation, the Danish Nurses' Association, the Danish Union of Public Employees, Danish Regions, the regions, Local Government Denmark and the municipalities should produce recommendations for the future optimisation of the reporting system. Later, two representatives from the Danish Research Network for Patient Safety and Quality were brought in.

After a thorough process, the working group has now summarised its recommendations in this report: eight central recommendations that will optimise and futureproof the reporting system so that the Danish health service learns from its mistakes in a constructive and non-penalising way.

It is important and essential reading for anyone who wishes to contribute to the renewal of the system.

Ulla Astman, Chairperson, Danish Society for Patient Safety

March 2016

Contents

Summary

The reporting system for patient safety incidents is an important tool in securing knowledge of what goes wrong in the health service. Since the reporting system was established, there has been a great deal of focus on the system and reporting itself. A culture has been created around reporting in all sectors and among health care professionals, patients and relatives alike. At the same time, however, it has become clear that the reporting system as a whole is too bureaucratic, and that there is too much focus on reporting and not enough on acting and improving the systems as a result of the reports.

The Board of the Danish Society for Patient Safety has therefore appointed a working group that has critically discussed ways of optimising the reporting system. The working group has come up with eight recommendations for an optimised reporting system, one that can provide support in improving the health service for the benefit of patient safety. The eight recommendations can be summarised under the following headings:

The original spirit of the reporting system must be retained:

The perspective on, and reactions to, patient safety incidents can be divided into those from an individual perspective (where penalties are imposed on individuals as a result of patient safety incidents) and those from a system perspective (where the reaction to the incident is to improve the system so the incident does not occur again). The reporting system has been conceived from, and should remain solely rooted in, a system perspective. This is entirely in keeping with the knowledge available, which shows that, in the vast majority of cases, patient safety incidents are a result of inappropriate systems – not the carelessness or negligence of individuals. Moving on from this, if health care staff are to have trust in the reporting system, it is vital to maintain the protection afforded to those submitting the reports against any penalties resulting from reporting.

We need to report the things that are important and root the system at local level:

The working group recommends that, from now on, health care professionals should only report the things that are important, rather than – as is currently the case – being obliged to report all patient safety incidents. The reporting process must also be made easier, and where possible the reports must be used locally. The working group does not take the view that it is possible to monitor patterns systematically at an overall level and find trends among the many thousands of incidents. On the other hand, the working group recommends an exchange of experiences across the board in the form of a learning network among risk managers etc.

The reporting system must be thought of in conjunction with the quality programme:

The experience that the incidents cannot be viewed in isolation, and that reporting in itself does not lead to improvement, shows that there is a need to think of the reporting system in conjunction with a national quality programme. Patient safety incidents must not be prevented in isolation; rather, they must be used throughout to provide the incentive for improvement to the quality system that is being built, where each individual unit works systematically towards achieving local targets that fit in with the overall quality targets.

The reporting system must support a legitimate, transparent health service:

The reporting system must contribute to a transparent public system. There is experience internationally of the publication of anonymised incidents, which the working group recommends should be studied along with possible pilot tests. Finally, systems must be established that ensure that the person submitting the report receives feedback on how the system has been improved as a result of the report.

Introduction

In 2003, Denmark became the first country in the world in which patient safety was enshrined in law. An important element of the legislation was the establishment of a reporting system for patient safety incidents, and since 2004 it has been mandatory for health care staff in hospitals to report such incidents. This was then applied to the primary sector (municipalities, pharmacies and medical practices) in 2010, while the opportunity for patients and relatives to report incidents was made available in 2011 (1). The purpose of the reporting system itself was to provide support to patient safety by collecting, analysing and communicating knowledge about patient safety incidents and solutions.

Health care professionals find, however, that the procedures involved in reporting are cumbersome and bureaucratic, contributing neither to learning nor to improved safety for patients. The recent Danish Broadcasting Corporation programme 'Spild af Dine Penge' ('A Waste of Your Money') recently showed, for example, how staff at a nursing centre spent 20 minutes reporting and registering on the Danish Patient Safety Database (DPSD) that a tablet had been dropped on the floor.

A service review of the DPSD conducted in 2014 showed that there are a number of areas in which the system could usefully be improved. There is a need for clarification of the division of roles between the players in order to examine the extent of reporting, to differentiate the management of reports and to improve the technical options of the system (2).

In November 2015, the national audit agency of Denmark (Rigsrevisionen) published an audit (3) of the work done by the Patient Ombudsman on patient safety incidents. The Agency concludes 'that the reporting system used by the Patient Ombudsman does not assist the Ombudsman in being able to identify easily the most fundamental national challenges.

The Patient Ombudsman is obliged to review the reports manually, which means that the Ombudsman is only able to review a limited proportion of the reports. A great potential for learning may therefore be going unused.'

Initiatives have been put in place in several parts of the system to address the conclusions of the reports. In connection with this, the Danish Society for Patient Safety hopes that the recommendations below may help to qualify the discussions about the system for reporting patient safety incidents.

The need to discuss the reporting system is being brought into focus by plans by the Danish government and the regions to set up a common national quality programme for the health sector (4). The most extensive plans for the quality programme are in the hospitals, where accreditation will be phased out. However, the quality programme describes how it will cover the entire health service. The reporting system and the quality programme must therefore be viewed as one.

Process

At the meeting of the Board of Directors of the Danish Society for Patient Safety (DSPS) on 23 November 2015, it was decided that a working group consisting of the Danish Disabled People's Organisations, the Association of Danish Pharmacies, the Danish Medical Organisation, the Danish Nurses' Association, the Danish Union of Public Employees, Danish Regions, the regions, Local Government Denmark and the municipalities should produce recommendations to the Board of the DSPS for the future optimisation of the reporting system.

It was then decided to involve two representatives of the Danish Research Network for Patient Safety and Quality. A seminar was then held in the working group on 19 and 20 January 2016.

Based on the discussions of the working group, the recommendations below were put forward. These recommendations were subsequently adopted by the Board of the DSPS.

Why do we have a reporting system?

Studies show that 9.0 per cent of all somatic inpatient admissions are wholly or partly affected by the complications of patient safety incidents (5). A review of deaths in five hospitals found an incidence of preventable death of 2.0–3.2 per cent (6). Both studies add to the picture of a health service that has a duty to work towards the prevention of patient safety incidents.

In general terms, the objective of the reporting system is to support learning, with a view to developing and improving the health service. A number of interim objectives contribute to this overall aim:

The reporting system provides the knowledge as to where there is a need to strengthen patient safety and thereby establish the 'burning platform', i.e. the urgency of the improvement work. Without a reporting system containing descriptions of how patients are harmed in our health service, we as a system will be unable to act and make improvements, and we may risk forgetting that we cause serious harm to patients every day.

By focusing on faults with the system rather than individuals, the reporting system helps to build up and strengthen a culture of learning and patient safety, one where staff, patients and relatives are encouraged – using a reporting and analysis system – to reflect on how the system harms patients, and how this can be improved.

When the reporting system helps to contribute knowledge, analysis and action following specific serious patient safety incidents, it increases the legitimacy of the system in the eyes of patients, relatives and staff.

Recommendations

Based on the discussions of the working group, eight recommendations are described here for an optimised reporting system:

WE MUST ONLY REPORT THE THINGS THAT ARE IMPORTANT

Currently, health care staff find that they are obliged to report trivialities.

The working group recommends that, in future, only the following should be reported, analysed and acted upon:

• Serious patient safety incidents*

• Incidents that reveal new types of problem or surprising combinations of problems

• Incidents where the person submitting the report finds that lessons could or should be learned

• Incidents that – contrary to expectation – 'turned out well', and where lessons could therefore be learned

• Focused reporting of incidents of local significance

*A serious patient safety incident means an adverse event where the actual injury, according to the current classification system, is categorised as 'Moderate', 'Severe' or 'Fatal'. In other words, an incident that is currently categorised as 'No injury' or 'Mild' (see the explanation in the figure from the DSPD) need only be reported if it meets one of the other criteria.

Based on the classification of incidents reported in 2014, the above will significantly reduce the number of reported incidents – by around 80 per cent in hospitals and around 90 per cent in the municipalities.

This will allow resources to be released for the improvement of work procedures.

Seriousness	**Actual injury**
No injury	No injury
Mild	Mild, transient injury that does not require any increased treatment or care effort
Moderate	Transient injury that requires admission, treatment by a general practitioner or an increased care effort, or – for inpatients – increased treatment
Severe	Permanent injury that requires admission, treatment by a general practitioner or an increased care effort, or – for inpatients – increased treatment, or other injury requiring emergency life-saving treatment
Fatal	Fatal outcome

The working group has also discussed the option of aggregated (e.g. the reporting of four case episodes in a single report) and focused reporting (e.g. 'This month, we would like to receive reports on all medication errors'). In principle, the working group recommends this. However, it is important to maintain the protection afforded to those reporting incidents against any penalties resulting from reporting. Consequently, the working group is unable to recommend aggregate reporting if this is based on a 'drawer reporting system' where health care staff have to report to a system where they are not afforded the protection of the law.

IT MUST BE EASIER TO REPORT

As it currently stands, the reporting system is not particularly user-friendly (for example, it takes a long time simply to state where the incident took place), and the reporting format is not tailored to the individual area, e.g. general practice, pharmacies, municipalities or hospital departments. Simplified reporting will afford greater legitimacy to the system and reduce the time spent reporting.

The working group recommends simplified reporting and has discussed a number of ways in which it may be made easier to report patient safety incidents, such as by setting up suitable templates for the various sectors, the opportunity to use more free text when reporting, the option to choose to report by putting crosses and ticks in boxes, etc.

THE REPORTING SYSTEM MUST NOT BE USED IN A PENALISING WAY

The aim of the reporting system is to ensure that lessons are learned about the systems in which we treat patients. Studies show that the vast majority of patient injuries are due to inappropriate systems, with only a minor proportion being due to the carelessness and negligence of individuals.

The working group recommends retaining this sharp distinction between the parts of the overall Danish patient safety system. The reporting system must not be used in a penalising way, as mixing the two aims will remove the staff's incentive to report. There are other bodies whose purpose it is to supervise individuals, and a reporting system must not take away managers' supervisory responsibility for their employees. Where there are health care staff who do not meet the professional standards, it is the job of management to deal with this. Knowledge of how individual employees solve their tasks is obtained from daily clinical work, not by waiting for reports to be made in the reporting system.

THE REPORTS MUST BE USED LOCALLY AS FAR AS POSSIBLE

In the current form of the reporting system, all incidents are reported via the DPSD to local, regional/municipal and national level alike. By forwarding the reports through the system, the intention is to 'find patterns' and 'monitor the system' at regional/municipal and national level, and to react to rare signals. The result, however, is that people at local level do not feel that they are experts in their own system. They can lose ownership of the incidents and can feel that the incidents are for other people to deal with. Finally, at local level there may be an expectation that 'someone will come and tell us what to do'. At the same time, at the more general levels people are overwhelmed by thousands of incidents, with no chance to work systematically through them to find patterns or take action. The reality is that the vast majority of reports are about inappropriate organisation of local procedures (communication, processes, training, work environment and barriers). The ones best placed to improve these are the individual units themselves.

The working group therefore recommends that all reports, irrespective of the sector initially targeted, be received and used at the local level.

A small proportion of incidents may not be resolved locally, or may be better resolved at a higher level. These include, for example, cross-sector incidents or incidents occurring when building IT systems. For this reason, these incidents must be transferred from the local level to a risk management function at regional/municipal level.

If the incidents cannot be resolved using this arrangement (for example, incidents regarding national IT, medical equipment, medicinal product packaging, back orders and standards), the incidents must be transferred from the regional level to a risk management function at national level, which will be responsible for dealing with them.

In the case of the examples above of incidents that are to be forwarded rather than handled locally, the working group recommends that, as a starting point, responsibility for reacting to the incidents should lie at local level (see the figure on page 11).

In this regard, there have been discussions in the working group on whether there needs to be an option at local level to create separate categories for sorting the incidents. The options for this need to be clarified. It must also be

NEW REPORTING SYSTEM FOR PATIENT SAFETY INCIDENTS

• Only important incidents* are reported • Cases are brought to a complete close at the lowest effective organisational level • Openness in managing cases • No change to the system perspective and personal protection * Important incidents: • Severe • New/surprising • Particular learning perspective • 'Turned out well all the same' • Focused reporting	Patient safety incidents are reported by patients and relatives and by all health care staff in the private and public sector to the local level **Close completely >95%**** **The local level** ⬇ Only incidents best resolved at a higher organisational level – e.g. Applies to the entire municipality/region – Transitions between units – Cross-sectoral **Close completely 2−4%**** **The regional and municipal level** ⬇ Only incidents of obvious national interest – e.g. Medical equipment – Medicine packaging – Back orders – IT systems – Standards **The national level** **Close the rest**

**The percentages are approximate, of course

clarified how communication will take place between the various levels – for example, about the context for a given incident or problem.

EXPERIENCE MUST BE EXCHANGED ACROSS THE BOARD

There were discussions in the working group about what the real chances are, at the top level (e.g. nationally), of discovering and finding patterns in rare incidents and trends that have not been seen at a local level. It was agreed that this is difficult, and the purpose of the reporting system is not to find patterns in rare incidents but rather to provide support for the creation of a local culture of improvement.

It does not make sense, however, if problems are not discussed and experiences not shared across units. Nor is it sensible if local actions at some point in the system counteract local solutions implemented in other parts of the system.

It was thus agreed within the working group that there is a need for sparring and for experiences to be exchanged regarding the safety challenges and solutions across hospitals, municipalities, regions, pharmacies and medical practices, etc.

The working group therefore recommends the establishment, at national level, of a learning network across the board that is able to address serious current general problems (e.g. the challenges of preventing mix-up incidents, identification errors and medication errors) and then working together to find and implement solutions (7). Exchanges of experiences of the implementation and improvement of patient safety initiatives across the board must not be managed separately; it must be integrated with activities under the direction of the quality programme.

It is agreed that there should be a national risk management function, yet uncertainty as to where such a function should be located from an organisational perspective, as it is important for the function to have the opportunity to reach into, have an effect on and motivate many

different systems to change. This includes not only state, regional and municipal systems but also private players such as the pharmaceutical industry.

THE REPORTING SYSTEM MUST BE AN INTEGRAL PART OF THE QUALITY PROGRAMME

Reports of patient safety incidents – along, for example, with data from clinical databases, patient complaints, compensation cases and letters from patients – must help to prioritise what quality initiatives are required in the health service (e.g. enhancing the safety of ECT treatment following a number of incidents). In addition, reports of patient safety incidents can help contribute knowledge about how we can achieve the overall aim of high quality (e.g. by studying the descriptions in the reports of when and where the incidents relating to ECT took place).

The working group therefore recommends that knowledge from the reporting system for patient safety incidents be integrated into a future quality programme.

THE REPORTING SYSTEM MUST CONTRIBUTE TO A TRANSPARENT PUBLIC SYSTEM

The working group recommends that consideration be given to how – in order to enhance patient safety, the legitimacy of the system and, not least, its focus on improvement – we can routinely publish anonymised summaries of serious patient safety incidents, and in particular the improvements brought by the work done on the incidents. Publication may, for example, take place on the appropriate institution's website, or where it makes sense in the context of the incident.

This recommendation is built on experiences from Norway (http://www.ahus.no/fagfolk_/temasider_/Sider/3-3□meldinger□om□uonskede□hendelser□.aspx), where, for example, so-called '3-3' incidents are published on a hospital website. In Denmark, the publication of patient safety incidents is not widespread, although there is experience of publication, e.g. bit.ly/1ou0Cyt.

Greater openness will support the use of patient safety incidents in the work on improvement, with openness emerging in the prioritisation of the improvement efforts, where patient safety incidents are considered together with other data on patient safety and quality in general.

It is vitally important, however, to ensure that this openness does not create unnecessary concern among staff about inappropriate exposure in the press. The principles of openness must therefore be discussed in detail with the institutions and the central professional organisations. This is where the experiences from Norway should be brought in.

It would be an obvious thing to do to initiate a pilot project to build up experiences of the method before dissemination.

FEEDBACK MUST BE PROVIDED TO THE PERSON MAKING THE REPORT

It is fundamental that the reporting system should contribute to the development of a patient safety culture among managers, employees and patients/the public.

The working group therefore recommends that systematic work be carried out to provide feedback on incidents and actions at several levels:

- Local and direct feedback (e.g. from a manager or risk manager of the person who submitted the report). Patients and relatives must receive a personal response.
- In summary form at unit level (e.g. on quality boards integrated with the other quality work).
- At organisational level (e.g. hospitals, municipalities, pharmacies, etc.) – such as on the website.

This will help create a transparent system of high legitimacy.

Resources

By choosing to follow the recommendations detailed above, it is expected that resource savings will be achieved because:

• The future system will receive fewer superfluous reports.

• There is no requirement for detailed classification.

• Many fewer incidents proceed to the regional level.

• Many fewer incidents proceed to the national level.

This frees up resources to act and implement at the local level.

Legislation

With regard to the above, the working group has not considered what legislative changes will be necessary in order to implement the recommendations.

References

1. Danish Ministry of Health. Bekendtgørelse om rapportering af utilsigtede hændelser i sundhedsvæsenet m.v. [Executive Order on the reporting of patient safety incidents in the health service etc.] (online). 2011. Available from: https://www.retsinformation.dk/pdfPrint.aspx?id=134520

2. The Patient Ombudsman, Danish Ministry of Health. Rapport om serviceeftersyn af rapporteringssytemet for utilsigtede hændelser [Report on service review of the reporting system for patient safety incidents]. 2014.

3. National Audit Agency of Denmark (Rigsrevisionen) Beretning til Statsrevisorerne om Patientombuddets arbejde med utilsigtede hændelser [Statement to the Auditors of Public Accounts on the Work of the Patient Ombudsman on Patient Safety Incidents]. 2015

4. Danish Ministry of Health. Nationalt Kvalitetsprogram for Sundhedsområdet 2015–2018 [National Quality Programme for the Health Care Sector 2015–2018] (online). 2015. Available from: http://www.sum.dk/~/ media/Filer Publikationer_i_pdf/2015/ Nationalt- kvalitetsprogram for sundhedsomraadet/Nationalt kvalitetsprogram for sundhedsomr%C3%A5det april 2015. ashx.

5. Schiøler, T., Lipczak, H., Pedersen, B. L ., Mogensen, T. S., Bech, K. B., & Stockmarr, A. (2001). Forekomsten af utilsigtede hændelser på sygehuse [The incidence of patient safety incidents in hospitals] Ugeskrift for Læger, 163(39), 5370–5378.

6. Danish Society for Patient Safety. Forekomst af forebyggelige dødsfald på fem danske sygehuse [The incidence of preventable deaths in five Danish hospitals] (online). 2013. Available from: http://patientsikkerhed.dk/ content/uploads/2015/12/rapport_om_ forebyggelige_d_dsfald_cowi_2013.pdf

7. Danish Society for Patient Safety. Et kvalitetsprogram. Fra Patientsikkert Sygehus til forbedringsarbejde på sundhedsområdet [A quality programme. From patient-safe hospitals to improvement work in the health care sector] (online). 2015. Available from: http://patientsikkerhed.dk/materialer/ et- kvalitetsprogram fra patientsikkertsygehus til forbedringsarbejde paasundhedsomraadet/

Appendix 1

Participants in the working group under the Board of the Danish Society for Patient Safety

The Danish Medical Association	Chairman	Andreas Rudkjøbing
Local Government Denmark	Consultant	Maj Fjordside
Local Government Denmark	Centre Manager, Gildhøjhjemmet, Brøndby Municipality	Mia Linda Møller
The Danish Union of Public Employees	Health policy consultant	Jakob Bro
The Danish Nurses' Association	Profession Manager	Tine Lyngholm
The Danish Nurses' Association	Consultant	Janne Due Sommerset
The Danish Research Network for Patient Safety and Quality in Healthcare (FPKS)	Deputy Director, IKAS (Danish Institute for Quality and Accreditation in Healthcare)	Carsten Engel
The Danish Research Network for Patient Safety and Quality in Healthcare (FPKS)	Medical Coordinator, Patient Insurance	Kim Lyngby Mikkelsen
The Association of Danish Pharmacies	Pharmacist, Consultant in the Association of Danish Pharmacies	Rikke Lundal Nielsen
The Danish Disabled People's Organisations	Chairman	Freddy Nielsen
Danish Regions	Unit Manager, Quality & Patient Safety, Capital Region of Denmark	Annemarie Hellebek
Danish Regions	Regional Risk Manager, Central Denmark Region	Heidi Aagaard
Danish Regions	Regional Risk Manager, Region of Southern Denmark	Inge Pedersen
The Danish Society for Patient Safety	Director (until 1 February 2016)	Beth Lilja
The Danish Society for Patient Safety	Acting Director	Britt Wendelboe
The Danish Society for Patient Safety	Consultant Doctor	Ove Gaardboe
The Danish Society for Patient Safety	Consultant Doctor	Louise Rabøl
The Danish Society for Patient Safety	Consultant	Jens Reventlov
Moderator	Consultant at Muusmann	Inge Kristensen

PS! Danish Society for
Patient Safety

Danish Society for Patient Safety
Dansk Selskab for Patientsikkerhed

Tel.: (+45) 36 32 21 71
Fax: (+45) 36 32 36 07
E-mail: info@patientsikkerhed.dk