International Society of Blood Transfusion

ISBT Haemovigilance Working Party

December 2025


“Alone we can do so little;
together we can do so much”
Helen Keller
American author and activist

In this issue

From the Chairperson's Desk

Dr Gopal Patidar
Chairperson, ISBT HV WP

Dear Working Party Members,

We are pleased to share the final newsletter of 2025—an issue that reflects the collective energy, commitment, and engagement of our Haemovigilance Working Party. This edition brings together key updates, insights, and developments that showcase the progress we have achieved together.

A major highlight of this issue is the summary of our first Working Party members' survey. We are delighted by the enthusiastic responses and thoughtful ideas you shared. Your input demonstrates a strong commitment to advancing haemovigilance and supporting the global transfusion medicine community. As a Working Party built on collaboration and inclusivity of members, we value your suggestions and remain dedicated to integrating them into our future activities.

Beyond the survey, this newsletter features updates on ongoing Working Party initiatives, recent publications, and important announcements that underscore our collective efforts. We are also honoured to highlight the contributions of one of the most respected figures in haemovigilance, **Dr Barbee Whitaker**, whose remarkable dedication and lifelong commitment have significantly shaped haemovigilance practices worldwide.

Additionally, we provide a preview of upcoming events intended to expand knowledge, encourage dialogue, and promote best practices in haemovigilance and transfusion medicine. Through new research, educational opportunities, and collaborative projects, our aim is to keep you connected to the latest global developments in our field.

Your voice continues to be central to our progress. We warmly welcome your feedback, suggestions, and ideas for future editions. Whether you wish to share your work, propose a topic, or introduce an initiative, we encourage you to remain engaged. Our Working Party thrives because of your participation.

As we close another productive year, we extend our heartfelt gratitude for your ongoing support and commitment. Thank you for being an essential part of this journey. We look forward to our continued collaboration in the coming year.

With warm regards,

Gopal Patidar

Through the Eyes of an ISBT HV WP Past Chair

Reflections on Serving as Chair of the ISBT Haemovigilance Working Party (2020–2024)

Dr Mary Townsend
Immediate Past Chair, ISBT HV WP

I was asked to share a few reflections from my time as Chair of the ISBT Haemovigilance Working Party (HV WP), a role I assumed in 2020 following Kevin Land. My goal throughout my term was to follow Kevin's lead—advancing the work on Definitions of Adverse Events while also supporting new haemovigilance initiatives.

A major foundation of our work was the **2014 Standard for Surveillance of Complications Related to Blood Donation**, developed collaboratively by AABB, ISBT, and IHN, and adopted by these organisations as well as the European Blood Alliance (EBA). Building on this, a subsequent joint effort began in 2018 to create a **Severity Grading Tool for Adverse Donor Events**. The tool categorised events into five levels based on CTCAE criteria, using indicators such as symptoms, need for medical care (ranging from none to hospital admission), treatments required (from minor care to sutures, surgery, or IV hydration), and impact on activities of daily living (ADL).

The ISBT HV WP met to consider the adoption of this new tool as an addendum to the 2014 standard, and it was ultimately approved by all participating organisations (*M. Townsend, H. Kamel, N. VanBuren, J. Wiersum-Osselton, M. Rosa-Bray, J. Gottschall, S. Rajbhandary. "Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events." Transfusion 2020; 9999:1–12*).

Another important initiative emerged from an international collaboration inspired by the WHO Aide-Mémoire supporting countries in implementing haemovigilance programs. One of the identified needs was to provide **tools and resources** to facilitate system development. In December 2020, more than 20 experts from IHN, ISBT, WHO, and other partners formed a Working Group that met weekly for many months to identify existing materials and develop a consolidated set of resources.

This led to the publication of the **WHO User Guide for Navigating Resources on Stepwise Implementation of Haemovigilance Systems** in 2022. The associated tools and resources were collected on the ISBT HV WP webpage, where they are freely available to anyone seeking support in building haemovigilance capacity.

To maintain this repository, the HV WP established a new **HV Tools Management Group**, tasked with reviewing, updating, and expanding these materials—now a routine component of the Working Party's work.

During my term as chair, several other initiatives were also launched:

- **Regular WP newsletters**, published roughly quarterly, to inform members of ongoing projects, highlight haemovigilance leaders, and encourage participation - especially from early-career professionals.
- The **Imputability Project**, led by then-Secretary (now Chair) Dr. Gopal Patidar, aiming to standardise imputability assignment for adverse events, much like our earlier work on definitions and severity grading. This remains an active initiative.
- Development of a **brief (5-minute) educational video**, co-sponsored and co-branded by ISBT, IHN, and AABB - an ongoing collaborative effort.
- A joint project with the **Paediatrics Working Party** to define TACO risk assessment approaches.
- Contribution of several articles to the April 2022 **Transfusion Today** issue focused on haemovigilance.

Serving as Chair of the ISBT HV WP was truly a highlight of my career. I had the privilege of working alongside exceptional colleagues, collaborating across organisations and continents, and contributing to the advancement of haemovigilance worldwide. I hope the work undertaken during this time continues to support and strengthen haemovigilance systems internationally.

With Best Wishes

Mary Townsend

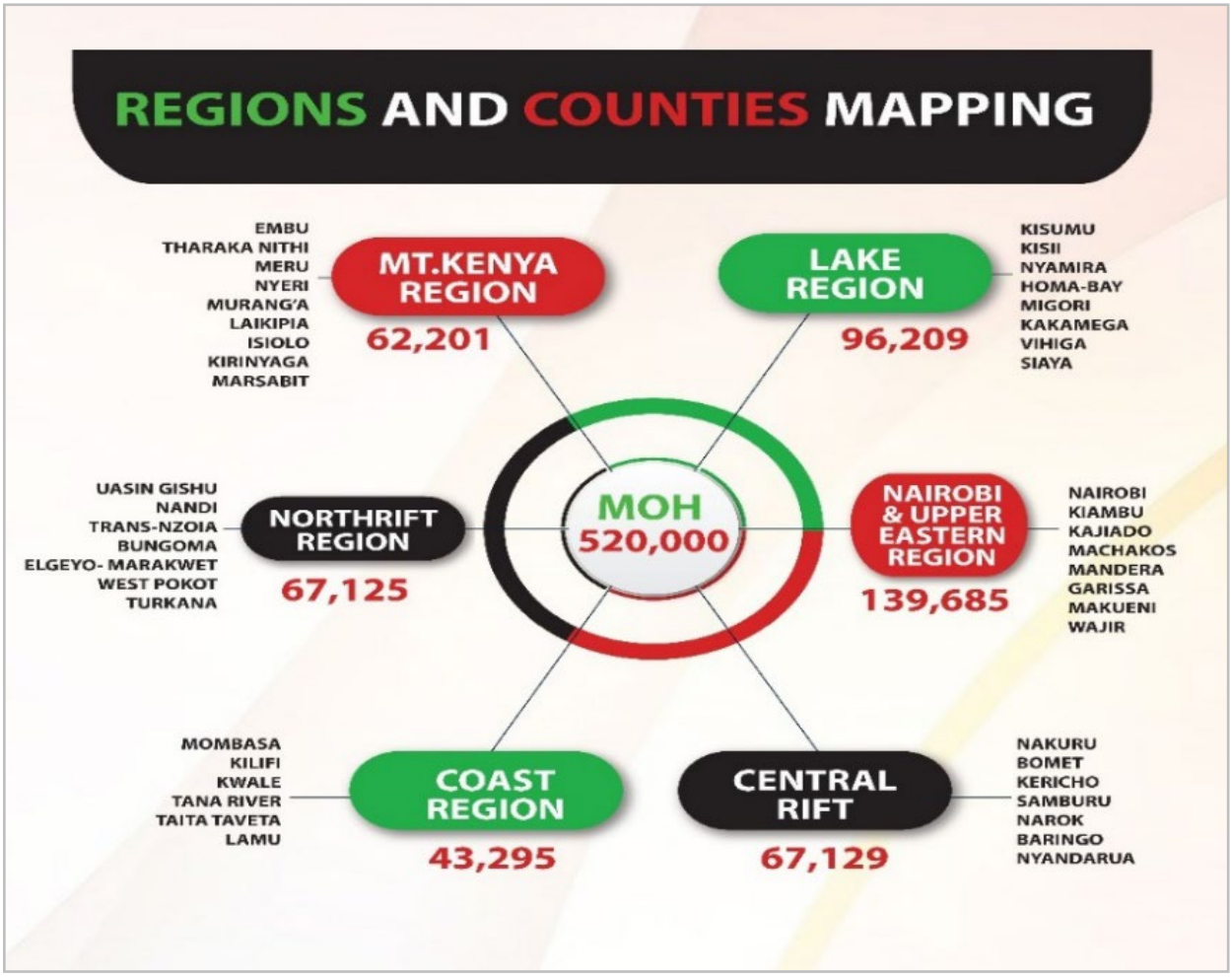
Member's Blog

The Haemovigilance System in Kenya

Dr Gratia Muru

Haemovigilance/ Public Health/Supply Chain
Kenya National Blood Transfusion Service

The Kenya National Blood Transfusion Service (KNBTS) is mandated to ensure access to safe blood transfusion services in Kenya. It is centrally coordinated with 6 Regional Blood Centres and 43 county satellite blood banks. The blood service operates in a 'hub and spoke' model with the satellite blood banks mapped to Regional Blood Centres for transfusion-transmissible infection (TTI) screening and blood grouping.

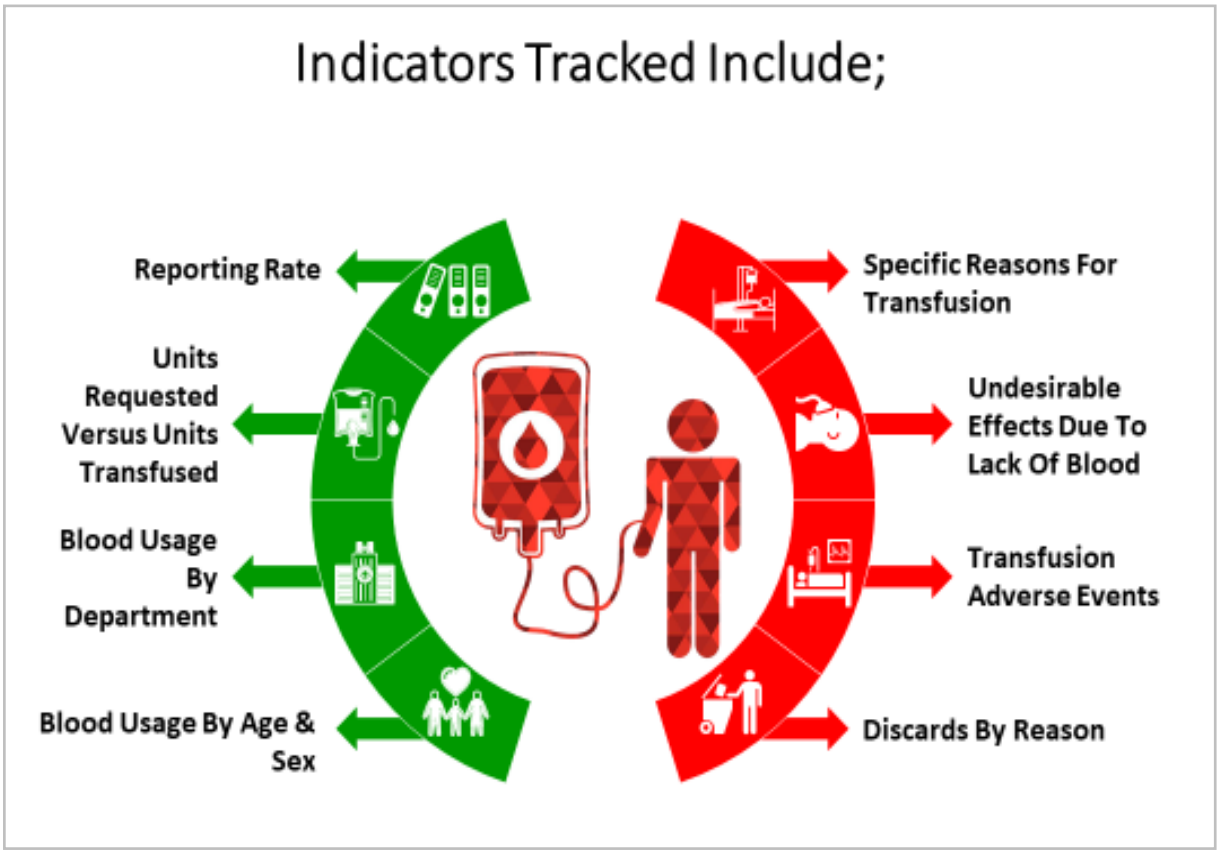


The national hemovigilance system is a centralised, passive, voluntary, nonpunitive, anonymised, corrective, and comprehensive model. It receives reports from public, faith-based, and privately owned transfusing facilities. Kenya has national and regional haemovigilance technical working groups with TORs in promoting haemovigilance nationally and regionally, respectively. ISBT 128 has been adopted to standardise product identification. Kenya has a web-based management information system, DAMU-KE, for vein-to-vein visibility. “Vein 2” deployment in progress.

Haemovigilance is increasingly integrated with broader patient safety and pharmacovigilance systems. Some facilities have haemovigilance in quality improvement teams. There is increasing emphasis on interoperability with facility management information systems and the Kenya Health Information System for smooth reporting and digitisation of “Vein 2”. There is continuous sensitisation on the availability and appropriate use of blood and components.

KNBTS organised a very successful 3-day symposium on ‘Appropriate Use of Blood and Blood Components’, with financial support from the ISBT Academy, and hosted 2777 online attendees on the first day, 2562 on the second day, and 2972 on the third day.

County Blood Transfusion Coordinators compile haemovigilance reports from transfusing facilities within their counties. In Kenya, all transfusion-related adverse events and reactions, irrespective of their grade of severity, are eligible for reporting. The reports are reviewed by the national haemovigilance office and evaluated regarding classification, imputability and severity. The respective transfusing facility is then contacted or visited regarding root cause analysis and corrective action.



Conclusion

There's evidence that the implementation and performance of haemovigilance in Kenya are growing and still provide room for improvement. A well-implemented haemovigilance system impacts positively on donor safety, blood product quality and transfusion safety.

It is clear that training, qualification and capacity building remain fundamental in all aspects of blood safety. This further reveals the need to set up targeted and customised technical support, coupled with prioritised interventions to strengthen the capacities of transfusing facilities. There is a need to sensitise transfusing facilities on the identification and reporting of transfusion reactions.

Although there has been marked improvement in hemovigilance activities, there are still areas that need to be enhanced, including the formation and strengthening of facility transfusion committees, optimising haemovigilance reporting, digitisation of "Vein 2" processes, adverse events identification and reporting, feedback mechanisms as well as donor and device vigilance.

Haemovigilance Star!

Dr Barbee Whitaker

Barbee is a member of the ISBT Haemovigilance Working Party and a member of the International Haemovigilance Network's (IHN) Board of Directors. She was the first chair of the IHN Seminar Committee and has worked to organise IHN seminars, symposia, and webinars since 2018.

She recently retired from her position as Director, Division of Analytics and Benefit Risk Assessment, in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration (FDA), although she remains active in the field of blood safety surveillance.

While at the FDA, Barbee worked to standardise terminology for biologically derived products and adverse events. She explored the use of large language models and artificial intelligence to identify adverse transfusion events, involving networks of hospital electronic health record systems to collect, report, and share information about adverse events associated with blood transfusion. She was also the FDA's lead for the Transfusion-Transmissible Infection Monitoring System or TTIMS.

Barbee began working in the area of haemovigilance in 2007 at the invitation of Dr. Michael Strong when he was President of AABB (the Association for the Advancement of Blood & Biotherapies). She led the collaboration of many professionals in blood safety and biologics surveillance to design the US recipient hemovigilance system, implemented at the CDC in 2012, and the donor vigilance system, DonorHART, later implemented at a few blood centres within the US but no longer available. Key to both efforts was the development of standardised definitions for transfusion and donation adverse events, their severity, and imputability.

More recently, Barbee engaged with other leaders in the field as the WHO "Tools" core editing group to develop the WHO User Guide for Navigating Resources on Stepwise Implementation of Haemovigilance Systems and to make the tools available to all on the ISBT Haemovigilance Working Party website.

Links that may be of interest:

- International Haemovigilance Network
- CDC Biovigilance Hemovigilance Protocol
- WHO User Guide for Navigating Resources on stepwise implementation of haemovigilance systems

WP Member survey

WP Member survey was conducted between September and October 2025 to understand the topics and/or activities members would like the working party to focus on and to inform future work plans.

Thank you to everyone who took the time to respond to the survey and provide such valuable feedback!

The following summarises the survey responses, noting that some editing of the raw data may have been necessary or beneficial.

Origin of responses

Total responses: 76 from 34 countries, majority from India (n=15; 20%).

Figure 1: Map showing origin of responses

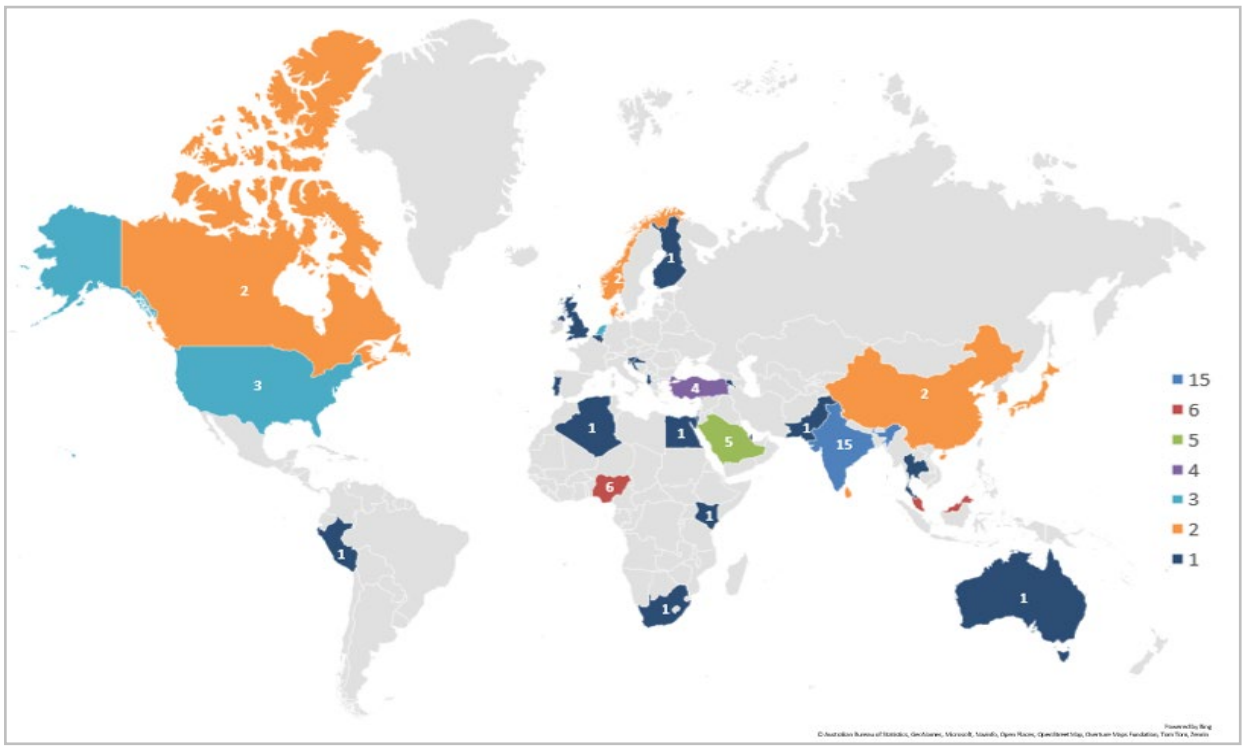
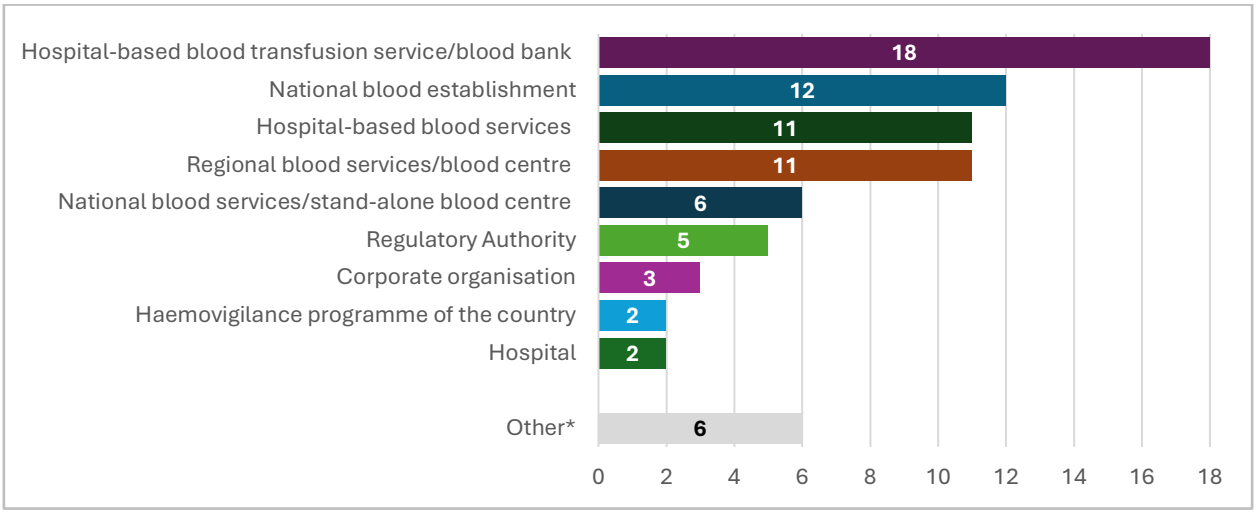


*Table 1: Country providing two or more responses (n=14)**

Country	Number	%	Country	Number	%
India	15	20	**Canada**	2	3
Malaysia	6	8	**China**	2	3
Nigeria	6	8	**Denmark**	2	3
Saudi Arabia	5	7	**Japan**	2	3
Turkey	4	5	**Norway**	2	3
Netherlands	3	4	**Republic of Korea**	2	3
USA	3	4	**Sri Lanka**	2	3

* Countries providing a single response (n=20): Albania, Algeria, Armenia, Australia, Belgium, Croatia, Egypt, Finland, Hong Kong, Israel, Kenya, Pakistan, Peru, Portugal, Qatar, Singapore, Slovenia, South Africa, Thailand, UK

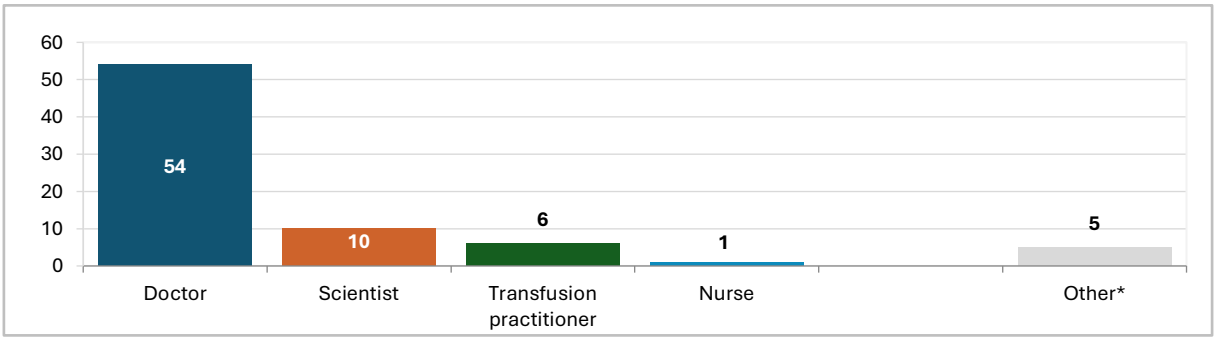
Type of organisation where participants work



Other*: Regional and hospital-based blood transfusion service (both); Haemovigilance programme of the country: Government, NGO; Volunteer for the national transfusion society; Combination of regional and hospital-based blood bank

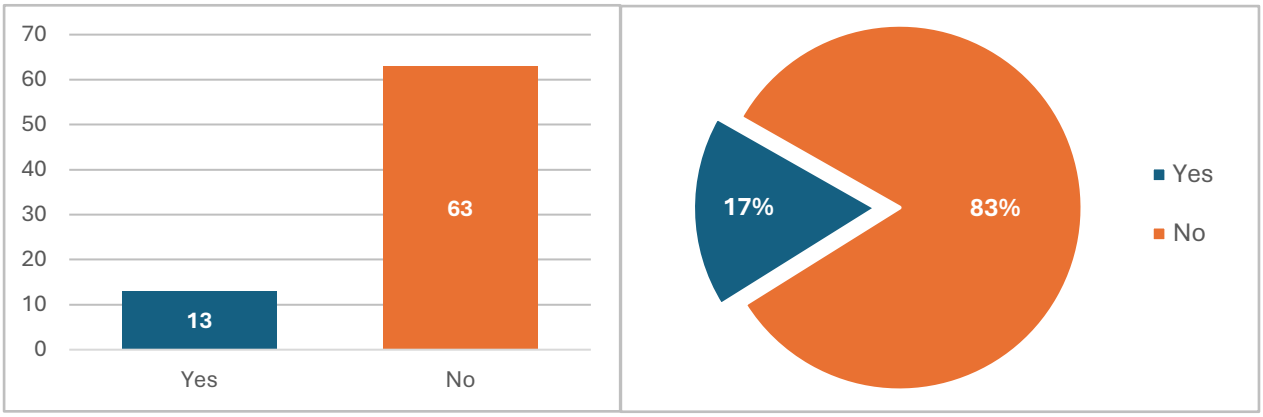
Professional background of participants

Doctors were the largest professional group (71%; 54/76), followed by scientists (10/76; 13%) and Transfusion Practitioners (6/76; 8%).



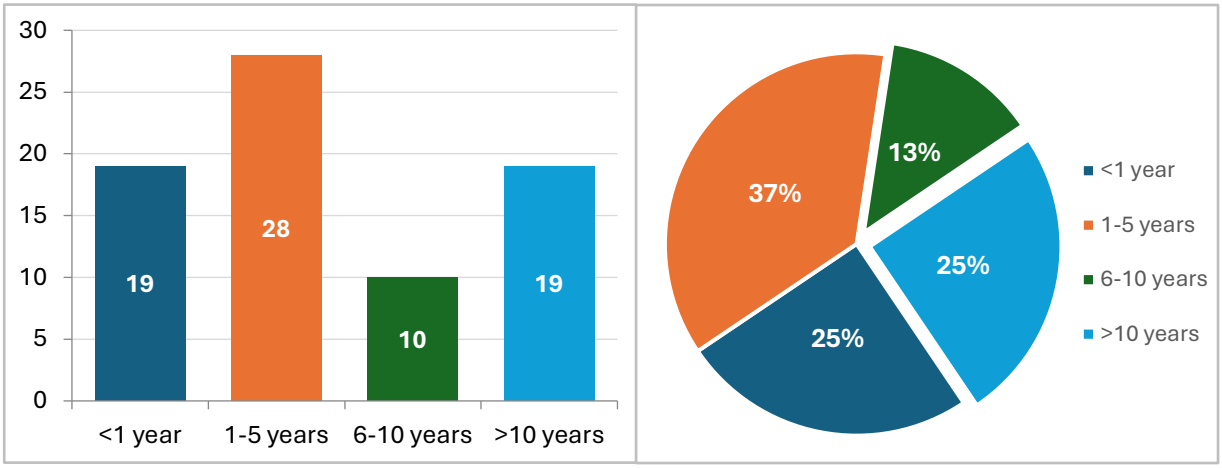
Other*: Epidemiologist; Industrial engineer; Pharmacist, PhD; Senior pathology lecturer

Young professionals (< 40 years of age): 17% (13/76)



Length of WP membership

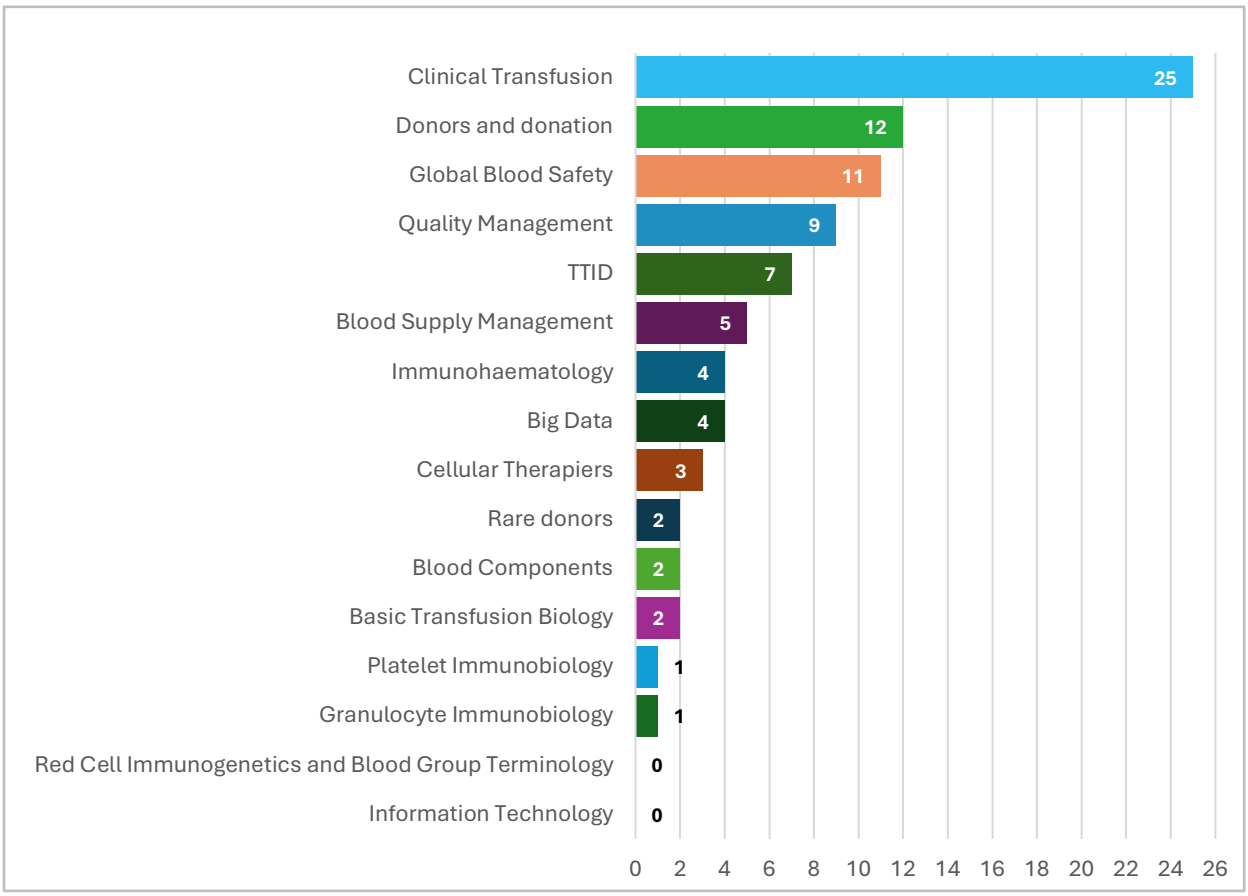
Most participants (62%) have been members of the WP for up to 5 years.



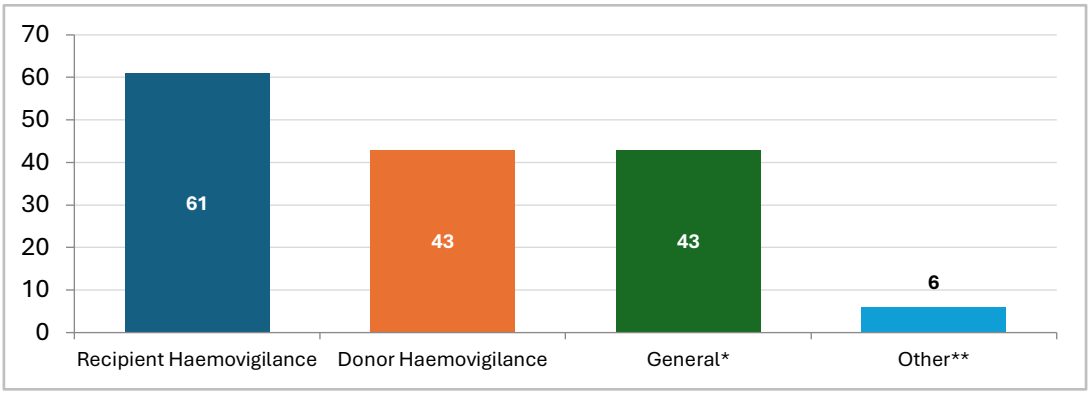
Membership of other ISBT working parties

This question was answered by 43 participants. The 104 responses clearly showed membership of multiple working parties, with the Clinical Transfusion WP the most common choice.

For the following chart, responses (n=16) indicating membership of the Haemovigilance WP have been removed.



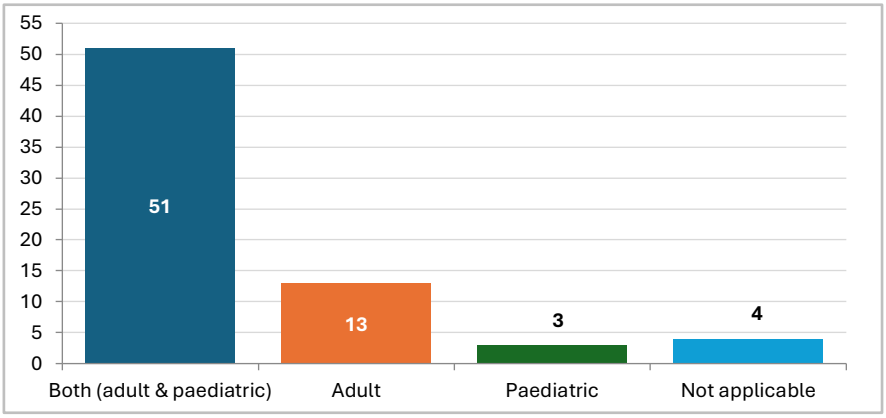
Primary area of interest



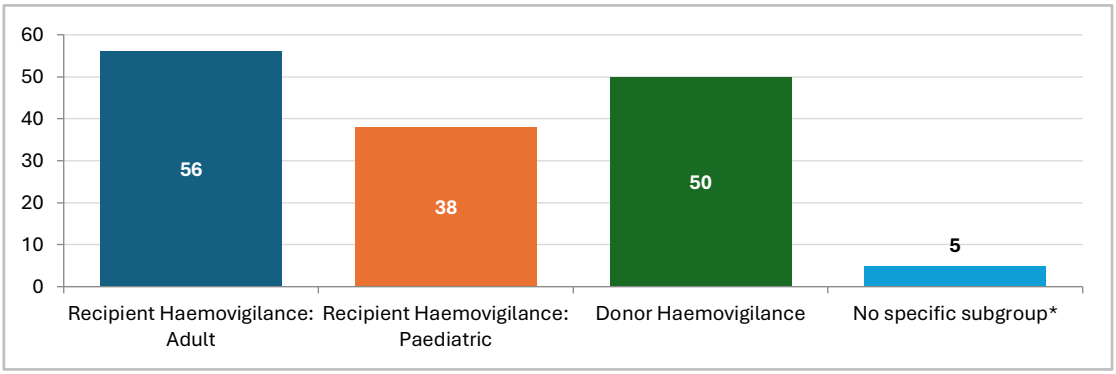
General*: e.g. quality systems, human factors, error detection and management, traceability

Other:** Blood component; Advisor for the regional hemovigilance department of national authority; Implementation of the system, Education & Awareness; Haemovigilance systems as a source of clinical data for regulatory post-market reporting; Education; Definitions

Recipient haemovigilance: Patient age group of interest

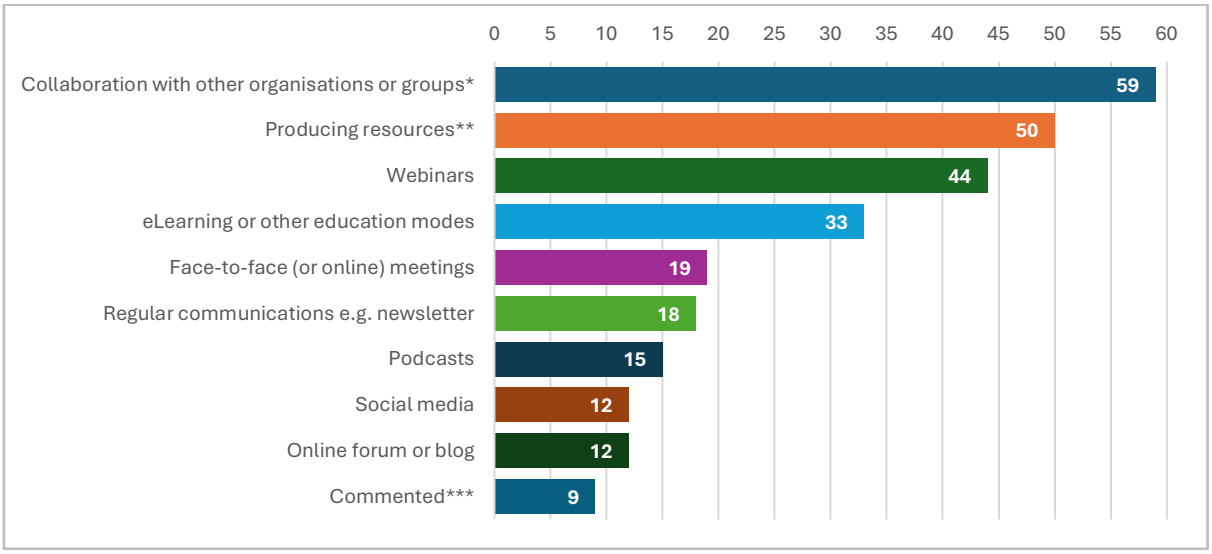


Activities participants would like to become involved in



No specific subgroup* but interested in: Global national haemovigilance system; Research; Surveys; Education; Resource development; Quality management

Expectations of working party



* **Collaboration with other organisations or groups:** e.g. ISBT working parties, IHN, AABB, SHOT, WHO, collaboration with national societies for example 'National Society of Clinical Pathology and Society of Haematology'

** **Producing resources:** e.g. definitions, "how to" guides: IHN guiding local haemovigilance setup; models of HV system implementation; how to start up haemovigilance in resource-poor countries

*** **Also commented:** Nothing additional; Involve members in research and survey activity; Need efforts to harmonise hemovigilance definitions, systems, approaches and regulatory reporting requirements; and Member surveys to identify differences among countries

Areas for the working party to focus on

The following summaries were generated using MS CoPilot from free-text comments in response to Q11, Q12, and Q14. They provide insight into what members would like the working party to focus on. As can be seen, there is a broad range of issues that will need to be prioritised.

Topics for the working party to discuss or present	
Donor Vigilance	• Apheresis procedures, donor retention/motivation, iron deficiency monitoring, and long-term donor health. • Adverse donor reactions and seroconversion rates.
Recipient Vigilance	• Paediatric haemovigilance, delayed transfusion reactions, pulmonary complications, TRALI/TACO redefinition.
Regulatory and Harmonisation	• Adaptation to new SoHO regulations, global harmonisation (EU, FDA, China), SAE/SAR alignment.
Data and Technology	• Use of AI/machine learning for adverse event prediction, global data sharing.
Implementation and Quality	• National/local HV system implementation, quality assurance in low-resource settings.
Other Specific Interests	• Cold platelets, plasticisers in transfusion, and cost analysis of universal leucocyte reduction.

Unmet areas of haemovigilance	
Donor Health and Safety	• Long-term monitoring (iron deficiency, cumulative donation effects), vigilance beyond physical reactions.
Standardization and Harmonization	• Reporting criteria, SAE/SAR definitions, process validation, CAPA integration.
Emerging Technologies	• AI, big data, biomarker integration for adverse event detection.
Special Populations and Procedures	• Paediatric haemovigilance, therapeutic apheresis, stem cell vigilance.
Global Gaps	• Implementation in developing countries, South America representation, and mentorship programs.
Other Areas	• Traceability/look-back processes, RhD alloimmunization post-NIPT, organ vigilance.

Suggestions to enhance working party effectiveness	
Member Engagement and Support	• More participation, regular online meetings, mentorship programs, and certification opportunities.
Capacity Building and Education	• Training modules, webinars, workshops at ISBT congress, systematic reviews/publications.
Operational Improvements	• Administrative support for project leaders, structured collaboration, and avoiding overlapping WP meetings.
Global Inclusion	• Involve developing countries, provide guidance for setting up HV systems.
Technology and Accessibility	• AI-powered dashboards for real-time surveillance, a user-friendly website with structured resources.
Industry Perspective	• Greater focus on the use of haemovigilance data outside hospital/blood bank QA systems.

Haemovigilance publications 2025

Recipient Haemovigilance

1. D'Alessandro A, Zimring JC. From Metabolomics to transfusion-associated immunomodulation. Curr Opin Immunol. 2025 Oct;96:102646.
2. Bagheri S, Hajiabadi F, Vahabzadeh R, et al. Investigating the impact of mitochondrial DNA: Insights into blood transfusion reactions and mitigation strategies. Vox Sang. 2025 Apr;120(4):354-365.
3. Tao K, Tao K, Wang J. The potential mechanisms of extracellular vesicles in transfusion-related adverse reactions: Recent advances. Transfus Clin Biol. 2025 May;32(2):205-227.
4. Kuriri FA. Transfusion-related acute lung injury (TRALI): Current understanding, challenges, and future directions. Saudi Med J. 2025 Aug;46(8):865-877.
5. Badu SA. Transfusion-associated circulatory overload: A retrospective audit of risk assessment practices in a large teaching hospital. Transfus Apher Sci. 2025 Jun;64(3):104105.
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7. Hirayama F, Kuroishi A, Matsuyama N, et al. Recent progress in understanding of allergic transfusion reaction. Curr Opin Immunol. 2025 Oct;96:102644.
8. Jones VM, Nakahara H, Choudhary SK, et al. Immunologic investigation of an allergic transfusion reaction suspected due to alpha-gal syndrome. Transfusion. 2025 Oct;65(10):1989-1995.
9. Malard L, Beuscart C, de Chaisemartin L, et al; Biomedical Excellence for Safer Transfusion (BEST) Collaborative. Association between group B major ABO-incompatible platelet or plasma transfusion and severe allergic reactions: A nationwide haemovigilance analysis suggesting a role for α-gal syndrome. A Biomedical Excellence for Safer Transfusion Collaborative study. Vox Sang. 2025 Oct 29. doi: 10.1111/vox.70136.
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14. Thiyagarajan K, Ganesan SK, Gurumoorthy R. Artificial Intelligence in Hemovigilance: Advancing Blood Safety and Monitoring Systems. J Young Pharm [Internet]. 2025 Nov 13;17(4):770–6.

15. Horck S, Fahy N, Greenhalgh T. Implementation challenges of electronic blood transfusion safety systems: Lessons from an international, multi-site comparative case study. Transfus Med. 2025 Feb;35(1):48-59.

16. Taha OB, Liu T, Mandernach MW. Management of severe acute chest syndrome in a patient with a history of severe delayed haemolytic transfusion reaction. BMJ Case Rep. 2025 Apr 29;18(4):e258680.

17. Brown M, Sharma D, Atchison K, et al. Incorrect blood typing and mis-transfusion due to low-titer group O whole blood resuscitation. Transfusion. 2025 Jun;65(6):1203-1209.

18. Chen YJ, Lin CL, Er TK. Trends and Incidence of Transfusion Reactions: a Single-Center 5-Year Retrospective Analysis. Clin Lab. 2025 Apr 1;71(4).

19. Alp Kirkizlar T. Five-year review of acute transfusion reactions and transfusion errors at a tertiary center. Transfus Clin Biol. 2025 Aug;32(3):280-285.

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23. Patel PD, Simpson EA, Acker JP. Irradiation and beyond: mitigating TA-GVHD in transfusion. Transfus Apher Sci. 2025 Oct;64(5):104237.

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26. Tung JP, Simonova G, Hewlett E, et al. Pre-storage leucoreduction of platelet concentrates reduced biological response modifier concentrations and TRALI incidence in an in vivo sheep model. Sci Rep. 2025 Nov 26;15(1):42081.

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31. Vlaar APJ, Zwaginga JJ, Wiersum-Osselton JC. How I diagnose and treat cardiorespiratory complications of transfusion. Blood. 2025 May 15;145(20):2283-2292.

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36. Silva, Lucas Braulino Reis, et al. "Hemovigilância no Brasil: uma análise dos eventos adversos relacionados à transfusão de sangue e hemoderivados." (Brasil) *Revista Delos* 18.67 (2025): e5072-e5072.

37. Booth C, Davies P. Transfusion sample mislabelling and wrong blood in tube in the UK: Insights from the national comparative audits of blood transfusion in 2012 and 2022. Transfus Med. 2025 Feb;35(1):41-47.

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Donor Haemovigilance

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Looking forward to 2026!

International Haemovigilance Network 2026 Seminar Rome

Registration and abstract submission

are now open.

39th International ISBT 2026 Congress
Kuala Lumpur

Registration and abstract submission are now open.

Join the Working Party

If you or your colleagues are members of ISBT but not currently members of the Haemovigilance Working Party, we would love you to join us!

Please click **here** to join.

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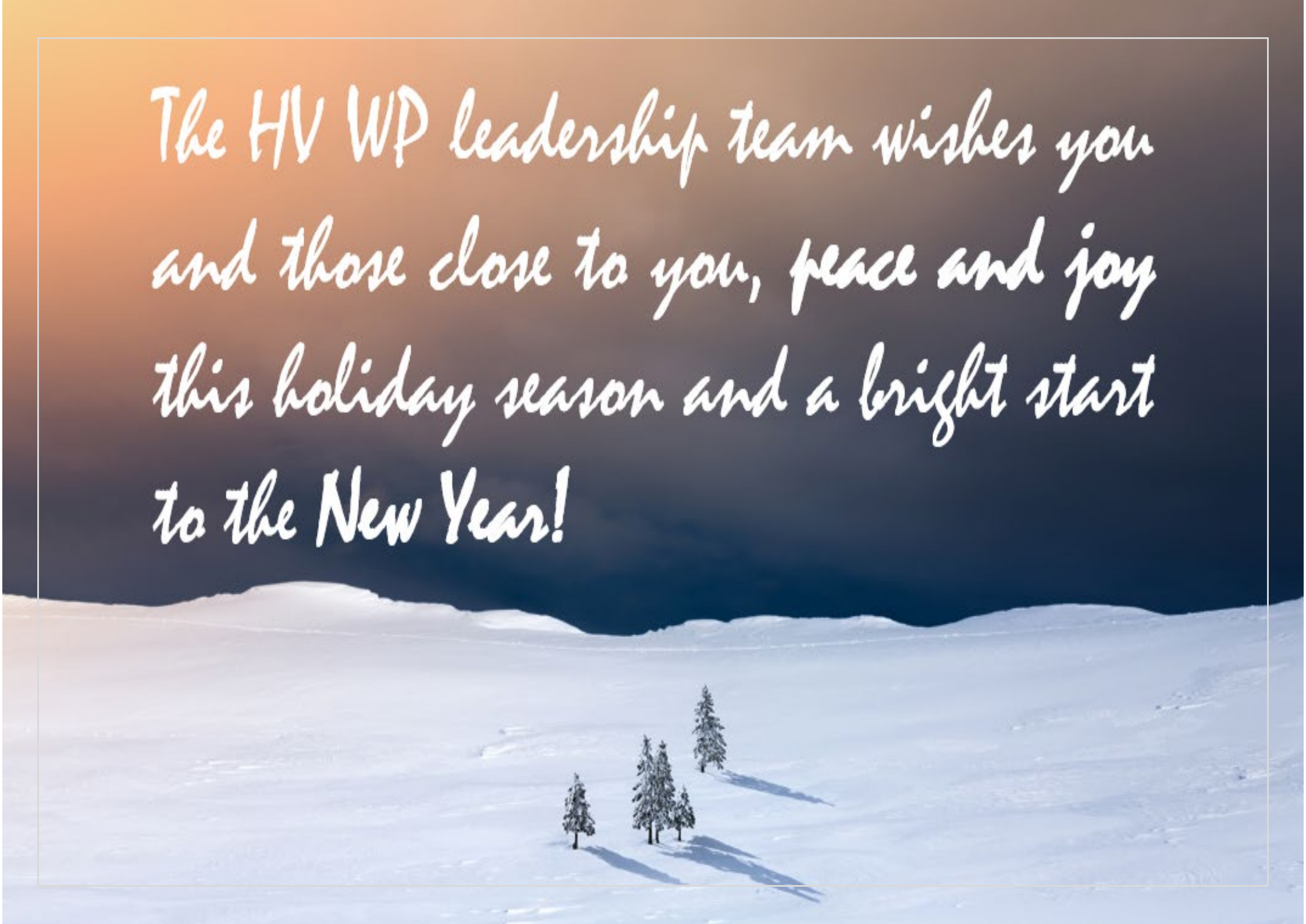
The HV WP leadership team wishes you
and those close to you, peace and joy
this holiday season and a bright start
to the New Year!