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Lack of clarity about 'patient safety incidents'

PERSPECTIVES

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Two neonates are lying side by side in a maternity ward. A nurse notices that one infant has no name tag. The other infant is experiencing breathing difficulties, and it is discovered that the infant has received the wrong medication. Both are examples of incidents that should not happen, i.e. *uønskede hendelser* (patient safety incidents). How do current definitions differentiate between them?

In recent years, the term *uønsket hendelse* (patient safety incident) has been used in Norway in relation to events in the health service that should be prevented in the future. Meanwhile terms such as *avvikshendelse* (deviation), *uheldig hendelse* (untoward event) *utilsiktet* (unintended event) and *nesten-hendelse* (near miss) are used. Drawing on our extensive practical experience with reporting systems and research on patient safety incidents, we are of the opinion that such a plethora of terms leads to a lack of clarity and threatens patient safety. In this article, we propose a classification that both simplifies and clarifies the terms.

Challenging terminology development

Our experience is that there are different understandings of the term *uønsket hendelse* (patient safety incident) among health personnel, specialists, researchers and healthcare administrators. This may be because the term has no precise definition or that the definition is difficult to understand.

> ***«A lack of clear, common definitions means that local authorities, hospital trusts, institutions and specialist groups develop and use their own definitions based on their interpretations of the regulations and specialist literature»***

Most of those working in the health service have been involved in or affected by a patient safety incident. Such events can occur in health care as a result of errors in medication management, surgery or diagnostics, for example. A lack of clear, common definitions means that local authorities, hospital trusts, institutions and specialist groups develop and use their own definitions based on their interpretations of the regulations and literature (1). For instance, some hospital trusts use 'patient safety incident' as a collective term for events that have or could have resulted in patient harm (2, 3), while in academic circles, the term is used for events that have resulted in patient harm (4).

Need for a review

In 2023, the expert group on the reporting system for serious patient safety incidents in the healthcare systems submitted its report *Fra varsel til læring og forbedring* (From reporting to learning and improvement) (5). The group has evaluated Norwegian reporting systems and proposes, among other things, a new system for reporting serious patient safety incidents in the healthcare service. In the report, the committee points out that the terms *uønskede hendelser* (patient safety incident), *nesten-alvorlige hendelser* (near serious events) and *nesten hendelser* (near misses) should be defined in the legislation and described in more detail in national guidelines. Meanwhile, the expert group defined several terms in the report. This can be interpreted as an attempt to sort out the terms, but is this actually the result?

The expert group proposes a broad definition of adverse events, including: '... *alvorlige hendelser* (serious events), *nesten-alvorlige hendelser* (near serious events), *nesten-hendelser* (near misses), *bagatellmessige hendelser* (minor events), *hendelser uten alvorlig skade* (non-serious events), etc.' (5). How should health personnel and health service managers interpret events described as 'minor'? It is inappropriate to use one term for both the type of event and the consequence for a patient, as, for example in *nesten-alvorlige hendelser* (near serious events). This makes it difficult for health service employees to understand which events must be reported and where to report them. Where does the 'neonate with no name tag' fit into this wide-ranging definition? And is a *hendelse uten alvorlig skade* (non-serious event) the same as a *nesten-alvorlig hendelse* (near serious event) or something different? And can all this be evaluated in just a few minutes, which is the time health personnel often have at their disposal to report an event?

An attempt at simplification

Rather than this mixed bag, we propose an alternative classification with three types of incidents inspired by the World Health Organization's guidance on the classification of patient safety incidents (6).

Our proposal differentiates between whether an incident has reached the patient or not. Incidents that do not reach the patient are classified as *nesten-hendelser* (near misses). Incidents that reach the patient are differentiated according to whether the incident has resulted in patient harm or not: i.e. *skadelig hendelse* (harmful incident) and *ikke-skadelig hendelse* (no harm incident). See examples in Figure 1 of the three main types of incidents exemplified by patient safety incidents related to medications. Moreover, the three types of incidents should be classified according to severity and preventability based on, for example, the Norwegian coding system for adverse events (7).

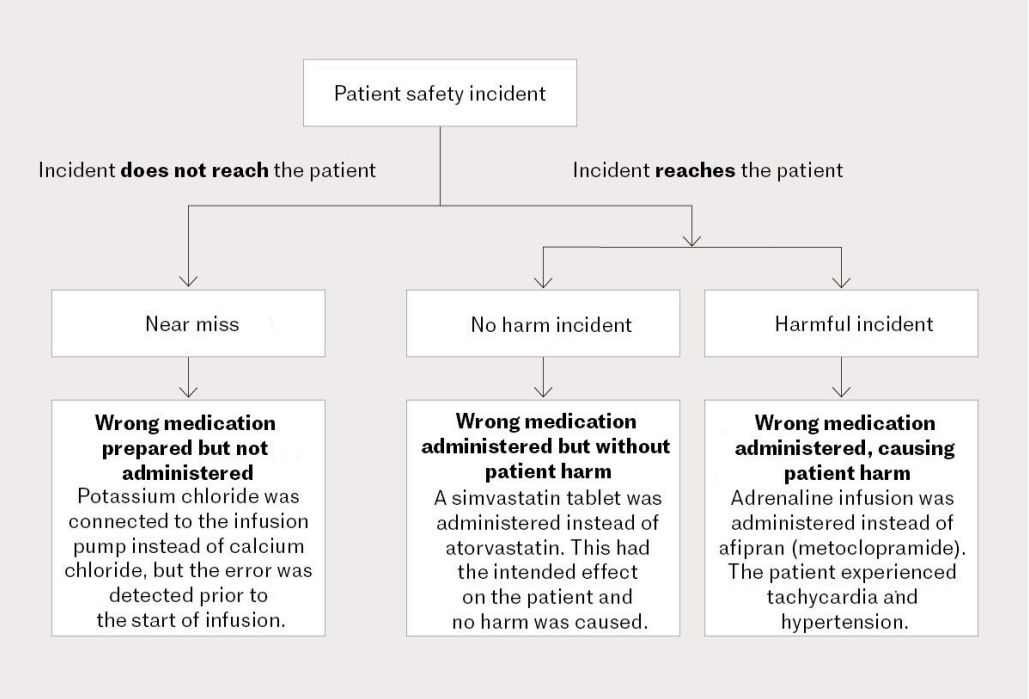

Figure 1 Proposed classification of patient safety incidents. The figure has been adapted by the authors (6). The World Health Organization (Licence CC BY-NC-SA 3.0 IGO) is not responsible for the content or accuracy of the adaptation.

Such a classification system that differentiates between incidents that reach the patient and those that do not, can promote a common understanding and a simpler and more accurate classification. It may also mean that the most serious reports of patient harm are not overshadowed by less serious reports. Moreover, the classification can simplify data extraction and provide a broader basis for learning and improvement.

Different understandings of terminology are nothing new

Patient safety is a relatively new field that came into being at the turn of the millennium with the report, *To Err Is Human*. The report presented alarming figures on patient harm and deaths as a result of errors in the health service (8).

Since then, terms related to patient safety have undergone a development. As early as 2000, Peter F. Hjort tackled the problematic issue of different terms in the wake of the global patient safety movement (9). Hjort replaced *feil* (error) with *uheldig hendelse* (untoward event), a neutral term that does not allocate blame.

In 2010, the Norwegian National Unit for Patient Safety (10) carried out an evaluation of the terms related to patient safety. This report showed early on that there are many names for the same concept. In addition to 'patient safety incident' and 'untoward event', there is mention of 'unintended event', which is also used by Danish experts in their work on patient safety. The terms describe an event that could have led to patient harm or has led to patient harm but says nothing about the consequence for the patient.

Avvik (deviation) is another term with which Norwegian health personnel are familiar. However, deviation is associated with the failure to meet specified requirements or denotes violations of laws, regulations and protocols. In recent years, there has apparently been informal agreement to use 'patient safety incident', but there is no agreement about what the term entails.

Unclear terminology has several implications

Reporting systems in the health service are characterised by underreporting, and the number of incidents reported only represents the tip of the iceberg (11). A survey conducted by the Norwegian System of Patient Injury Compensation showed that only 33 per cent of the cases involving patient injury compensation were found in the hospitals' reporting systems (12). Thus the hospitals may have lost opportunities to learn from errors and improve practices. If there is systematic underreporting of certain types of incidents or specialist areas, this may lead to incorrect prioritisation of efforts to improve patient safety.

One explanation for the underreporting may be a lack of a common understanding of the term 'patient safety incident'. For example, the missing name tag may be classified as an administrative incident and not a patient-related incident (13). Consequently, the uncertainty of both the person reporting and executive officers may undermine the learning outcomes from the reporting systems.

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Norway greatly benefits from comparing and learning about patient safety work in other countries, but also plays a contributing role internationally. In order to utilise international data from publications on adverse events and patient safety incidents, which are established terms in the literature, an appropriate translation of the terms into Norwegian is required.

The international literature often defines 'adverse event' as an incident that has resulted in patient harm. 'Patient safety incident' has a wider scope than adverse event and includes incidents regardless of whether they have reached the patient or resulted in harm. Thus 'patient safety incident' can be used as the translation of *uønsket hendelse*.

Currently, therefore, there does not seem to be a suitable Norwegian term for 'adverse event'. An example that illustrates this is the use of the Global Trigger Tool. This tool measures adverse events (incidents that result in patient harm) per 1 000 patient days, per 100 admissions, and the percentage of admissions with an adverse event (14, 15). In the absence of a better Norwegian translation of 'adverse event', we measure *pasientskade* (patient harm) and not events that have resulted in patient harm (16). Should we continue to translate 'adverse event' as *pasientskade* (patient harm), or should we introduce a suitable term that indicates that this relates to an incident and not merely the consequence of

an incident, for example *skadelig hendelse* (harmful incident) as we propose? Clearer terminology would enable comparisons of the number of incidents resulting in patient harm across national borders and studies (17).

'Do not let a hundred flowers bloom'

Patient safety is a rapidly evolving field and is the subject of increasing research (18). Nevertheless, there is a lack of monitoring and discussion in relation to the development of terminology in the field.

We see a need for a national expert group to propose common terminology, classification and standardisation nationally and internationally. Weeding out unnecessary terms is also important to allow the technological advancement to contribute to automatised classification and analysis of adverse events.

While politicians are tasked with deciding the way forward in relation to incident reporting systems, the time is ripe to sort out the terminology.

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