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ISBT ACADEMY DAY: HAEMOVIGILANCE

The start of Haemovigilance and its early days

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According to the World Health Organisation (WHO), blood safety can be best achieved through a blood system (BS) which has the following characteristics: it should be a robust and balanced construct, with a solid foundation of 3 LAYERS:

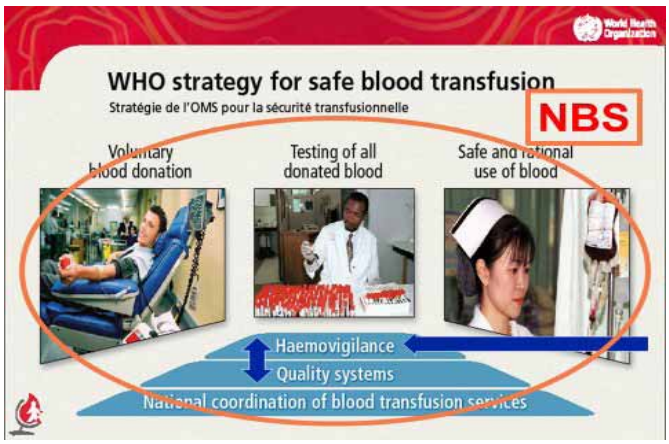
- national or nationally coordinated blood services
- haemovigilance (HV, being working optimally if embedded into a national system)
- quality management (QMS through systems called QMS in blood centers and also hospitals)

and

3 PILLARS standing on this foundation:

- voluntary, non-remunerated blood donations (VNRBD)
- testing of all blood donations for relevant transfusion transmittable infections (TTI) viruses; at least for Hepatitis B virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV).
- appropriate clinical use of blood (where hospital transfusion committees are the gatekeepers).

Figure 1: WHO strategy for safe blood transfusion



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HISTORY OF HAEMOVIGILANCE (HV):

Looking far into the past, one can see that there were some forms of vigilance since the first blood transfusions were undertaken: there were spontaneous, episodical descriptions of accidents with transfusions (from Jean-Baptiste Denis who undertook animal-to-human transfusions starting in 1628; James Blundell who performed human-to-human blood administrations in 1818). Already at that time, "actions" were taken in case of accidents due to blood transfusion (for example, interdiction of blood transfusion by the French King Louis XIV).

Similar to modern haemovigilance where research is an integral part, structured works were undertaken to investigate accidents in relation with transfusions to come up with solutions (nowadays we would call them CAPA: corrective and preventive actions). Karl Landsteiner discovered blood group antigens A, B and O in 1900 and the antigen AB in 1901 making up the most important blood group system: ABO. In the following years, more studies followed on blood groups and also serologic compatibility (for example, by Wiener and Levine in 1939 discovering the Rh blood group system). The decades afterwards were dominated by intensive research on infectious diseases: starting with Australia-antigen (HBsAg, in the 1960s), HIV (≥1983), HCV (≥1987) and more viruses (West Nile Virus, Zika, Dengue), but also: malaria, Chagas and others, leading virtually to the elimination of TTIs, at least in the developed world, a goal which is still to be reached in the developing world.

The first "systems" for HV appeared probably in Greece or Japan. The big boost for HV happened when blood scandals hit many European countries between 1989 and 1999. In France, a thorough criminal investigation was launched ending in a long and most famous court case on "transfusion" (the "Blood Scandal"). It was recognized that a structured scheme was needed to oversee all activities related to blood transfusion and the term 'Haemovigilance' (HV) was coined in the French law of January 4, 1993 and outlined in the Decree no 94-68 (24.01.1994). Shortly afterwards, the United Kingdom developed a structured scheme called SHOT (Serious Hazards of Transfusion, October 1996), followed by several European countries: TRIP in the Netherlands, NHO in Ireland, TRAP in Denmark and others.

At the level of the European Communities, decisive actions were also taken: the European Blood Directive 2002/98/EC was coming into force for the Member States of the European Union *(with general provisions setting the frame for blood quality, safety and supply)*, followed by executive Commission Directives: 2004/33/EC *(on donors and donations)*, 2005/62/EC *(on quality systems)* and finally, 2005/61/EC *(on haemovigilance)*.

In the latter legal provision, the following definition of HV is given: 'A set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors'.

In February 1998, five European countries (Benelux countries, France, Portugal) were meeting to found the *EHN (European Haemovigilance Network)*, aiming at:

- facilitating exchange of valid, specific information on HV between its members
- setting up rapid alert & early warning in the context of the blood chain
- fostering education & research
- giving expert input to national authorities, European institutions (EC, European Commission, CofE Council of Europe) and also to WHO.

EHN was growing rapidly to more 10 European Union member states and beyond, leading to a change in name and membership, but not in its orientations, in 2008. EHN became IHN (International Haemovigilance Network), working in close cooperation with the ISBT WP on HV (Working Party on Haemovigilance at the International Society of Blood Transfusion).

BASIC REQUIREMENTS FOR HV:

The characteristics and requirements for HV can be found in several references:

- 'European Blood Directives' (as already mentioned: of the European Communities and the European Parliament, of the European Commission)
- Council of Europe (CofE)/EDQM (European Directorate for Quality in Medicines) Guidance:
  Rec. R (95)15: 'Guide to the preparation, use and quality assurance of blood components'. The newest edition of it (19th version, published in 2017) contains a detailed chapter on HV, in line with Commission Directive 2005/61/EC and fully compatible with IHN/ISBT definitions and process descriptions.
- Commission Directive 2016_1214 of July 26, 2016 is rendering the "Guide" of the CofE/EDQM compulsory for all EU MS.
- WHO Aide-Mémoire on Haemovigilance (pursuant to the Global Consultation on HV in Dubai, United Arab Emirates, 2012)
- WHO Guidance on establishing a National Haemovigilance System (another deliverable of Global Consultation on HV, Dubai, UAE).

Right from the beginning, the concept of HV is seen as comprehensive surveillance of the entire blood chain (from the donor to the transfused patient):

- it is designed as a network of the different actors in the field of blood transfusion
- it involves the responsibility of the competent National Authority (cNA)
- it is based on operational linkages between the stakeholders in HV (hospitals and blood banks (HBB), blood establishments (BE) and national authorities) requiring close cooperation and good communication between the parties involved.

This is also reflected in the 'European Blood Directives' 2002/98/CE and 2005/61/CE and detailed in Article 15 on 'Notification of serious adverse events/reactions', where it is required that:

1. Member States shall ensure that:
   - any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority,
   - blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

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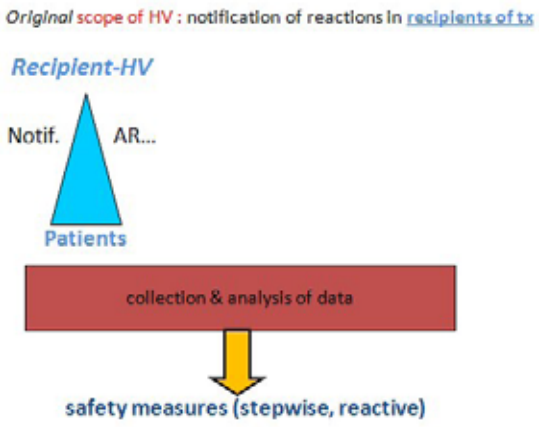
2. These serious adverse events and reactions shall be notified in accordance with the procedure and notification format".

In the beginning, HV was basically focusing on patients (or recipients) during and after blood transfusion as well as quality and safety of the blood products transfused:

Figure 2: Original scope of haemovigilance: Notifications of reactions in recipients of transfusion



In the (early) days of HV, the main objectives were to observe and detect clinical and biological signs of side effects in transfused patients, to investigate and assess the incidents, to report them, to collect and analyse these data. Such adverse reactions were:

- acute (immediate) reactions, like NHFTR (non-hemolytic febrile transfusion reaction), AHTR (acute haemolytic transfusion reaction), allergic and anaphylactic reaction, TA-GVHD (transfusion associated Graft-versus-Host Disease), TRALI (transfusion related Acute Lung Injury)
- delayed reactions, like DHTR (delayed hemolytic transfusion reaction due to allo-antibodies)
- transfusion transmitted infections (TTI, due to viruses, bacteria, parasites)
- allo-immmunisations (formation of allo-antibodies)
- others (unclassified transfusion reactions)

Some systems (like SHOT in the UK) incorporated also 'incorrect blood component transfused' (IBCT, in other words: 'wrong blood to wrong patient'), but also 'near misses' and errors, mistakes.

In the 'European Blood Directives', serious adverse reactions (AR) in recipients of transfusion are classified as follows (according to 2005/61/EC):

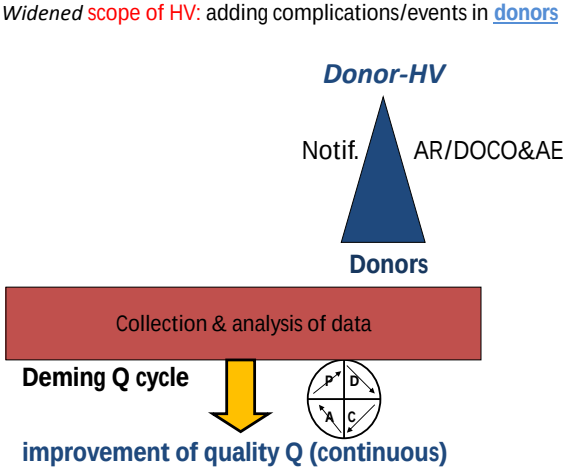
- Haemolysis, immunologic due to ABO incompatibility
- Haemolysis, immunologic due to other allo-antibodies
- Haemolysis, non immunologic
- Infection, bacterial, transmitted by transfusion (TTBI)
- Anaphylaxis / hypersensitivity
- Transfusion Related Acute Lung Injury (TRALI)
- Infection, viral, transmitted by transfusion HBV
- Infection, viral, transmitted by transfusion HCV
- Infection, viral, transmitted by transfusion HIV-1/2
- Infection, viral, transmitted by transfusion, other (TTVI)
- Infection, parasitic, transmitted by transfusion (malaria)
- Infection, parasitic, transmitted by transfusion, other (TTPI)
- Post-transfusion Purpura (PTP)
- Graft-versus-Host Disease (GvHD)
- Other serious reaction(s).

Under an enlarged HV scope, several newly recognized risks of transfusion were added:

- Transfusion associated Dyspnoea (TAD)
- Inflammation, post-transfusion
- Hyperhaemolysis, post-transfusion (e.g. in sickle cell patients)
- Transfusion Associated Circulatory Overload (TACO)
- Under-transfusion (mainly due to delays, low transfusion triggers, excessive PBM (patient blood management)
- Blood salvage complications (e.g. extra-corporeal recuperation of blood in wounds)
- Specific paediatric reactions (post-transfusion necrotising enterocolitis, metabolic changes - hyper-K+ and others).

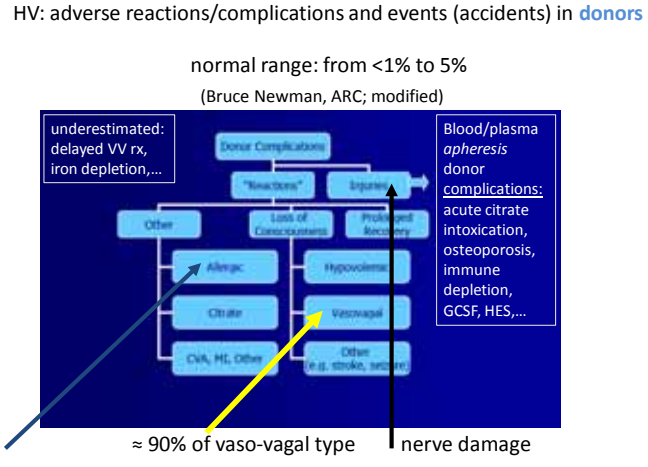
In the next evolutionary step of HV, attention was focusing on blood donors. Although blood and plasma donations were considered very, very safe, still some reactions, complications and events were happening in the context of donations. Learning from the lessons in recipient-vigilance, it was recognized that donor-vigilance was an important added-value in quality management:

Figure 3: Widened scope of Haemovigilance : Adding complications/ events in donors



Generally, less than 1% of donations come with a donor reaction (most of them are of vaso-vagal type, are mild and donors recover very rapidly). Nonetheless, the frequency can go up to 5% (for example, with high temperatures in summer, when drawing young female donors in school drives).

Figure 4: Haemovigilance : Adverse reactions/ complicaitons and events (accidents) in donors



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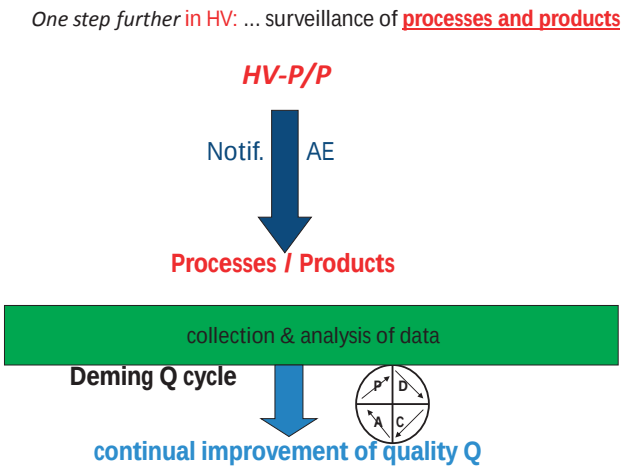
With more and more data being collected in the context of donations, it became apparent that some risks were underestimated: iron depletion (especially in low body weight female donors), but also nerve injury (through venipuncture) and above all, delayed vaso-vagal reactions (e.g. donors fainting when they are out of direct surveillance by blood center staff). Also, it was documented that there are *aphaeresis* donor complications, like acute citrate intoxication, possible osteoporosis, immune depletion in frequently drawn plasma donors, reactions to GCSF and HES (both used in apheresis procedures) and others.

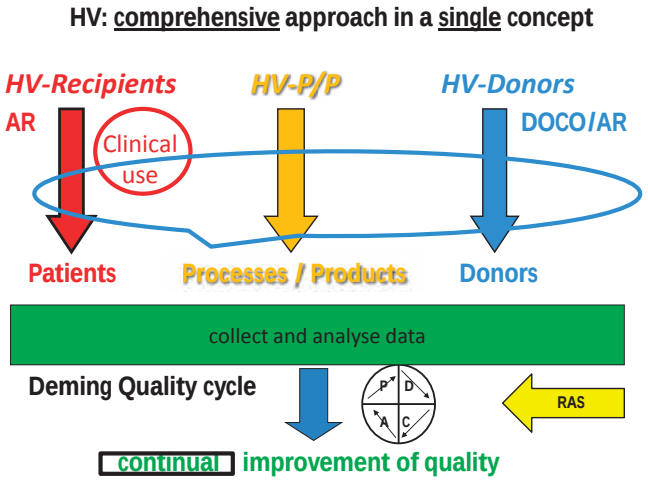
Finally, process and product deviations and abnormalities came under the umbrella of HV and linked QM actions for correction and avoidance of occurrence/recurrence.

Figure 5: One step further in Haemovigilance-surveliance of processes and products



A complete and full-blown HV scheme consists of comprehensive surveillance in a single system for recipients, donors and processes and products. It starts with observation and detection of abnormalities, deviations, reactions and events, documentation and investigation of them, it continues with data collection and analysis and ends with appropriate actions being taken (corrective or preventive in nature). In this way, the Quality Cycle is closed (the Deming cycle with "plan, do, check, act" is completed) and continual improvement of quality and safety in donations and transfusions can be achieved.

Figure 6: Haemovigilance: Comprehensive approach in a single concept



ACHIEVEMENTS OF HV SO FAR:

In the past, specific recommendations for hospitals have helped in reducing significantly ABO incompatible blood transfusions and, above all, deaths due to transfusion:

- Better medical prescription, correct choice of blood components, safe administration procedures have reduced hospital specific risks
- HTC (hospital transfusion committee) are put in place and are safeguarding quality and safety of blood transfusions in health care institutions
- HTC have taken responsibility for ACUB (appropriate clinical use of blood) and related issues (tx alternatives, patient blood management-PBM)
- Additional safety measures in the hospital help prevent IBCT (incorrect blood component transfused) and blood incompatibilities (through wrist bands, use of IT systems, bedside tests)

Also, specific recommendations have helped avoiding TRALI (transfusion related acute lung injury):

- achieve best clinical use of Fresh Frozen Plasma (FFP)
- reduce or eliminate passive transfer of leucocyte antibodies by:
- replacing plasma with additive solution (e.g. in platelet concentrates - apheresis and random)
- diluting plasmas through pooling (SD plasma – plasma, virus-inactivated by solvent-detergent)
- using exclusively plasma drawn from male donors ("male" only plasma for FFP transfusion).

Likewise, specific recommendations have contributed to diminish bacterial contamination of blood components (especially of platelets):

- improve donor arm cleansing
- divert the first 20-30 ml of collected blood from the "mother-bag" into a diversion pouch: exclude it from blood component preparation and use it for testing
- perform bacterial screening (culturing until distribution of platelet products)
- discuss pathogen reduction for platelet products

It has been a 'long' way of HV up until now:

- starting in France (January 1994), followed by UK (October 1996)
- HV systems appearing stepwise
- with significant conceptual and organisational differences:
  - -mandatory vs. voluntary
  - centralised vs. decentralised
  - notifying solely adverse reactions (vs. AR and adverse events)
  - reporting serious incidents vs. all
  - reporting newer categories (IBCT, near-miss, errors/mistakes,…)
  - recipients only (vs. patients and donors)
- some convergence has been achieved through the European Blood Directives
- all together, results reported are similar (types)
- at the same time, they are also different (frequency).

One lesson learnt from the past: HV systems work best if they are appropriately embedded into existing blood systems in the countries and are robustly linked to QMS (in blood centers, but also in hospitals).

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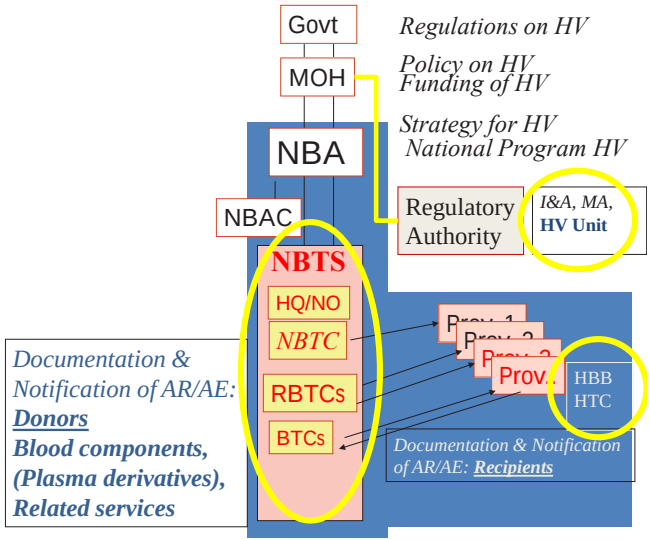
Figure 7: National HV system embedded in NBS



With a retrospective view, one can conclude:

- HV is (and has been) a dynamic field, expanding from surveillance of recipients, to donors and then to processes and products.
- It has proven to be a very effective quality tool when fully integrated into existing QMS at different levels (blood establishments, hospitals,…).
- It should be based on sequential QM steps, from active detection to evaluation, assisting decision making and resulting in efficient actions (CAPAs).
- It has had a major impact on blood systems (regulation, organisation, standardisation/ harmonisation).
- It has moved from re-active to pro-active, triggered corrective actions leading to continuous improvement, once the Quality Cycle has been closed.
- It has sentinel function to detect emerging threats and very rare events may become apparent (if data bundled).
- HV has contributed in a striking way to reduce the most dramatic adverse reactions in recipients (ABO-incompatibilities, TTBI and TRALI).
- Beyond any doubt, haemovigilance has increased significantly safety of the entire blood chain.

Establishing a National Haemovigilance Scheme

Etablissement d'un Systeme National d'Hemovigilance

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Blood transfusion is life-saving intervention in many circumstances. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. Its goal is a continuous quality improvement of the transfusion chain through corrective and preventive actions to improve donor and patient safety.

Indeed, a national haemovigilance system can have a positive impact on many stakeholders throughout the blood transfusion chain such as blood donors, blood transfusion services, hospital and health care facilities, transfused patients, physicians and other health care professionals, health authorities, community and international bodies.

WHO has published in September 2016 a guide on establishing a national haemovigilance system and this presentation highlights the main steps to implement such a system.

A number of possible organizational models exist in which a national haemovigilance system can be organized, but for a particular country the best model will depend on the way in which the blood and health systems are structured and administered, even though it is recommended that a non-punitive and anonymized approach be used. For a national haemovigilance system to be effective there needs to be a certain degree of national coordination of transfusion activity, from the national blood policy and strategic plan to a hospital-based transfusion committee, as well as the availability of adequate human and financial resources.

To implement a national haemovigilance system, the planning of activities is needed. The organization and coordination of a well-established system include the haemovigilance in the donation and provision of blood, the haemovigilance in clinical transfusion and the national activities. In addition, this implementation requires an effective management and use of haemovigilance data through a requirement of a national haemovigilance data management system, standard forms to report adverse events including their severity and their imputability, analysis and feedback reporting and a rapid alert report.

The capacity and skill building of all health workers involved in blood transfusion activities are also essential. Furthermore, the monitoring and evaluation of process and outcome indicators should be developed to track planned haemovigilance activities and assess the effective functioning and success of the haemovigilance system. Collaborations with international haemovigilance bodies are proposed as initiatives that aim to stimulate country participation in global haemovigilance.

La transfusion sanguine est une intervention vitale dans de nombreuses circonstances. Cependant, il existe des risques d'événements indésirables associés au don de sang et de ses composants, ainsi qu'à la transfusion de sang et de produits sanguins aux patients. L'hémovigilance est un ensemble de procédures de surveillance couvrant l'ensemble de la chaîne transfusionnelle, depuis le don et la préparation du sang et de ses composants, jusqu'à leur délivrance et transfusion aux patients et à leur suivi. Son objectif est une amélioration continue de la qualité de la chaîne transfusionnelle à travers des actions correctives et préventives pour améliorer la sécurité des donneurs et des patients

En effet, un système national d'hémovigilance peut avoir un impact positif sur de nombreux intervenants dans la chaîne transfusionnelle à savoir : les donneurs de sang, les services de transfusion sanguine, les formations sanitaires, les patients transfusés, les médecins et autres professionnels de la santé, les autorités sanitaires, les communautés et les organisations internationales.

L'OMS a publié en septembre 2016 un guide l'établissement d'un système national d'hémovigilance et cette présentation met en évidence les principales étapes de la mise en place d'un tel système.

Il existe un certain nombre de modèles organisationnels possibles de système national d'hémovigilance, mais pour un pays donné, le meilleur modèle dépendra de la manière dont les services de transfusion et les systèmes de santé sont structurés et administrés, même s'il est recommandé l'utilisation d'une approche non-punitive et anonyme. Pour qu'un système national d'hémovigilance soit efficace, il faut qu'il y ait une certaine coordination nationale de l'activité transfusionnelle, depuis la politique et le plan stratégique national de transfusion sanguine jusqu'au comité hospitalier de transfusion sanguine, ainsi que la disponibilité des ressources humaines et financières suffisantes.

Pour mettre en place un système national d'hémovigilance, la planification des activités est nécessaire. L'organisation et la coordination d'un système bien établi comprennent l'hémovigilance dans les services de transfusion sanguine, l'hémovigilance dans les services cliniques et les activités d'hémovigilance au niveau central. En outre, cette mise en œuvre nécessite une gestion et une utilisation efficace des données d'hémovigilance, des formulaires standards pour déclarer les événements indésirables y compris leur gravité et leur imputabilité, des rapports d'analyse et de retro information.

Le renforcement des capacités et des compétences de tout le personnel de santé impliqué dans les activités de transfusion sanguine est également essentiel. De plus, le suivi et l'évaluation des indicateurs de processus et de résultats devraient être développés pour suivre les activités d'hémovigilance planifiées et évaluer le fonctionnement efficace et le succès du système d'hémovigilance. Les collaborations avec des organismes internationaux d'hémovigilance sont proposées comme initiatives visant à stimuler la participation des pays à l'hémovigilance mondiale.

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Global Haemovigilance
Initiatives and Developments

Initiatives et Développements Mondiaux en Matière d'Hémovigilance

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Many countries in the world have, or are in the process of developing, haemovigilance systems. Haemovigilance is defined by the International Haemovigilance Network (IHN) as 'A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.'

Some countries or regions use modifications of this IHN definition as their systems extend beyond labile blood products to include plasma-derived (fractionated) products, or are part of a broader biovigilance framework. The scope and content of haemovigilance systems vary around the world: for example, voluntary or mandatory reporting? Donor, product and recipient events [true 'vein to vein'], or only recipient adverse reactions? All events or just serious ones? All reports, or only confirmed cases? Importantly, there is no 'right' or 'wrong' way to 'do' haemovigilance – what is more important is that the system is conceived to work within the health system in the particular country. Additionally, all established systems have evolved over time, for example by moving from paper-based to computerised systems, or expanding to capture of additional events (such as 'near miss' events, cell salvage or incidents related to RhD immunoglobulin).

Definitions of most major adverse reactions have been published collaboratively by the International Society of Blood Transfusion (ISBT), AABB and IHN. Additional work is underway, including on definitions for the paediatric setting. These will require updating over time, reflecting experience with their applicability in practice, and as our understanding evolves of the pathophysiology of some types of adverse reactions.

Most established haemovigilance systems publish reports, and are happy to share information on their processes, tools, and results. Guidance on establishing and sustaining haemovigilance systems is available from the World Health Organization and other sources. Individuals interested in haemovigilance are welcome to join ISBT's working party on haemovigilance, and haemovigilance systems are welcome to join IHN. Through these activities we can share experience and participate in international collaborative activities including education, data sharing and analysis, and benchmarking.

De nombreux pays dans le monde ont développé ou sont en train de développer des systèmes d'hémovigilance. L'hémovigilance est définie par le Réseau international d'hémovigilance (RIH) comme 'un ensemble de procédures de surveillance couvrant toute la chaîne transfusionnelle (de la collecte du sang et de ses composants au suivi des receveurs), destiné à recueillir et évaluer les informations sur effets indésirables résultant de l'utilisation thérapeutique de produits sanguins labiles, et de prévenir leur apparition ou leur récidive.'

Certains pays ou régions utilisent des modifications de cette définition du RIH car leurs systèmes s'étendent au-delà des produits sanguins labiles pour inclure des produits dérivés du plasma (fractionnés) ou font partie d'un cadre de biovigilance plus large. La portée et le contenu des systèmes d'hémovigilance varient à travers le monde: par exemple, le signalement volontaire ou obligatoire? Les donneurs, le produit et les événements du receveur [vrai veine à veine], ou seulement les réactions indésirables du receveur? Tous les événements ou juste les plus graves? Tous les rapports ou seulement les cas confirmés? Il est important de noter qu'il n'y a pas de "bonne" ou "mauvaise" façon de "faire" l'hémovigilance - ce qui est plus important, c'est que le système est conçu pour fonctionner dans le système de santé du pays concerné. De plus, tous les systèmes établis ont évolué au fil du temps, passant par exemple de systèmes papier à des systèmes informatisés, ou élargissant à la capture d'événements supplémentaires (tels que les incidents évités de justesse ou les incidents liés aux immunoglobulines RhD).

Les définitions de la plupart des effets indésirables majeurs ont été publiées en collaboration par la Société internationale de transfusion sanguine (ISBT), l'AABB et la RIH. Des travaux supplémentaires sont en cours, notamment sur les définitions du milieu pédiatrique. Celles-ci nécessiteront une mise à jour au fil du temps, reflétant l'expérience avec leur applicabilité dans la pratique, et que notre compréhension évolue de la physiopathologie de certains types d'effets indésirables.

La plupart des systèmes d'hémovigilance établis publient des rapports et sont heureux de partager des informations sur leurs processus, outils et résultats. Des directives sur l'établissement et le maintien de systèmes d'hémovigilance sont disponibles auprès de l'Organisation Mondiale de la Santé et d'autres sources. Les personnes intéressées par l'hémovigilance sont invitées à rejoindre le groupe de travail de l'ISBT sur l'hémovigilance, et les systèmes d'hémovigilance sont invités à rejoindre la RIH. Grâce à ces activités, nous pouvons partager notre expérience et participer à des activités de collaboration internationales, y compris l'éducation, le partage et l'analyse de données, et l'analyse comparative.

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Haemovigilance: Role of Multidisciplinary Teams

Hémovigilance: l'Importance de la Collaboration Multidisciplinaire

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Haemovigilance is about monitoring and where possible improving safety throughout the transfusion chain. In this session at the Academy day on haemovigilance we will consider who are the players at various stages:

1. Safe blood components
2. Prescribing and safe administration of blood components
3. Haemovigilance of recipient adverse reactions
4. Haemovigilance of errors and incidents
5. Traceability
6. Audit and appropriate blood use
7. Donor haemovigilance
8. Assessing the reports which come in
9. Analyses – annual haemovigilance report
10. Doing something with the results

Examples of reported cases from SHOT (the UK haemovigilance system), TRIP (the Dutch haemovigilance system) and the literature will be discussed to illustrate the importance of transfusion safety officers (transfusion practitioners) and collaboration in multidisciplinary teams.

L'hémovigilance a l'objectif de veiller sur la sécurite dans toutes les étapes de la chaîne transfusionnelle et de l'améliorer dans la mesure du possible. Dans ce séance dans la journée à focus hémovigilance de l'Académie SITS il s'agira des acteurs dans les étapes différentes:

1. Produits sanguins labiles sécurisés et de qualité assurée
2. La prescription appropriée et la transfusion correcte des produits sanguins
3. L'hémovigilance des réactions transfusionnelles
4. L'hémovigilance des erreurs et défaillances dans la chaîne
5. La traçabilité
6. L'audit et l'utilisation appropriée des produits sanguins
7. L'hémovigilance-donneurs
8. La vérification des déclarations des réactions et évènements indésirables
9. Les analyses – le rapport annuel d'hémovigilance
10. Mise en pratique des leçons et recommandations

Certain cas déclarés à SHOT (Serious Hazards of Transfusion, bureau d'hémovigilance au Royaume Uni) et TRIP (Transfusion and Transplantation Reactions in Patients, bureau d'hémovigilance et biovigilance aux Pays-Bas) ou décrits dans la litérature seront discutés pour illustrér le rôle essentiel des professionnels d'hémovigilance (transfusion safety officer, transfusion practioner) et de la collaboration multidisciplinaire.

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Meeting Challenges of Haemovigilance by partnering with Hospitals (i.e. HTCS)

Relever les défis de l'Hémovigilance en établissant des partenariats avec des Hôpitaux (c.-à-d. des CHT)

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BACKGROUND

Namibia developed a haemovigilance system according to the established WHO guidelines. The Namibian annual haemovigilance report was broadened to beyond adverse event reporting to include all these. The aims of the haemovigilance system remain universal but have been adapted to Namibian circumstances solely to enhance blood transfusion standards in the country in general.

METHODS

The Namibian Blood Programme includes the 3 main stakeholders in blood transfusion and demands regular quality controls of procedures in all of them. The haemovigilance report includes any identified challenges.

The Better and Safer Transfusion (BeST) programme started in 2010, is revised regularly, and not only monitors the programme, but promotes education on blood transfusion in all universities and colleges.

Monitoring of the whole blood transfusion process is done by regular internal and external audits of all hospitals. Auditing includes the WHO depicted areas of the national blood transfusion service, hospital blood banks as well as clinical areas.

RESULTS

Audits have identified strengths and weaknesses in blood transfusion, and ways to rectify problem areas were devised. By partnering with hospitals, and establishing HTCs was the main approach, relative good progress was made. Non-conformances (mostly minor) had been resolved, and some major challenges could be improved by logical and 'Namibianized' interventions. This could be seen by follow-up audits, and feedback from hospitals. Post-audit training further enhanced knowledge of all health care workers on the non-conformances detected.

CONTEXTE

La Namibie a mis au point un système d'hémovigilance conforme aux directives de l'OMS. Le rapport d'hémovigilance annuel de la Namibie a été élargi au-delà des rapports d'événements indésirables pour inclure tous ces éléments. Les objectifs du système d'hémovigilance restent universels mais ont été adaptés aux circonstances namibiennes uniquement pour améliorer les normes de transfusion sanguine dans le pays en général.

MÉTHODES

Le programme de Transfusion sanguine namibien comprend les trois principales parties prenantes dans la transfusion sanguine et exige des contrôles de qualité réguliers des procédures dans tous les cas. Le rapport d'hémovigilance comprend tous les défis identifiés. Le programme Better and Safer Transfusion (BeST), lancé en 2010, est révisé régulièrement et non seulement surveille le programme, mais promeut l'éducation sur la transfusion sanguine dans toutes les universités et tous les collèges. Le suivi complet du processus de transfusion sanguine est effectué par des audits internes et externes réguliers de tous les hôpitaux. La vérification comprend les zones de l'OMS décrites par le service national de transfusion sanguine, les banques de sang des hôpitaux ainsi que les zones cliniques.

RÉSULTATS

Les audits ont identifié les forces et les faiblesses de la transfusion sanguine et des moyens de remédier aux problèmes ont été mis au point. En établissant un partenariat avec les hôpitaux et en établissant des CHT, l'approche principale a été relativement bonne. Les non-conformités (pour la plupart mineures) ont été résolues et certains défis majeurs pourraient être améliorés par des interventions logiques et 'namibalisées'.

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Some minor non-conformances were rectified quite easily by good communication with hospitals, by establishing trust with HTCs, and often without costly interventions. Some should have been rectifiable easily, but remain challenges due to staff turn-over, non-discipline and lack of M&E in the hospitals themselves, and by irregular external visits . Lack of knowledge was identified as an important challenge, but regular education is difficult, due to distances, time constraints and understaffing. Other challenges seem insurmountable, especially due to lack of funding and often slow progress by protocol-regulated, finance-strained organizations.

RECOMMENDATIONS

Challenges remain, even after 8 years of the BeST programme, and these are due to clearly identifiable reasons. It was established without doubt that partnering with hospitals directly has enhanced blood transfusion in Namibia, and this can be recommended to all countries embarking on the path of haemovigilance.

Cela pourrait être contrôlés par des audits de suivi, et les commentaires des hôpitaux. La formation ultérieure à l'audit a permis d'améliorer les connaissances de tous les travailleurs de la santé sur les non-conformités détectées. Certaines non-conformités mineures ont été corrigées assez facilement grâce à une bonne communication avec les hôpitaux, en établissant une relation de confiance avec les CHT, et souvent sans interventions coûteuses. Certains auraient dû être rectifiés facilement, mais restent problématiques en raison du roulement du personnel, de la non-discipline et du manque de S & E dans les hôpitaux eux-mêmes, et de visites externes irrégulières.

Le manque de connaissances a été identifié comme un défi important, mais l'éducation régulière est difficile, en raison des distances, des contraintes de temps et du manque de personnel. D'autres défis semblent insurmontables, notamment en raison du manque de financement et de la lenteur des progrès réalisés par les organisations soumises à des contraintes financières et réglementées par le protocole.

RECOMMANDATIONS

Des défis subsistent, même après 8 ans du programme BeST, et ceux-ci sont dus à des raisons clairement identifiables. Il a été établi sans aucun doute que le partenariat avec les hôpitaux a directement amélioré la transfusion sanguine en Namibie, ce qui peut être recommandé à tous les pays qui se lancent sur la voie de l'hémovigilance.

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Haemovigilance
concepts and frameworks

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Key words

Haemovigilance, patient safety, transfusion reactions.

ABSTRACT

BACKGROUND AND OBJECTIVES

This article reviews the principles and objectives of haemovigilance and provides suggestions on important elements to consider in establishing a haemovigilance system.

RESULTS

Various local, regional and national haemovigilance models exist, reflecting the diversity of health systems and blood systems in different countries. Some systems are coordinated by professional bodies, some by blood suppliers, and others by health authorities. Participation may be voluntary or mandatory, and may differ depending on whether all events or only serious ones are reportable. Some capture events with all levels of imputability, whereas others record only confirmed or highly probable cases. 'Near miss' events are captured by some systems, and many valuable lessons can be learned from these.

Process-related problems are a major cause of serious transfusion complications. Human and system factors, such as lack of awareness or training, working environment, interruptions and inadequate communications between clinical teams, or between clinical teams and the transfusion laboratory, are important contributors to these events.

Investigation of transfusion reactions, incidents and events is essential to identify clinical consequences and contributing factors, and to develop and implement plans to prevent recurrence. Transfusion safety officers and similar roles in many countries are a key part of the haemovigilance team. Adequate medical and transfusion laboratory support for hospital activities is also essential. Hospital transfusion committees should oversee haemovigilance activities and reporting, and ensure that hospital senior management is aware of, and responds to, serious reactions and events, especially where systems issues are contributory.

ISBT's Working Party on Haemovigilance brings together ISBT members with an interest in haemovigilance, and works closely with the International Haemovigilance Network, a collaboration of regional or national haemovigilance programmes, for education, data sharing and benchmarking.

CONCLUSION

Haemovigilance reporting can identify priority areas for action and monitor the implementation of solutions. An important feature of haemovigilance is the sharing of experiences and results nationally and internationally to improve patient outcomes.

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WHAT IS HAEMOVIGILANCE?

Haemovigilance is an important element of blood safety. It aims to identify, monitor and prevent adverse reactions, incidents and adverse events related to transfusion for both donors and patients (from 'vein to vein'). Investigation of transfusion reactions, incidents and events is essential to identify contributing factors and clinical consequences, and to develop and implement plans to prevent recurrence. Reportable incidents should be defined and notified to the haemovigilance programme in order to identify priority areas for action (either where the events have serious clinical consequences, and/or occur frequently) and then to develop and monitor the implementation of solutions.

The International Haemovigilance Network (IHN) defines haemovigilance as 'A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence'.[1]

IHN works closely with the Working Party on Haemovigilance of the International Society of Blood Transfusion (ISBT) in developing and publishing definitions concerning major donor and patient-related complications. These definitions are covered in more detail in another paper in this series.[2]

The first published haemovigilance reports clearly identified hospital process-related problems as a major cause of serious complications for transfused patients.[3, 4] These include 'incorrect blood component transfused' events, where the blood component was intended for another recipient (frequently due to errors in patient identification at the time of collection of the pre-transfusion sample, or at the time of bedside administration), or did not meet the patient's special needs (such as a patient with a red cell antibody who did not receive the required antigen-negative unit).[3] Human and system factors, such as lack of awareness or training, working environment, interruptions and inadequate communications between clinical teams, or between the clinical teams and the transfusion laboratory, are very important contributors to these events, and these factors are also equally at play in process-related problems occurring in blood centres.

HAEMOVIGILANCE: WHY DO IT?

The aims of haemovigilance are to improve outcomes (for patients and donors, for hospitals, blood centres and other suppliers), to reduce risks, costs and need for re-work, and to make better use of precious blood components and plasma products. Increasingly haemovigilance activities are specified by legal and other requirements, such as national or supra-national (e.g. European) health directives, standards, recommendations and guidelines.[5, 6]

One key aim is to develop an 'open' culture about transfusion within donor centres and hospitals, where reporting of blood donation and transfusion hazards, near-misses and actual adverse consequences can occur without blame or punishment (or fear of blame or punishment).

The intention is to encourage participation and reporting rather than achieving a seemingly 'perfect' zero score (with no apparent events/problems to address!) For this reason, numbers of events reported may actually increase rather than decrease over time after introducing a haemovigilance system.

Ideally, haemovigilance systems link with other national/institutional programmes for healthcare quality and safety improvement (for example, around medication safety), so that development and use of common mechanisms for reporting, assessment and monitoring can thereby raise awareness of reporting generally, and simplify and streamline processes.

WHAT TO INCLUDE AND HOW TO DO IT?

There are many differences in haemovigilance systems operating internationally, from scope to structure to whether participation is voluntary or mandatory. Some may have a mix of elements (for example, mandatory reporting of certain very serious, events, with voluntary reporting of others). There is no single 'ideal' or 'correct' type of haemovigilance system, and all systems reflect their context – both their place within their healthcare system, their aims, and their stage of development. [7, 8]

Many countries and haemovigilance systems are truly 'vein to vein' covering all aspects from blood collection at the donor centre and the manufacturing steps in preparation of blood components, through to laboratory and clinical transfusion practice in hospitals and their effects on patients. Other systems focus primarily on the transfusion recipient.

Some systems include all reporting of all types of events, others include only ones they define as serious. Serious events are, fortunately, usually uncommon (such as an incorrect blood component transfused leading to a haemolytic transfusion reaction from ABO incompatibility) but these frequently have elements in common with more common events (for example, the failures in patient identification procedures leading to wrong blood in tube events and many near miss events in blood administration). Some systems include 'near miss' events while other systems do not, usually for practical reasons – there are typically many more 'near misses' than actual events, and it can be timeconsuming to report and investigate all of them; however, many valuable lessons can be learned from these cases.

Many systems include only confirmed or highly probable cases, which are usually a minority of the cases initially suspected to be associated with transfusion. However, since many events cannot be conclusively proven (for example, due to incomplete clinical or laboratory information), this raises the important questions of what is required to consider something a confirmed case, and how that assignment is made, when and by whom. Some systems assign imputability and severity scores, which indicate the likelihood of an event being ascribable to the donation, transfusion or related process, and the seriousness of the occurrence, respectively. These can be helpful in prioritising incidents for review and/or interventions to be made.

In each case, there are many questions to consider when planning or setting up a haemovigilance programme:

1. Who are the stakeholders? How will they be involved? Since donors, patients and the broader community are the ultimate stakeholders – how can they be involved?
2. How to best engage healthcare professionals and through what channels (for example, via special societies and educational/training organisations)?
3. What information is desired? Collecting a lot of information is time-consuming and not always possible, but collecting too little may mean that cases cannot be adequately analysed.

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4. How will standardised reporting be achieved? This is essential for comparisons of results over time and with other settings or programs, and for benchmarking. It requires case definitions (which may be developed anew or adapted from other settings or haemovigilance programmes), case report forms (which may be electronic or paper or both) and a mechanism for submitting reports and collating them.
5. Will case validation be performed? If so, by whom: by the donor centre, hospital (hospital transfusion team or transfusion committee – they will have access to all available information but may not necessarily be independent or have the transfusion expertise to review the case) or by a central expert group (independent, but remote in time and place from the actual event)?
6. Who will operate the system? Will it be run by a government agency such as the ministry of health? A health regulatory authority? A blood service? An independent professional body? Will it be operated centrally (e.g. a single national 'office' or devolved to regional departments but with national coordination? What will be the governance structures around the operation of the system? There are differences between oversight and responsibility for making sure haemovigilance occurs (for example, this is typically the responsibility of the ministry of health in line with national blood policies) but the day to day operation of a haemovigilance system may be devolved to others (e.g. professional groups or blood services) in many settings. How will structures and roles be defined?
7. Could or will the system link with other current incident reporting system/s? Could the current incident reporting system (e.g. for pharmacovigilance or sentinel events) be redesigned or expanded to include the additional information? Would a broad 'biovigilance' programme be more useful than a 'standalone' haemovigilance programme?
8. What resources will be required? For example:
   (i) People: who, how many, where should they bebased and what training do they need? Transfusion safety officers, transfusion nurses and similar roles have been introduced in many countries and they play important roles in haemovigilance, especially at the hospital level. Haemovigilance programme staff will need project management skills and, transfusion content knowledge. It is not necessarily essential to have every resource 'on staff' in the haemovigilance programme office – in many cases it is possible to use the expertise of hospital partners, an expert review group, a professional society, blood centre etc. in a collaborative arrangement.
   (ii) Supporting structures: Blood centre and hospitalquality managers, and transfusion committees, should oversee event identification, investigation and reporting within their institution, and should ensure that senior management is aware of and responds to serious reactions and events, especially where systems issues are identified to be contributory. The haemovigilance system at regional and/or national level also requires a defined structure and guidance for submission of events, case validation, data analysis and reporting.
   (iii) Information technology: while paper-based systems can be practical and inexpensive, especially for pilot projects, electronic reporting is preferable for convenience and reliability. A stable, secure database is required for receipt, management and analysis of reports.
   (iv) Money: ongoing financial support will be requiredfor the programme. Budgets should include costs for personnel, office costs, preparation of programme materials and reports, travel if required etc. Costs can be offset against reductions from avoidance or minimisation of poor practice (reduction in re-work, insurance premiums and blood wastage).
9. How will participation be measured?
10. What denominators are defined and what data are available or need to be collected? For example, will the denominator be blood components issued vs. transfused? Will it be possible to request numbers of patients transfused from the transfusing facilities?
11. How will the information be used? Health policy development? Clinical practice standards and guidelines? Education for blood centre and hospital staff? Reports to the community? Hopefully, all of these! An important feature of haemovigilance programmes is the sharing of experiences and results. Haemovigilance reports can both provide valuable feedback to blood centres and clinical teams and hospitals locally, as well as share experiences nationally and internationally to improve donor and patient outcomes.
12. How will professional groups be engaged to support implementation of recommendations?
13. How will progress be measured? And so on.

WORDS OF ADVICE ON SETTING UP A HAEMOVIGILANCE SYSTEM

From international experience, the following tips may be useful during the initial and ongoing phases of establishing a new haemovigilance programme:

1. Set clear goals and review progress on these frequently. The majority of goals will be common goals, but it is important to recognise that individuals and institutions may have additional goals – for example, hospitals may wish to improve efficiency and reduce medicolegal exposure in transfusion clinical or laboratory work by improving adherence to patient identification procedures as part of their haemovigilance aims. Good teamwork will identify the broad range of driving factors and how best to incorporate these within the overall objectives of the haemovigilance programme.
2. Learn from others. Individuals, groups and institutions working in haemovigilance are very willing to share their experience – both the things that have 'worked' and the things they wish, in retrospect, that they might have done differently. Most programmes publish annual reports which are freely available on line.[3, 9-12] There is an international textbook on haemovigilance and an increasing number and diversity of published papers in the peerreviewed literature.[7, 13-19] There are also many examples from other areas of medicine, such as outlined by the World Health Organization,[20] and from outside medicine – for example, other settings such as the airline and mining industries, where better understanding of rare but serious events has led to improved safety.

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3. What can be linked with established risk management/ incident reporting systems (if these exist)? When starting out, it may be simpler and perhaps cheaper to incorporate monitoring of transfusion practice into other existing systems, such as by developing specific transfusion modules, rather than having multiple parallel systems. In many settings, pharmacovigilance reporting systems are already in place and these may be suitable for expansion to include haemovigilance. On the other hand, there may be challenges in incorporating transfusion into an existing structure for monitoring complications in other healthcare settings, or there may be difficulties in getting agreement or progress for a broader programme, which can be frustrating and cause delays.
4. Get started – even if your system is not 'perfect' at least get going. Consider a pilot in a few wards or a few hospitals where people are enthusiastic. Consider starting with a paper pilot or simple electronic pilot while a more complex database is being developed.
5. Monitor and review periodically: is it working? What are the gaps where progress is needed?
6. Report back regularly so the contributors understand the value of the information and how it is used to encourage continued or improved reporting.
7. Work with blood centres and hospitals to remove the stigma of reporting (no blame system) to encourage reporting to improve practice and ultimately donor and patient safety.

INVITATION TO PARTICIPATE IN IHN (NETWORK OF HAEMOVIGILANCE PROGRAMMES) AND ISBT WORKING PARTY ON HAEMOVIGILANCE (NETWORK OF INDIVIDUAL ISBT MEMBERS INTERESTED IN HAEMOVIGILANCE)

At an international level, ISBT's Working Party on Haemovigilance (www.isbtweb.org/working-parties) brings together ISBT members with an interest in haemovigilance. ISBT works closely with IHN (www.ihn-org.com), an international collaboration of regional or national haemovigilance programmes, and other partners. IHN operates the ISTARE database for international data sharing and benchmarking and holds annual educational seminars. These organisations are pleased to assist with ideas, sharing of materials and data, benchmarking and feedback, including for countries setting up haemovigilance programs.

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AIDE-MÉMOIRE
for ministries of health

Aide-mémoire produced by the Service Organization and Clinical Interventions unit, Department of Service Delivery and Safety, World Health Organization, Geneva, Switzerland.

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The transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion. Learning from adverse events and identifying systems problems can drive the introduction of measures to enhance the quality, safety, efficacy, and cost-effectiveness of blood and blood products as well as the donation and transfusion processes.

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their followup. Haemovigilance includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, as well as the development and implementation of recommendations to prevent their occurrence or recurrence. The ultimate goal of haemovigilance is continuous quality improvement of the transfusion chain through corrective and preventive actions to improve patient safety and outcomes, enhance donor safety and reduce wastage. Haemovigilance should be fully integrated into the quality systems of all institutions involved in the donation and provision of blood and blood products, including processing, inventory management, storage and distribution, and in clinical transfusion.

The organization of a haemovigilance system is largely determined by the structure of the national blood system and the health system. A system of haemovigilance is dependent on the traceability of blood and blood products from donors to recipients and vice versa, and on the monitoring, reporting, investigation and analysis of adverse events. The rigorous management of information generated through this system is key to introducing amendments in blood policies and guidelines that lead to changes in processes and practices in donation and transfusion.

CHECKLIST

Leadership and governance

- ☐ *Haemovigilance as an element of the national blood policy and plan, and legislative and regulatory framework*
- ☐ *Haemovigilance advisory committee(s)*
- ☐ *Adequate human and financial resources*
- ☐ *Standards and definitions*
- ☐ *Confidential and non-punitive system*
- ☐ *Traceability of blood and blood products from donors to patients and vice versa*
- ☐ *Quality system throughout the transfusion chain*
- ☐ *Corrective and preventive action.*

Organization and coordination

- ☐ *Identification of stakeholders and responsible organizations and institutions*
- ☐ *Organizational arrangements for the haemovigilance system*
- ☐ *Coordinated links with organizations and institutions involved in the system*
- ☐ *Defined roles and responsibilities of all stakeholders*
- ☐ *Haemovigilance education and training for all health-care staff*
- ☐ *Monitoring, reporting, investigation and analysis of adverse events, with recommendations for safety and quality improvements.*

Haemovigilance in clinical transfusion

- ☐ *Patient haemovigilance: recognition, clinical management, monitoring, reporting, investigation and analysis of adverse events associated with transfusion*
- ☐ *Clinical guidelines, hospital protocols, standard operating procedures, patient identification and sample labelling*
- ☐ *Hospital transfusion committees*
- ☐ *Response to recall and look-back notification*
- ☐ *Coordination between hospital departments and services, and liaison with blood transfusion services.*

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The establishment of a haemovigilance system involves coordination and collaboration among all stakeholders, including the ministry of health, blood transfusion services, hospitals, professional bodies, public health institutions and regulatory agencies, as well as patient and donor groups.

KEY ELEMENTS

Leadership and governance

The ministry of health (MoH) holds ultimate responsibility for its national blood system and for the quality, safety and sufficiency of the supply of blood and blood products. A haemovigilance system contributes to the safety of donation, blood products and transfusion. It improves risk management, increases trust and should be confidential and non-punitive in nature. The MoH should provide effective leadership and governance for a national haemovigilance system, including:

- systematic and comprehensive surveillance of the entire transfusion chain as an element of the national blood policy and plan, and legislative and regulatory framework;
- haemovigilance advisory committee(s) with medical, scientific and quality expertise;
- adequate human and financial resources for the establishment, development and sustainability of the haemovigilance system
- standards and definitions in line with international recommendations.

The MoH should define the scope and elements of the haemovigilance system for a stepwise development of the system. This should include:

- Reporting characteristics: whether it is mandatory, voluntary or mixed;
- Coverage: whether it concerns donors, processes, clinical practices or patients;
- Blood products: whether it covers only blood components for transfusion or also plasma-derived medicinal products;
- Types of events to be reported: whether it covers all types of adverse events or selected reactions, near misses and errors;
- Severity of adverse events to be reported: fatal, serious or all levels of severity;
- Imputability: the probability of attribution (definite, probable and possible, or also unlikely and excluded) in the context of blood donation, processing and clinical transfusion;
- Collection and use of denominators to calculate rates of adverse events.

An efficient haemovigilance system requires:

- Traceability of the blood product from donor to patient, and vice versa;
- Effective structure and clear channels for adverse events reporting, investigation, feedback and communication of findings, as well as monitoring and evaluation;
- Methods and mechanisms for data collection, validation and analysis;
- Guidelines, procedures and formats for notification and modalities of reports;
- A quality system throughout the transfusion chain, and implementation of corrective or preventive actions to quickly rectify weaknesses and deficiencies.

Words of advice

- ☑ Provide effective leadership, governance and adequate resources for establishing and maintaining an effective haemovigilance system
- ☑ Incorporate haemovigilance into national blood and health policies and systems
- ☑ Adopt a stepwise approach in establishing a haemovigilance system
- ☑ Engage all stakeholders in the blood transfusion chain
- ☑ Set up efficient organizational arrangements for the haemovigilance system and ensure integration with institutional quality management systems
- ☑ Develop a confidential and non-punitive system

Organization and coordination of a haemovigilance system

A haemovigilance system requires coordination and collaboration between multiple stakeholders involved in the donation, provision, transfusion, surveillance and regulation of blood and blood products. Haemovigilance may operate at local and institutional levels, but national coordination and management are vital for effective surveillance. The MoH should:

- Establish organizational arrangements and mechanisms to engage and coordinate all key stakeholders;
- Define the roles, responsibilities and accountabilities of all stakeholders;
- Facilitate international cooperation with existing haemovigilance networks.

Core haemovigilance coordination and management functions include:

- Establishment of links and communication with participating organizations and institutions;
- Education and training of all personnel on haemovigilance;
- Collection, management and review of data on adverse events from all organizations involved in the blood transfusion chain;
- Identification of underlying systems and process failures, weaknesses, gaps and deficiencies that have led to adverse events;
- Recommendations for the improved safety of donors, blood products and patients through changes in policies, strategies, standards, guidelines and procedures;
- Production and dissemination of reports and recommendations;
- Development of a rapid alert and early warning platform to communicate and share information;
- Periodic review, monitoring and evaluation of the haemovigilance system.

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Haemovigilance in the donation and provision of blood and blood products

In a national haemovigilance system, blood centres and transfusion services have the following roles and responsibilities:

- Donor haemovigilance, including recognition and clinical management of adverse events associated with donation, and their monitoring, reporting, investigation and analysis;
- Implementation of policies, guidelines, protocols and standard operating procedures for all processes in the donation and provision of blood and blood products;
- Epidemiological surveillance of donors, post-donation information and look-back;
- Identification, recording and reporting of:
  - Near misses, errors and deviations associated with these processes;
  - Abnormalities in intermediate and finished blood products.
- Traceability of each donation from the donor to blood processing, the blood product, its issue to a health-care facility and transfusion to the patient, and vice versa;
- Response to notification of a patient adverse event, by retrieval of all blood components associated with the index blood component(s);
- Implementation of haemovigilance as part of the quality system, and mechanisms for taking corrective and preventive actions and monitoring their outcomes;
- Training and assessment of staff involved in all steps of the donation and provision of blood and blood products;
- Liaison with hospitals: administration, blood banks, transfusion committees and clinical services.

Haemovigilance in clinical transfusion

In a national haemovigilance system, hospitals and other health-care facilities have the following roles and responsibilities:

- Patient haemovigilance, through recognition and clinical management of adverse events associated with transfusion, and their monitoring, reporting, investigation and analysis;
- Correct identification of patients, samples and blood products, and appropriate labelling;
- Implementation of hospital standards, clinical guidelines and protocols for safe blood transfusion, investigation of adverse events and reporting by clinical services;
- Traceability and documentation of transfused blood products in patient records;
- Response to product recall and look-back notification;
- Active participation in a hospital transfusion committee;
- Integration of haemovigilance in the hospital quality system, and mechanisms for taking corrective and preventive actions and monitoring outcomes;
- Training and assessment of staff involved in all steps of clinical transfusion, including clinical decision-making, pre-transfusion sampling, laboratory practice, handling of blood units in the clinical area, bedside administration of transfusion and patient monitoring;
- Regular audit of clinical transfusion practices;
- Mechanisms for coordination between hospital departments and clinical services, and liaison with blood transfusion services.

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