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Congratulation, Appraisal, and Comment on the 25 Years Anniversary of Serious Hazards of Blood Transfusion

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One of the best error reporting systems for hemovigilance, the serious hazards of blood transfusion (SHOT), celebrated silver jubilee by publishing its 25th yearly report last year in 2022 (https://www.shotuk.org/home/shot-silver-jubilee/) [1]. It started early in 1995, even before the EU council resolution on blood safety on November 12th, 1996, was released for the European Community. The first annual report, 1996–1997, already covered 25 recommendations for improvement and better transfusion safety. To date, some of them are no longer necessary, such as the recommendation to establish a transfusion committee for the directory of guidelines and procedures within the hospital. Others had to be changed by a continuous learning system by assessing the wrong blood in tube entity: "Pre-labeled tubes for blood group/cross-matching should not be used."

In summary, SHOT has demonstrated its effectiveness in improving transfusion safety since 1997. The SHOT efforts reported great hallmarks like the reduction of AB0-incompatible deaths (Fig. 1) or the rise and fall of TRALI [2]. It can be assumed that the existence of a reporting system together with the lessons learned from investigated errors are responsible for these achievements, but lessons learned could be even more infiltrating daily practice to more safety [2]. In comparison, current critical incident reporting systems were credited, especially if they provide the substance for the development of tools for future error correction and prevention [3]. The last SHOT report [1] contained the following key messages for healthcare systems:

- While modern blood products are largely safe, errors in the administration process chain such as poor communication and distraction can result in patient harm.
- Near-misses reports provide the potential to construct corrective and preventative action plans. Consequently, they are important for identifying and controlling existing risks before actual harm occurs.
- Since insufficient staffing in clinical and laboratory areas threatens transfusion safety, adequate numbers of appropriately trained staff must be available for staffing levels below a minimum level and for times of high workload.
- TACO continues to be the most common cause of death and major morbidity and may be preventable. Vulnerable patients should be identified, and appropriate measures for prevention instituted.
- Avoidable transfusion delays continue to contribute to patient deaths, and measures recommended by SHOT must be implemented.

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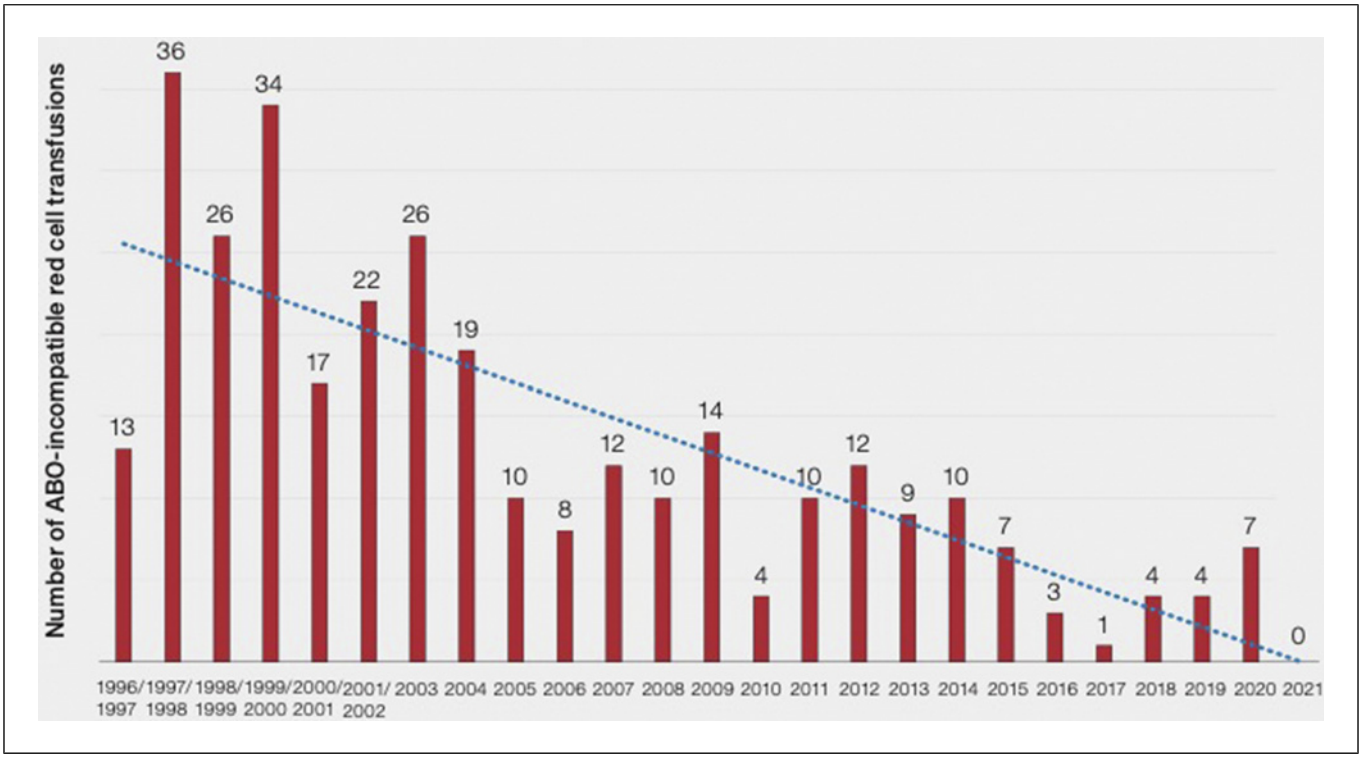

Fig. 1. Reduction of AB0-incompatible deaths during the years of the SHOT registry (1996/7 to 2021). (With permission from S Narayan [Ed] D Poles et al. on behalf of the Serious Hazards of Transfusion [SHOT] Steering Group. The 2021 Annual SHOT Report [2022]).

In addition, there are several core selections for other system to be adopted from the SHOT:

- Technical prevention measures: the consideration of the SHOT's focus on reporting categories of errors in the administration process of blood directs research efforts and technical investments to increase transfusion safety [4]. The SHOT clearly recommends that technical solutions and software to reduce human error are necessities. Safeguard systems based on scanners, RFID technology, and decision support are getting implemented increasingly [5, 6]. However, the last SHOT report comments on increasing alerts in the software systems in use. The lesson is that the configuration of IT software solutions needs significant medical and administration process knowledge to avoid alert fatigue. This might facilitate the implementation of IT-based transfusion safety in other countries.
- Errors during the administration process: the focus on product safety has limited success since a high level of product safety is already attained in developed countries. If we could improve administration safety to the same degree as product safety currently, we can reach another security dimension. The number of avoidable errors during the administration process is remaining high over more than 2 decades (Fig. 2). Furthermore, the risks associated with therapy should be known by both physicians and patients. The recipient consent information comprises the risk of transfusion-transmitted disease of HIV or hepatitis in the 1-per-million category. Conversely, administration-associated risks such as inadequate blood product transfusion, wrong dosage, liberal transfusion strategy, and delayed transfusion are not getting the same attention. However, they should be documented reliably with similar caution since they were named by the actual SHOT report 2021 [1] as the most frequent events. If the same error type occurs with other pharmaceutical drugs (as opposed to blood), the potential to harm is less. Consequently, transfusion administration safety should be more in the apprehension of patients and physicians.
- Prevention of errors is the most important goal of a HV. In consequence, avoidable errors are the most important messages of the SHOT report. The risk of death related to transfusion in the UK is 1 in 62,753 components issued, and the risk of serious harm is 1 in 17,431 components issued [1]. In 2021, errors continue to account for most of the reported events (81.3%). Almost half (45.7%) of reported deaths are preventable. However, this has been constant during the last years. Despite promising revenues and great impact, the economic interest in prevention techniques is limited. We should concentrate on the prevention of errors a lot

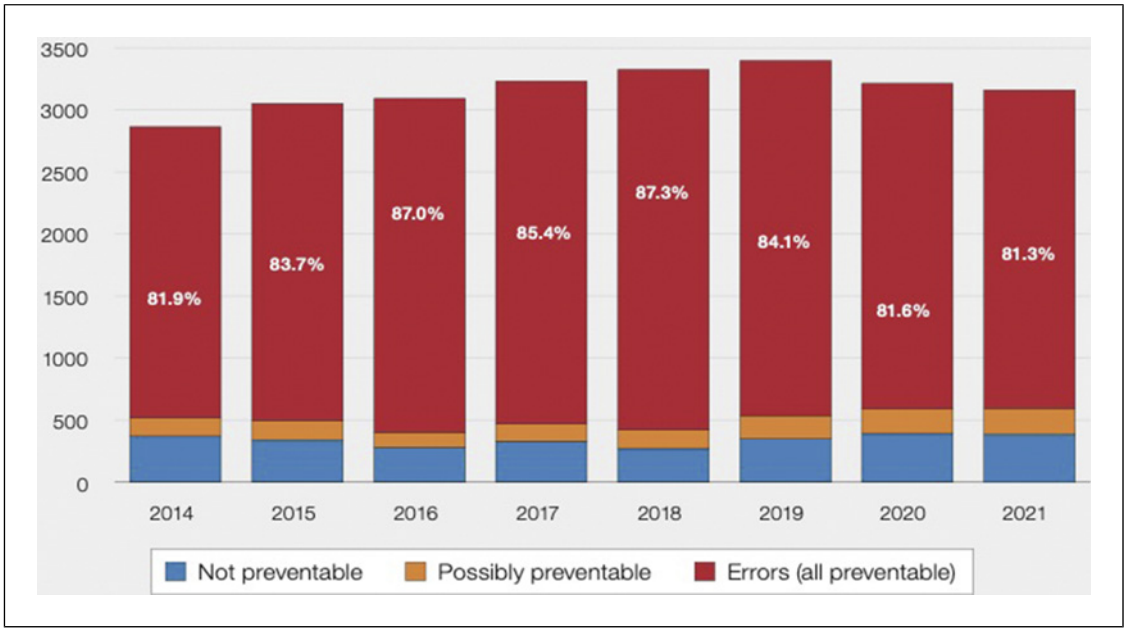

Fig. 2. Number or errors as a percentage of total reports, 2014–2021. (With permission from S. Narayan [Ed] D. Poles et al. on behalf of the Serious Hazards of Transfusion [SHOT] Steering Group. The 2021 Annual SHOT Report [2022]).

more than we did in the past. Harm to transfused subjects as well to transfusing staff is costly. A recent cost-effectiveness analysis emphasized the necessity to shift to noninfectious threats [7].

International Hemovigilance: Strengths and Weaknesses of the SHOT

A considerable variation of hemovigilance performance and structure exists in other healthcare systems. According to a WHO statement in 2018, hemovigilance is performed in only 47% of all countries reporting to the WHO. Even if the existence of a hemovigilance system is guaranteed, it seems that the selected "modus operandi" impacts the efficacy tremendously.

Thus, to be effective, the WHO states that a reporting system should be used frequently to produce the learning and change potential. In 2021, every NIH Health Board submitted at least one report, adding to the total number of received submissions of n = 4,088. In comparison, SISTRA, the Italian hemovigilance system, registers stable over the last 8 years below n = 2,000 of notifications addressing recipient issues. In comparison, the Austrian and German HVs only collect a tenth of notifications below n = 200, based on the same or even higher numbers of units transfused.

Besides the high number of yearly reports in the SHOT, deducible from the long history and expertise of analysis, other strengths of the SHOT compared to other European hemovigilance systems exist. The substantial funding by various international blood transfusion services provides a professional structure for the SHOT initiative, the multidisciplinary profile of the analysis experts, and a detailed yearly report resulting in a proven efficacy of preventive measures. Best practice examples in the NIH group spread internationally, such as a dedicated person for hemovigilance in every institution. European countries with governmental control of blood supply, such as Italy, the Netherlands, and others, had their hemovigilance fed by dedicated hemovigilance officers responsible for collecting hemovigilance data.

That Tells Us that Not Only Dedicated Persons Are Important, Also the Mandatory or Voluntarily Reporting Obligation

In Austria and Germany, adverse events from donation to transfusion have to be reported mandatory to the "Bundesamt für Sicherheit im Gesundheitswesen" (BASG) [8] or the "Paul Ehrlich Institute" (PEI) [9]. Near misses, however, remain on regional exchange platform among donation center and organization and are not transferred to BASG or PEI. Administration of blood units to the wrong recipient has to be reported in Austria but not in Germany. The mandatory German HV solely comprises severe and lethal transfusion reactions with documented laboratory proof. If the administration of a wrong blood unit does not cause a transfusion reaction, it must not be reported.

Those systems' learning potential is very limited since near misses are lost in these mandatory reportings. They tend to state a high safety of blood products, but the errors

(near misses) during administration are not considered at all. The actual SHOT report 2021 states the value of near misses accounting for a large portion of reported incidents (36.5%). Hemovigilance should not be performed as an imposition but immanent for a healthy health system. The SHOT system gained reliability and significance through the creation of a culture of willingness to learn in NHS institutions, although or because the reporting of serious adverse events (SAE/IBCT/Near Miss events) is by regulatory standards voluntary (reporting of SAE is mandatory to the MHRA via SABRE; reporting to SHOT [SAE/IBCT/Near Miss] is by regulatory standards voluntary). The shift from "system beyond errors" to a "culture of failure" is hard but rarely achieved by legal obligation. Therefore, SHOT excellence is important and an encouraging example for other voluntary hemovigilance systems.

The SHOT report told us that near misses have great learning potential and help most close safety gaps or identify handling errors (Fig. 2). The organization and report form is an institution for transfusion error reporting for many other HVs rightly. However, weaknesses arise in traditional systems when actual knowledge is not included in time. For example, the evidence about correct dosing, restrictive or liberal, guided by developing evidence and monitoring, is growing every day. The SHOT reporting categories are best when a continuity over the years can be stated.

Chances to Improve Transfusion Safety

Avoidance of Under- and Overdosing, Incorrect Handling, and Inadequate Component Selection

Thus, dosing issues were not strictly categorized and reported in the same error typology. Errors such as double unit applications, TACO, unnecessary transfusion, liberal transfusion strategy, and others result in overtransfusion but are listed in separate chapters. Whereas the SHOT is the example of other HV setting up reporting categories, the listing misses overtransfusion or overdosage. For example, the SHOT categories "incorrect component transfused," "specific requirements not met," "handling and storage errors," "avoidable, delayed, or under-/overtransfusion" are adapted by the Swiss HV Swissmedic, a well-maintained mandatory national HV with over 4,000 notifications yearly [10]. The complexity of international guidelines for specific diseases and situations in sepsis or the critical ill following heart surgery, for example, is nowadays available. A recommendation for many clinical situations is adjustable to a report. So, the inventory of a running system needs to be updated. Consequently, international standard categories of undertransfusion recently are suggested by a dedicated working group of the American Association of Blood Banks (AABB) [11]. Those more complex and deriving from various causes of overdosing blood and coagulation products are still open for discussion. However, the impact of over-transfusion of all kinds for patient safety is probably in the range of no other error considered before due to its frequency (for example, the unnecessary blood unit in cases of untreated preoperative anemia [12, 13] or the use of plasma in the absence of coagulopathy or massive transfusion [14]).

The Risk of a Clerical Error – The Trauma of a Second Victim in Transfusion Administration

Sometimes the interpretation of the SHOT report's results by the author team seems very cautious and humble. For example, the introduction of the 2021 report starts with the SHOT's function to improve "transfusion safety, both for donors and patients." However, from a more discerning perspective, the so-called "second victim" should be considered [15]. When an AB0-incompatible transfusion caused by a clerical error occurs and the recipient is severely injured, there is also the distressed administrator in addition to the patient. Traumatized and inadequately prepared physicians have posttraumatic stress disorder, depression, drug abuse, and stress-related cardiac diseases [16, 17]. We should not forget that administration errors also harm administrators. Posttraumatic stress disorders, depression, addiction, and other professional deformations may represent different neglected outcomes as measures for avoidance are useful for a healthy health system.

Conclusion

In this respect, the SHOT's jubilee in 2022 was more than a regular anniversary. It is an opportunity to redirect research and international co-work for better and safer transfusion medicine, to include new evidence, and to consider additional benefits associated with avoiding errors to transfusion administrators and recipients.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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Author Contributions

Thomas Frietsch: conception, drafting, and final approval of the manuscript. Jerrold H Levy: idea, refinement of the manuscript, and review for critical intellectual content. Maria B Rondinelli: drafting, development of the manuscript, and review for critical intellectual content. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1 SHOT. SHOT Report 2021; 2022. Available from: https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/.
2 de Vries RR, Faber JC, Strengers PF; Board of the International Haemovigilance Network. Haemovigilance: an effective tool for improving transfusion practice. Vox Sang. 2011;100(1):60–7.
3 Goekcimen K, Schwendimann R, Pfeiffer Y, Mohr G, Jaeger C, Mueller S. Addressing patient safety hazards using critical incident reporting in hospitals: a systematic review. J Patient Saf. 2023;19(1):e1–e8.
4 Frietsch T. Research for transfusion safety-priority of administration safety. Transfus Apher Sci. 2019;58(6):102650.
5 Goodnough LT, Hollenhorst MA. Clinical decision support and improved blood use in patient blood management. Hematol Am Soc Hematol Educ Program. 2019;2019(1):577–82.
6 Schmidt-Hieber M, Schuster R, Nogai A, Thiel E, Hopfenmüller W, Notter M. Error management of emergency transfusions: a surveillance system to detect safety risks in day to day practice. Transfus Apher Sci. 2006;35(2):125–30.
7 Custer B, Hoch JS. Cost-effectiveness analysis: what it really means for transfusion medicine decision making. Transfus Med Rev. 2009;23(1):1–12.
8 BASG. Haemovigilanz_Bericht_2021; 2021.
9 PEI. Haemovigilanz-bericht-2020.
10 SWISSMEDIC. Haemovigilance-Bericht-2021; 2021.
11 Rajbhandary S, Andrzejewski C, Fridey J, Stotler B, Tsang HC, Hindawi S, et al. Incorporating the entity of under-transfusion into hemovigilance monitoring: documenting cases due to lack of inventory. Transfusion. 2022;62(3):540–5.
12 Shin HW, Park JJ, Kim HJ, You HS, Choi SU, Lee MJ. Efficacy of perioperative intravenous iron therapy for transfusion in orthopedic surgery: a systematic review and meta-analysis. PLoS One. 2019;14(5):e0215427.
13 Fowler AJ, Ahmad T, Phull MK, Allard S, Gillies MA, Pearse RM. Meta-analysis of the association between preoperative anaemia and mortality after surgery. Br J Surg. 2015;102(11):1314–24.
14 Xu X, Zhang Y, Tang B, Yu X, Huang Y. Association between perioperative plasma transfusion and in-hospital mortality in patients undergoing surgeries without massive transfusion: a nationwide retrospective cohort study. Front Med. 2023;10:1130359.
15 Ganahl S, Knaus M, Wiesenhuetter I, Klemm V, Jabinger EM, Strametz R. Second victims in intensive care-emotional stress and traumatization of intensive care nurses in western Austria after adverse events during the treatment of patients. Int J Environ Res Public Health. 2022;19(6):3611.
16 Wulf H. [Second victim: deliberations on dealing with treatment complications]. Anaesthesist. 2013;62(9):685–6.
17 Wulf H. [Patient safety – mission for the future: recommendations for the management of severe treatment complications and burdensome courses (preventing the "second victim")]. Anasthesiol Intensivmed Notfallmed Schmerzther. 2014;49(07/08):460–4.