

Haemovigilance Working Party **NEWSLETTER**

October 2026

“The most effective way to do it is to do it.”

Amelia Earhart, American aviation pioneer



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From the Chairperson

Dr Gopal Patidar
Chairperson, ISBT HV WP

Dear Working Party Members,

We are pleased to share another Working Party newsletter, highlighting our recent achievements, significant advancements, ongoing initiatives, and the future directions shaping haemovigilance globally.

The Working Party continues to play a pivotal role in promoting patient and donor safety through collaborative efforts, knowledge sharing, and the integration of innovative technologies. Our recent business meeting in Kuala Lumpur's ISBT Congress demonstrated strong member engagement. Jaap Jan Zwaginga's overview of biovigilance and updates from allied working parties underscored the interdisciplinary approach of the ISBT working parties.

The joint workshop with the Information Technology Working Party further emphasised the critical role of information technology in enhancing transfusion safety. Our commitment to education and knowledge dissemination is exemplified by our participation in a joint webinar celebrating World Patient Safety Day. This interactive session was organised in partnership with leading research and patient safety organisations.

In 'Member highlights', Dr Idaleswati Nor Mohamed presents Malaysia's haemovigilance journey. Similarly, our 'Haemovigilance star' article celebrates the exemplary career of Dr Yuyun Siti Maryuningsih Soedarmono, whose leadership and expertise have significantly advanced blood safety and haemovigilance both nationally and internationally. Her work at the World Health Organisation and in Indonesia underscores the global impact of dedicated professionals in shaping safer transfusion practices and regulatory frameworks.

Looking ahead, the ISBT Haemovigilance Working Party is dedicated to strengthening global haemovigilance through enhanced reporting completeness, timely notification of serious events, and robust root-cause analyses.

This newsletter reflects the collective efforts of our members and partners in advancing haemovigilance as a cornerstone of transfusion medicine. The shared commitment to patient and donor safety, continuous learning, and innovation drives our progress. We encourage active participation in upcoming events, engagement with educational resources, and cross-disciplinary collaboration to address emerging challenges and improve transfusion safety worldwide.

With warm regards,

Gopal Patidar



From the Secretary

Simon Benson

Secretary, ISBT HV WP

Welcome!

Welcome to this edition of the ISBT Haemovigilance Working Party Newsletter.

As I reflect on our activities since the last newsletter, I am reminded how fortunate we are to be part of such a dedicated, collaborative global community. Despite the challenges we face in our different healthcare systems, we share a common purpose: improving the safety and quality of transfusion practice for donors and patients.

One of the things I value most about our Working Party is members' willingness to share their experiences, successes, and lessons learned. Every presentation, discussion, publication, and conversation strengthens our collective understanding of haemovigilance and helps us learn from one another. This spirit of openness and collaboration is what makes our community so special.

This newsletter highlights just a few of the many activities, achievements, and initiatives our members undertake around the world. I hope you will find the articles informative, thought-provoking, and perhaps even inspiring.

Thank you for your ongoing support and commitment. I hope you enjoy this edition of the newsletter.

One further thing before you move on.

A bit of fun with a *tricky trivia teaser* to get the grey cells sparking and the synapses snapping!

Q: October is the month when the [Nobel Prizes](#) are announced. Who was announced as the recipient of the Nobel Prize in Physiology or Medicine on 30 October 1930?

You will find the answer at the end of the newsletter.



From the Recipient Subsection

Mark Fung

Chair, ISBT HV WP Recipient Subsection

The ISBT Haemovigilance Working Party Recipient Subsection is focused on adverse transfusion reactions that occur in recipients of all blood products.

We highlight articles of potential interest to the ISBT members in the literature as they are published. Additionally, we facilitate through presentations and conversations, the dissemination of knowledge regarding the implementation of and best practices of recipient transfusion reaction reporting into regional and national haemovigilance systems, and how best to utilise this aggregated data for the benefit of all members of the ISBT HV WP in promoting safer transfusions for our patients.

A specific project we are currently focused on is a scoping review of the literature and possibly of various haemovigilance systems for rare or previously undescribed transfusion reactions that currently have no standardised definition (WHO or ISBT). The goal of this project is to provide a resource for haemovigilance systems who might consider the addition of new transfusion reactions.

Examples of reactions that a smaller group of Subsection members will be considering include: transfusion-associated necrotising enterocolitis (TA-NEC), acute pain syndrome, alpha-gal syndrome, and inflammatory transfusion circulatory overload (HOT-TACO).



Member blog

Dr Idaleswati Nor Mohamed

Transfusion Medicine Consultant

National Haemovigilance Coordinating Centre, National Blood Centre, Kuala Lumpur, Malaysia.

Malaysia's Haemovigilance Journey: From National Reporting Towards Learning and Prevention

Malaysia's haemovigilance journey began with the recognition that valuable information on donor and recipient adverse events was already being collected locally, creating a foundation for a coordinated national programme. In 2002, a survey coordinated by the National Blood Centre across 117 Ministry of Health (MOH) hospitals identified variation in the reporting of donor and transfusion adverse events. The findings highlighted the need for greater consistency and national coordination.

Building national visibility

Building on this work, the National Haemovigilance Programme was established under MOH in 2003, with the National Haemovigilance Coordinating Centre (NHCC) based at the National Blood Centre to coordinate its national implementation. Standardised forms and reporting algorithms were subsequently developed, and structured national data collection commenced in 2004, with reports received from 81 MOH hospitals. By 2026, the programme's scope had expanded to include 143 MOH hospitals.

Hospital and State Transfusion Committees, supported by national training, policies and clinical guidelines, provide the link between local recognition and investigation of adverse events and national review through NHCC. A revised reporting form was introduced in 2016 and remains in use. NHCC has since published biennial national haemovigilance reports for 2016-2017, 2018-2019, 2020-2021 and 2022-2023.

The programme currently includes 143 MOH hospitals, of which 98 also undertake blood collection. NHCC also receives reports from private, university and Ministry of Defence hospitals, although MOH facilities provide the most comprehensive national dataset. Monthly reports encompass donor-, recipient- and process-related events, together with seroconvert donor notifications. NHCC verifies submitted information and assesses event type, severity and imputability before national analysis.

International references and learning

Malaysia's national haemovigilance programme draws on internationally recognised reference definitions, published haemovigilance experience and educational resources. These inform national classification and interpretation, while forms and guidance are adapted to Malaysia's service structure and reporting needs. International comparison remains valuable, but differences in definitions, participation, denominators and surveillance methods must be recognised.

Strengthening participation and governance

The programme operates predominantly through passive surveillance, with events entering the national system after being recognised, investigated and reported locally. A month in which a hospital confirms that no

reportable event was identified is distinguished from one in which no report was submitted, as non-submission cannot be interpreted as the absence of an event.

Since 2024, reporting compliance has been incorporated into the MOH Hospital Performance Indicator for Accountability, with a target above 80%. Compliance increased from 81.3% in 2024 to 86.4% in 2025, providing a clearer measure of participation and strengthening institutional accountability.

A major governance milestone followed in 2025. The second edition of the National Policy for Transfusion Medicine Services in Malaysia moved haemovigilance from voluntary to policy-mandated reporting. Hospitals and blood banks are now required to report adverse transfusion reactions and donation-related incidents. The policy also calls for trend and root-cause analysis, corrective action, education and feedback.

Digital integration provides another opportunity for progress. Blood Bank Information System (BBIS) version 1, introduced in 2007, established the foundation for electronic blood banking but did not include haemovigilance functionality. Implementation of BBIS version 2 began in 2018 and introduced a dedicated haemovigilance module. It currently covers 24 sites, with expansion to 118 sites planned by 2029. BBIS version 3 is scheduled for implementation in 2030 and will replace version 2 across participating sites. Wider electronic coverage should improve reporting completeness and timeliness, reduce manual data entry and allow NHCC to devote greater capacity to verification, analysis, feedback and safety improvement.

From reports to safer practice

Malaysia's experience shows that haemovigilance data must be interpreted in context. Increased reporting may reflect better recognition, participation and confidence in the system rather than worsening transfusion safety. Conversely, low numbers may indicate under-recognition, incomplete reporting or unavailable denominators.

Seroconvert donor surveillance provides a pathway for donor assessment, lookback and, where indicated, recipient investigation. It supports the evaluation of possible transfusion-transmitted infection and timely action to protect donor and patient safety, while recognising that donor seroconversion alone does not establish transmission.

Reported errors and near misses point to vulnerabilities in patient identification, sampling and labelling, laboratory testing, component selection and bedside administration. The 2024-2025 national report, currently in preparation, will include an appendix bringing together event definitions, classifications and reporting pathways to support consistent reporting and interpretation.

The shift from reporting to prevention requires timely notification and appropriate investigation of serious, life-threatening and fatal events. Root-cause analysis should support learning rather than assigning individual faults, and corrective and preventive actions should be evaluated to determine whether recurrence has been reduced.

The haemovigilance programme is well positioned for further development. Reporting completeness is already being strengthened through performance monitoring and policy-mandated reporting, while BBIS expansion is expected to improve electronic integration and reduce reliance on manual data entry. Further priorities include improving denominator and activity data, establishing more timely notification and structured follow-up of severe events, strengthening feedback to participating hospitals, improving donor-to-recipient information linkage where appropriate, and evaluating whether actions arising from national findings lead to measurable improvement and reduced recurrence.

More than two decades after its establishment, Malaysia's haemovigilance programme provides a national framework for identifying adverse events, learning collectively and supporting action through guidance and policy. The next phase focuses on earlier recognition of serious events, understanding why they occur, supporting hospitals to implement effective change and evaluating whether those changes reduce recurrence. National experience, international learning and a shared commitment to safer donation and transfusion guide the programme's continued development.



Haemovigilance star

Dr Yuyun Siti Maryuningsih Soedarmono

**Team Lead, Blood and Other Products of Human Origin
World Health Organization, Geneva**

Our 'Haemovigilance star' article celebrates the work of someone who has had a significant impact on haemovigilance and transfusion safety. For this issue, we are delighted to introduce **Dr Yuyun Siti Maryuningsih Soedarmono**.

For more than three decades, Dr Soedarmono has driven advances in blood safety, transfusion medicine, and haemovigilance, helping shape policies and practices that protect millions of patients worldwide. From local health services in Indonesia to global leadership at the World Health Organization (WHO), her career reflects an unwavering commitment to ensuring access to safe, quality-assured blood and blood products for all.

Dr Soedarmono began her journey as a medical doctor, graduating from Padjadjaran University before pursuing a Master of Science in Virology at the University of Adelaide and later earning a PhD in Biomedics from the University of Indonesia. Her doctoral research focused on improving protection against hepatitis B transmission through blood transfusion, laying the foundation for a lifelong dedication to strengthening blood safety systems.

Her professional career in transfusion medicine started with the Indonesian Red Cross, where she progressively assumed leadership roles, including Head of the Transfusion-Transmitted Diseases Section, Head of Reagent and Blood Component Production, and Director of the Central Blood Transfusion Service. In this role, she oversaw capacity building, monitoring, and quality improvement across more than 200 blood transfusion units nationwide, contributing significantly to the modernization of Indonesia's blood services.

Equally passionate about education, Dr Soedarmono spent more than 20 years teaching, mentoring, and developing future leaders in transfusion medicine. As Coordinator of the Master's Program in Blood Transfusion Science at the Faculty of Medicine, University of Indonesia, she helped cultivate a new generation of specialists while contributing to the development of professional curricula, training programmes, and technical guidance for physicians, nurses, and blood service professionals.

Her influence has extended well beyond academia and clinical practice. At the national level, she played a pivotal role in developing regulations, standards, and policies related to blood services, blood screening, plasma fractionation, quality systems, and good manufacturing practices. Her leadership as Chair of Indonesia's National Blood Transfusion Committee helped strengthen governance and support the country's progress toward safer and more sustainable blood systems.

Since 2018, Dr Soedarmono has served as Team Lead for Blood and Other Products of Human Origin at WHO Headquarters in Geneva, supporting countries around the world in strengthening blood regulatory systems, implementing haemovigilance programmes, improving plasma utilisation, and expanding access to safe blood products. Through WHO initiatives, workshops, and technical collaborations across Africa, Asia, Europe, and the Middle East, she has championed practical solutions to some of the most pressing challenges in transfusion medicine.

A recognised advocate for haemovigilance, Dr Soedarmono has coordinated and contributed to numerous landmark WHO publications and implementation tools, including guidance on haemovigilance systems, patient

blood management, emergency blood supply, plasma-derived medicinal products, and quality management in blood establishments. Her work continues to help countries build stronger systems that put patient safety at the centre of care.

Her contributions have earned international recognition, including awards from the **International Plasma and Fractionation Association** and the **Asian Association of Transfusion Medicine**. Yet colleagues often point first to her collaborative spirit, mentorship, and dedication to public health.

Throughout her distinguished career, Dr Soedarmono has remained guided by a simple principle: every patient, regardless of where they live, deserves access to safe blood and blood products. Her leadership, expertise, and passion continue to inspire the global haemovigilance community and advance patient safety worldwide.



ISBT Congress Kuala Lumpur

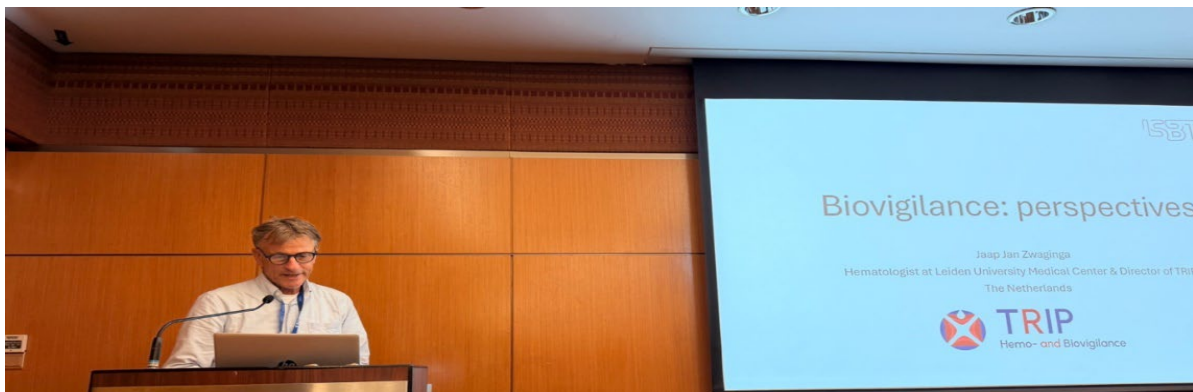
Working Party business meeting

The Working Party business meeting was held on 21 June 2026 at the ISBT Congress in Kuala Lumpur. A total of 47 members attended: 25 in person and 22 online

Presentation by ISBT Haemovigilance Liaison Officer: Satyam Arora



Educational session by Jaap Jan Zwaginga: “An Overview of Biovigilance”



IHN Update by Shruthi Narayan



Update on Working Party activities: Gopal Patidar, Simon Benson and Shruthi Narayan



Updates from other working parties

Information Technology Working Party: Karen Moniz



Quality Management Working Party: Nigar Ertuğrul Örüç



Coming together at the end of the business meeting



Wired for safety: Transfusion IT unplugged

Joint workshop of the Haemovigilance and Information Technology Working Parties

24th June 2026

Participants: 30

Moderators: Karen Moniz and Gopal Patidar



Overview of Transfusion IT system / Learning from IT errors reported to SHOT and human factors perspective: Megan Rowley



How can IT help with traceability? – Karen Moniz



Challenges with implementation of transfusion IT systems / Managing planned and unplanned IT downtime and future prospects- Julie Staves



Questions from the audience



All together!



World Patient Safety Day webinar

Enhancing haemovigilance: Current and future directions

NIHR | National Institute for Health and Care Research

IHN | International Haemovigilance Network

NIHR | Blood and Transplant Research Unit in Data Driven Transfusion Practice

Interactive webinar:

**Enhancing haemovigilance:
Current and future directions**

Date: 17th September 2026: 12pm – 1.30pm BST
Format: Online webinar

NIHR | Patient Safety Research Collaboration
NIHR Patient Safety Research Collaboration: Yorkshire and Humber

20 Years

NHS Blood and Transplant

The views expressed are those of the authors and not necessarily those of the NHS Blood and Transplant, the NIHR or the Department of Health and Social Care. Declaration: No competing interests.

To celebrate World Patient Safety Day on **17 September 2026**, the NIHR Blood and Transplant Research Unit in Data Driven Transfusion Practice, ISBT Haemovigilance Working Party, International Haemovigilance Network (IHN), SHOT, and NHSBT jointly hosted an interactive webinar.

The webinar focused on research into current and future directions to enhance haemovigilance, bringing together experts from healthcare, research, and patient safety organisations.

The programme featured:

- The patient perspective on transfusion safety
- A presentation of research findings covering data capture, analytics, feedback, learning, and implementation.
- A panel session with a live Q&A and audience polling

The primary objective of the session was to share research findings, gather audience input, and discuss future opportunities to improve haemovigilance practice and learning.



World Patient Safety Day 17 September 2026

You are in a practice session

SHOT- we

Septen

Enhancing Haemovigilance: Current and Future Di

Your **microphone is muted** by the host and will remain muted throughout the session

Please type any questions into the **Q&A** box below, do not use the chat facility for questions

- *Questions will either receive a response through Q&A or will be answered live*

Live captioning now available during the webinar, attendees can switch it off if not needed

The session will finish with a poll for your immediate feedback

Attendees are encouraged to record their learning from this session and can enter 1.5 CPD point for this webinar.

Thank you for attending!



Music: <https://v>

02:58:23

Dr Gopal Patidar

Dr Gopal Patidar

Shruthi Narayan

SHOT

SHOT

Simon Benson

Anna mamwell

Working Party Social Media Group

Social Media Posts

[Instagram](#) / [X](#) / [Facebook](#) / [LinkedIn](#)

Supporting Haemovigilance Implementation Worldwide

Prepared by Sharmila Menain, Malaysia

#ISBTHaemovigilance

SUPPORTING HAEMOVIGILANCE IMPLEMENTATION WORLDWIDE

Tools, guidelines and resources



Haemovigilance and Patient Safety

Prepared by Radheshyam Meher

#ISBTHaemovigilance

HAEMOVIGILANCE AND PATIENT SAFETY

Joining hands between transfusion
medicine experts and clinicians



Recent Publications

Recipient Haemovigilance

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Upcoming events

External

**ISBT
ROTTERDAM
2027**

76th Congress of the ISBT Rotterdam, the Netherlands
June 19-23, 2027

19 – 23 June 2027

ISBT Rotterdam 2027

ISBT Congress ROTTERDAM, NETHERLANDS

External



29 – 31 October 2026

**8th Transfusion medicine congress of
Serbia and 3rd International Congress
of TMAS**

SERBIA

External

**Molecular
Blood Group
Forum Frankfurt**

2026 November 2nd – 3rd
Frankfurt, Germany

2 – 3 November 2026

12th Molecular Blood Group Forum

External event FRANKFURT, GERMANY

External



The Royal College of Pathologists
Pathology: the science behind the cure



Advances in Transfusion Medicine Symposium
November 25-26, 2026

25 – 26 November 2026

**Advances in Transfusion Medicine
Symposium 2026 - Organised by
RCPATH and SHOT**

External event VIRTUAL

Haemovigilance resources highlights

User guide for navigating resources on stepwise implementation of haemovigilance systems

<https://www.who.int/publications/i/item/9789240047860>

WHO User Guide for Navigating Resources on the Stepwise Implementation of Haemovigilance Systems



Provides practical guidance for countries and organisations at every stage of development.

Access the WHO User Guide



ISBT Haemovigilance Tools Library

<https://www.isbtweb.org/resources/toolkits/hv-tools.html>

Haemovigilance Tools & Resources

The **ISBT Haemovigilance Tools Library** brings together practical resources to help countries and organisations establish, strengthen and expand haemovigilance systems.

- Guidance & resources
- Practical implementation tools
- Educational materials

A growing collection that complements the WHO User Guide and supports haemovigilance implementation at every stage.

Explore the tools and resources



Haemovigilance resources available for everyone: A report from the International Haemovigilance Tools Collaborative Project

<https://onlinelibrary.wiley.com/doi/abs/10.1111/vox.13570>

The International Haemovigilance Tools Collaborative Project

The tools and resources featured in this post are part of a broader collaborative effort to support the step-by-step implementation and strengthening of haemovigilance worldwide.

Key Partners:



Together, they support stronger haemovigilance systems and safer transfusion.

[Read the publication](#)



Answer to the tricky trivia teaser

Q: October is the month when Nobel Prizes are announced. Who was announced as the recipient of the Nobel Prize in Physiology or Medicine on 30 October 1930?

A. Dr Karl Landsteiner: “for his discovery of human blood groups”.

Although announced in October, the prize was awarded in Stockholm on 10 December 1930.



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

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