International haemovigilance: Challenges and opportunities

Erica Wood, Jo Wiersum, Paula Bolton-Maggs, Jean Claude Faber, Martin Schipperus, Peter Tomasulo for IHN and the ISBT Working Party on Haemovigilance

“Once again, zero income from endorsements.”
- International network of HV systems
- 37 country/regional systems
- Collaboration, sharing experience, benchmarking
- International database (ISTARE)
- Definitions (with ISBT)
- Education
- Seminars
- Award and medal

www.ihn-org.com

IHN members

Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Serbia Slovenia, Spain, Switzerland, Sweden, Turkey, UK, Iran, Pakistan, India, Sri Lanka, Singapore, Australia, New Zealand, Japan.
ISBT Working Party on Haemovigilance

Individual members of ISBT interested in HV

– Donor and recipient HV
– Definitions, guidelines and tools
– Interaction with other ISBT WPs
– International projects
– Share ideas and experience, support members

Chair: Dr Jo Wiersum, NL

“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.”
Different approaches to HV

- When and why established: health system, drivers
- Operating agency
- Model (voluntary/mandatory)
- Scope
  - V2V or recipients only, biovigilance
  - Confirmed/all, severity/all, ‘near miss’
- Resources
- Evolution over time

What is the scope of HV?

Transfusion-Related Activities

- Transfusion-Related Activities
  - Patient Sample Collection
  - Sample Handling and Testing
  - Inventory Management
  - Patient Monitoring

- Transfusion
  - Number of Components
  - Number of Patients

Adverse Events

- Reactions
- Incidents
  - Near Miss Incidents
  - Incidents Related to Transfusion (No Adverse Reaction)
  - Incidents Related to Transfusion and Adverse Reaction

www.cdc.gov/nhsn
Scope of HV?

- Blood and components
  - “Manufactured” conventional components
  - Cell salvage
- Fractionated plasma products
  - Pharmacovigilance
- Cellular therapies, tissues organs
  - Biovigilance
- Related products?
  - ESAs, rVIIa, antifibrinolytics, topical agents

**Blood:** Includes homologous and autologous whole blood. Blood including red blood cells, platelets, fresh frozen plasma, cryoprecipitate and cryodepleted plasma.\(^8\)

**Blood products:** Plasma derivatives and recombinant products, excluding medication products.\(^8\)

www.safetyandquality.gov.au
Scope of HV?

- Delayed reactions
- Delayed or under-transfusions
- Clinical decision-making
- Failure of expected benefit
- Procedural
- Product wastage

Making HV a policy priority

Affiliated to the Royal College of Pathologists
The Steering Group includes members representing the following professional bodies:
- British Association for Blood Transfusion
- British Society for Haematology
- British Society of Haematology
- British Committee for Standards in Haematology
- Faculty of Public Health
- Institute of Biomedical Science
- Public Health England
- Midland Haematology
- Royal College of Anaesthetists
- Royal College of Nursing

www.shotuk.org
International haemovigilance data

- Not comprehensive or comparable
- Events, denominators, rates
- Severity
- Imputability
- Suitable for analysis
  - Complete, validated, etc
- Outcome measures

Definitions

- Availability
- Content/scope: Focus to date on short-term outcomes
- Currency: Understanding of pathophysiology
- Functionality: For different purposes
- Applicability/universality: Different healthcare settings
- Mechanisms to implement, evaluate and update
Bacterial contamination (TTBI)

- Availability
- Content/scope/functionality
  - Manufacturing surveillance
  - Clinical management
  - Reporting to HV or public health program
- Applicability in different settings
  - Confirmatory testing: special techniques (e.g. PFGE)

58 respondents, 39 countries
27 countries had a HV program
23 had guidelines on TTBI investigation
17 had a TTBI definition, range of sources
Variety of arrangements for case validation
• IHN’s web-based database
• 122 national sets annual aggregated data, 25 countries covering 132.8 million blood components 2006 – 2012
• AR and AE, analysis by component with severity, imputability
  – Recipient ARs 68.8 per 100,000 components issued
  • 25% severe – of these, allergic (25%), DSTR (21%) and DHTR (16%)
  – Donor data (Jo Wiersum presentation)
• Plans: strengthen working group, data validation, accessibility, incl. peer-reviewed publication
  
  Personal communication, Prof Constantina Politis, June 2015

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**Infrastructure**

• Information
  – Data management, database support

• Processes
  – Case follow-up
  – Analysis
    • Expert review and interpretation
    • Statistical support
  – Feedback to hospitals
  – Education and training
Training and support

• Roles and responsibilities
• Education and training
  – Transfusion content
  – Quality and safety, e.g. clinical audit
  – Project management
  – Data and database management
  – Privacy, security etc
  – Analysis and reporting
• Position descriptions
• Qualifications, further study
• Professional support networks


Reporting

• Results and interpretation
• Timeliness
• Audience/language
• Recommendations
  (Implementation!)
• Permissions to publish
• Awareness/access

Culture of openness and transparency

The cone of silence, Get Smart, Talent Associates/NBC

Opportunities

Global information sharing:
– Rare and emerging complications
– Understand clinical and cost consequences
– Lessons learned
– Benchmarking
Opportunities

Practical aspects:

– Content-related
  • Definitions
  • Case report forms, database issues
  • Training requirements and tools
– Process-related
  • Managing reporting & analysis
  • Roles of steering committees and expert review groups

Opportunities

• More patient- and disease-related outcome measures:
  – Healthcare resource utilisation
  – Effects on treatment/outcomes of underlying conditions
• HV frameworks and data for research
• Peer-reviewed publications
• Advocacy to policy-makers
• International institutional collaborations
Notify Library

- Library collecting examples of well characterised cases of adverse events/reactions
- Medicinal products of human origin (MPHO)
  - Organs, tissues and cells and now blood
  - Patient, product and donor issues
- Examples of “what can go wrong” but also “risk of harm” where no harm occurred
- Complement not replace HV program data
Other ‘vigilances’

- 2014: First consultation on minimum information model for reporting and vigilance for safety in healthcare
- Patient safety groups, researchers, content experts (OHS, radiation, pharmacoV, medical devices, blood
- Definitions of key concepts across whole of health would be useful; many areas of uncertainty
- Awaiting report/next steps

From product safety to patient safety

- Historical focus: safety of blood supply
- Clinical practice improvement:
  - Governance
  - Patient-centred care
  - Process errors and incidents
  - Human factors
  - Guidelines and standards
  - Clinical audit

Photo: Thalassaemia Australia
From product safety to patient safety

Haemovigilance

• Changes in clinical practice, manufacturing and regulation
• Improved evidence base, including pathophysiology
• Development/evolution of concepts and HV systems
• Better systems and data and better use of data to inform practice

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