Medical Review of Medical Malpractice and SEVer Prevention List of the Patient Safety Action Alliance

From „Never Events“ to the SEVer prevention list

13,059 specialist medical reports on suspected treatment errors were issued by the Medical Service in 2022. According to this survey, an error and harm were found in every 4th case; in every 5th case, the error was the cause of the harm suffered. This is the result of the current annual statistics on the assessment of treatment errors, which the Medical Service (MD) presented in Berlin in mid-August of this year. Not least because the same errors happen again and again, the Aktionsbündnis Patientensicherheit (APS), like the MD, is calling for a so-called „Never Event“ register. In its SEVer prevention list, Aktionsbündnis Patientensicherheit e. V. has also defined 22 events. The APS defines these as incidents with a high potential for harm that could in principle be prevented. Since the same mistakes happen again and again, it is important to analyse what these mistakes are due to.

>> In order to improve patient safety, serious but certainly preventable events such as page or medication mix-ups („never events“) should be reported on a mandatory basis. „This is international standard in patient safety. From the patient's point of view, it is unacceptable that Germany does not implement this,“ said Dr. Stefan Gronemeyer, Chairman of the Board of the Federal Medical Service. The APS fully shares this point of view, but has already demanded this in 2019 with a position paper (1). However, this demand for complete and representative national statistics of all preventable adverse events is much older, as the Action Alliance wrote in its position paper at the time. The GSP referred to the IOM report „To Err is Human“ published in 2000, which in its Recommendation 5.1 included not only voluntary but also mandatory national reporting systems for serious harm as a central recommendation: „A nationwide mandatory reporting system should be established that provides for the collection of standardised information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings.“ (2)

„There is a fine line between honestly acknowledging that errors in health care can never be completely prevented and uncompromising commitment to patient safety,“ writes Dr Ruth Hecker, Chair of the German Coalition for Patient Safety (Aktionsbündnis Patientensicherheit e. V.), in her foreword to the recommendations for action of the SEVer list (3). In her foreword, she also emphasises that this is a balancing act, which the APS, however, has achieved with the present list („Serious events we want to prevent safely“). Hecker: „On the board of the APS we are aware that wherever people work, mistakes can happen. On the other hand, we firmly believe that institutions have a responsibility to do everything in their power to prevent the undesirable events listed here.“ How many these are and how they are distributed among the various specialties is made clear in the MD's current annual statistics on treatment error assessments - but not which ones could be avoided.

In order to draw up precisely this list of avoidable treatment errors, the APS Board had set up an expert group entitled „Never Events“. The aim of this expert group was to develop a list of events that should be safely prevented by systemic safety barriers. This first step was the basis for the now published SEVer prevention list, the content of which is to be developed in the following by one or more working groups of the APS. The experts of the Action Alliance assume that the events detected by the MD must always be seen as indications that the safety barriers to prevent patient harm in the facility concerned have not been fully effective.

„This goes hand in hand with the requirement that every SEVer that occurs is always dealt with vigorously in order to understand the systematic causes and to derive effective preventive measures for the future,“ Dr Ruth Hecker explained in this regard. To this end, the GSP has already published guidance on case analysis. Even more important than the number of absolute cases is the reaction of the institutions to these incidents. According to the APS, passages in the WHO's „Global Patient Safety Action Plan“ (2021-2030), which also includes the instrument of national lists of serious patient safety-relevant events (sentinel events), should be read in the same way (4).

In her foreword to the SEVer prevention list, however, the APS Executive Director also emphasises that recognising serious events and, in the best case, preventing them in the reality of care is by no means sufficient for safe patient care. Dr. Ruth Hecker: „This is only a first step towards a distinct safety culture in which all those involved work together to ensure that risks are identified and managed in the best possible way. Paving the way for this is the concern of the GSP also with the publication of this list.“

The 22 points of the SEVer list

The basis of the APS SEVer list was the established compilations in use in the American and British health systems. The APS-SEVers were determined on the basis of the current list of Serious Reportable Events (SRE) of the US National Quality Forum (NQF) and the Never Event List of the British National Health Service (NHS). After detailed discussion, all events were excluded that did not fulfil all previously defined criteria of the APS SEVer list. These were, in particular, events that were due to the local conditions of the countries from which they originated or which could not be sufficiently influenced by the health facility.

After a translation of the remaining events, they were discussed in detail according to the APS andchecked again with regard to the previously defined criteria, in particular the influenceability by a health facilityand the „absolute“ preventability. The recent publication of the NHS „National learning report: Never Events analysis of HSIB's national investigations report“ (5) confirmed the discussion on preventability already held in the expert group at the inaugural meeting and subsequently influenced the naming of the report. The consideration recommended there to reconsider the name „Never Events“ on the basis of the results of case analyses presented led to finding another name, namely SEVer. On the basis of the

procedure described, the 22 APS SEVer were then defined (see list) and also elaborated in detail from page 7 of the paper onwards (3).

MD treatment error assessment

How important and forward-looking the work of the APS was and is is shown in all clarity and severity by the current annual statistics on treatment error assessments (6) of the Medical Service (MD) presented in mid-August this year.

Last year, the Medical Service issued 13,059 expert opinions on suspected treatment errors nationwide. In every 4th case (3,221 cases), an error with damage was confirmed according to the present evaluation. In every 5th case (2,696 cases), the error was the cause of the damage suffered - only then would patients have a chance of compensation. The number of expert opinions is on the same level as in previous years. „The number of assessments only shows a very small part of what actually happened," explains Dr. Gronemeyer. „Scientific studies have shown that the number of unreported cases is significantly higher: Experts assume that about one percent of hospital cases are affected by treatment errors. Only about one percent of all adverse events are followed up."

Never events are of great importance for preventive measures. These are easily preventable adverse events that can lead to serious harm to patients: These include patient and page mix-ups, serious medication errors or unintentionally left foreign bodies after operations.

These events of harm appear every year in the assessment statistics of the medical services (2022: 165 cases; 2021: 130 cases), although the risks are known and suitable preventive measures are available. Such events would show that risks exist in the care process and that safety precautions on site are inadequate. For Gronemeyer, „never events" are therefore particularly important for the recognition, implementation and evaluation of safety measures and are therefore already successfully used for prevention in many other countries. „Germany should finally implement this. The planned amendment of the Patients' Rights Act offers the opportunity to introduce a mandatory National Never Event List and thereby strengthen patient safety in care," said Gronemeyer. „The reporting of harm events is solely for prevention purposes. It should be sanction-

SEVer-Präventionsliste des Aktionsbündnisses Patientensicherheit e. V.

I APS SEVer im Zusammenhang mit operativen Prozeduren:

1. Eine Operation oder andere invasive Prozedur, die am falschen Patienten oder an der falschen Stelle des Körpers begonnen wird bzw. von der eigentlich vereinbarten Intervention abweicht. Dies gilt unabhängig davon, ob der Irrtum während der Intervention oder erst danach entdeckt wird.
2. Unbeabsichtigtes Belassen eines Fremdkörpers im Patienten während einer Operation, anderen invasiven Prozedur oder in einer Körperhöhle.
3. Künstliche Befruchtung mit falscher Samen- und/oder Ei-Zelle.
4. Unentdeckte ösophageale Intubation

II APS SEVer im Zusammenhang mit Arzneimittel-, Hämotherapie und Transplantation:

5. Fehlapplikation eines Medikamentes auf eine der folgenden Arten:
   - 5.1. Intrathekale Gabe eines intravenös zu applizierenden Chemotherapeutikums
   - 5.2. Parenterale Gabe eines enteral/oral zu verabreichenden Medikamentes
   - 5.3. Intravenöse Gabe eines epidural zu verabreichenden Medikamentes
   - 5.4. Intraarterielle Gabe eines intravenös zu applizierenden Medikamentes
6. Irrtümliche intravenöse Gabe einer hochkonzentrierten Kaliumchloridlösung anstelle der verordneten Medikation
7. Insulinüberdosis, die aufgrund von fehlerhaft durchgeführter Applikation entsteht:
   - 7.1. Verabreichung des Insulins über eine Spritze, die keine Insulin-spezifische Markierung enthält
   - 7.2. Abziehen von Insulin aus einem Insulin-Pen und Verabreichung über eine Spritze
8. Überdosierung von Methotrexat für die nichtonkologische Patientenversorgung (z. B. tägliche statt wöchentlicher Gabe)
9. Verwendung eines kontaminierten Arzneimittels oder Biologikums, dessen Kontamination in der Gesundheitseinrichtung erfolgt ist
10. Fehltransfusion eines ABO-inkompatiblen Blutproduktes. Transplantation unter Verwendung ABO-inkompatibler Organe, Gewebe, Gewebezubereitungen oder Zellen. Die Inkompatibilität muss dabei klinisch relevant sein.



III APS SEVer im Zusammenhang mit dem Behandlungsprozess:

11. Beschickung einer Naso-/Orogastralsonde, deren Fehllage nicht ausgeschlossen wurde
12. Luftembolie im Rahmen der Behandlung
13. Verbrennung oder Verbrühung, die im Behandlungs- oder Pflegeprozess entsteht
14. Unsachgemäße freiheitsentziehende Maßnahmen im Behandlungs- oder Pflegeprozess
15. Unangemessene Versorgung mit Sauerstoff eines erkannt sauerstoffpflichtigen Patienten

IV APS SEVer aufgrund technischer oder organisatorischer Fehler:

16. Unsachgemäßer Gebrauch eines Medizinproduktes in der Patientenversorgung aufgrund von Mängeln in Einweisung oder Instandhaltung
17. Entlassung eines unmündigen, nicht geschäftsfähigen Behandelten (unabhängig von Alter oder Grund der eingeschränkten Entscheidungsfähigkeit) ohne angemessene Betreuung. Dies beinhaltet sowohl die alleinige Entlassung ohne betreuende Person als auch die Entlassung in die Obhut einer Person, die nicht zur Fürsorge oder Bestimmung des Aufenthaltsortes berechtigt ist.
18. Dauerhafter Verlust einer nichtwiedergewinnbaren Gewebeprobe
19. Nicht kommunizierter oder nicht nachbeobachteter interventionsrelevanter Untersuchungsbefund
20. Anziehen eines magnetisierbaren Objektes in den Magneten eines Kernspintomografen
21. Patientenversorgung durch Personen, die vortäuschen, dem entsprechenden Gesundheitsfach- oder Heilberuf anzugehören
22. Stationäre Patienten, die in Behandlungs- und Untersuchungsbereichen vergessen werden

free and pseudonymised for the facilities.

Allegations of errors in many specialties and in a wide variety of interventions

In the current annual statistics, two-thirds of all allegations of treatment errors made related to services in inpatient care, mostly in hospitals (8,827 cases). One third related to medical practices (4,208 cases). „Most allegations relate to surgical procedures. Since these often take place in hospitals, they are assigned to the inpatient sector," explained Dr. Christine Adolph, Deputy Chairwoman of the Board and Chief Medical Officer of the Bavarian Medical Service.

According to the evaluation, 30.3% of all allegations (3,960 cases) concerned orthopaedics and trauma surgery, 12.2% internal medicine and general medicine (1,599 cases), just under 9% each gynaecology and obstetrics (1,143 cases) and general and visceral surgery (1,133 cases). Dentistry also accounted for just under 8% (1,006 cases) and nursing for over 6% (834 cases). 26% of the allegations would have been spread across 29 other specialties.

In the 2022 annual statistics, 13,059 suspected cases for a total of 1,019 different diagnoses were recorded. The allegations concern faulty treatments for hip and knee joint wear and tear, bone fractures, circulatory disorders of the heart, gallstones or dental diseases.

The MD emphasises that the figures of the annual statistics are not representative; they only show the assessment figures and results of the Medical Service. „An accumulation of allegations in one specialty says nothing at all about the error rate or safety in the respective area," explains the head physician of the Bavarian Medical Service. „They only show that patients react when a treatment does not meet their expectations." Errors in surgical interventions are also usually easier for patients to recognise than medication errors, for example, which is why errors in operations are also more likely to be accused than in other treatments. In almost two-thirds (60.5 per cent) of the cases assessed, the patients' health problems were temporary, but an intervention or hospitalisation was still necessary and the patients recovered completely.

On the other hand, more than one third of the patients (35%) suffered permanent damage. The medical services distinguish between mild, moderate and severe damage. Mild permanent damage can be a slight restriction of movement or a scar. A medium permanent damage can be a chronic pain symptomatology, a considerable movement restriction or the disturbance of an organ function. Severe permanent damage is when injured persons have become dependent on care or they go blind or suffer permanent paralysis due to an error. In 3% of cases (84), however, a fault had led to or significantly contributed to death. <<

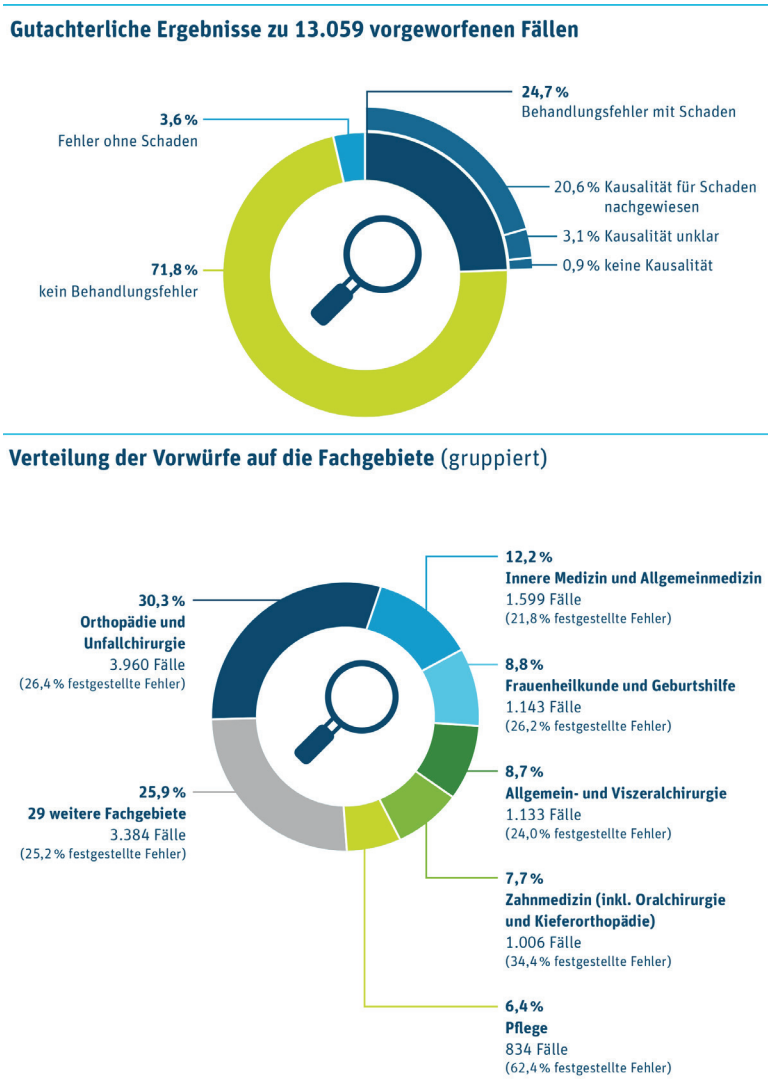


Fig. 1-2: Reporting of the 2022 annual statistics of the medical services community. Source: Medical Service

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