WHO WORKSHOP ON HAEMOVIGILANCE
20-23 October 2020

Topic	Reference Materials	Speakers and Panelists	Presentation (English)	Presentation (French)
Day 1 (moderated by Thierry Schneider)				
1. **Opening Remarks from WHO/AFRO**				
2. Status of haemovigilance in Zambia		Joseph Mulenga		
3. Status of haemovigilance in Burundi		Félicien Nzotungwanayo		
4. **Blood Safety** a. How safe is blood? b. How monitoring of adverse events (AE) and adverse reactions (AR) is linked to maintaining blood safety c. Historic examples	PDF 04_WHO_blood_trasfusion_safety.pdf PDF 04_10_WHO_Screening_donated_blood_for_Trasf-transmissible_infections.pdf	France Pirenne	PDF	PDF
5. **Establishing a national haemovigilance system within the National Public Health Program** a. Importance of a national system b. Roles of blood establishments, hospitals, national center c. Role of regulation	PDF 05_09_WHO_guide_to_establish_national_hemov_system.pdf	Andre Loua	PDF	PDF

6. **Developing a positive culture toward safety reporting and response** a. Culture of safety reporting i. No fault reporting ii. Barriers and motivations b. Effective communication and transparency i. Data sharing ii. Feedback from the database and the regulator		Aude Thiery Wided Sghaier		
7. Philipe Cabre **Progress toward haemovigilance – example of a country experience** a. Building up from the hospital		Philippe Cabre		
8. **Open Panel Discussion – Day 1**				

Topic	Reference Materials	Speakers and Panelists	Presentation (English)	Presentation (French)
Day 2 (moderated by Mary Townsend)				
9. **Methods in Haemovigilance** a. How to do surveillance i. key questions to answer ii. what process to employ (active versus passive; mandatory vs. voluntary) b. methods of reporting	WHO_guide_to_establish_national_haemov_system SHOT_materials_for_WHO_workshop	Shruthi Narayan		
10. **Adverse transfusion reactions/events** a. Scope of adverse events i. infectious ii. non-infectious	WHO_Screening_donated_blood_for_Trasf-transmissible_infections	Satyam Arora		
11. **Adverse Donor Events and Assessment of an adverse event or reaction** a. Categorization and analysis i. definition ii. severity iii. causality (imputability) b. Association versus causality i. Elements in consideration of causality	ISBT_IHN_TR%20definitions.pdf	Kevin Land		

12. **Case Studies – identifying an adverse reaction** a. Adverse reaction in a donor (e.g. vasovagal, hypotensive) b. Adverse reaction in a transfusion recipient (e.g. allergy, hemolysis)	https://www.cdc.gov/nhsn/pdfs/biovigilance/bv-hv-protocol-current.pdf https://www.cdc.gov/nhsn/PDFs/slides/Training1NHSNhemovigOverview.pdf	Mary Townsend		
13. **Open Panel Discussion – Day 2**				

Topic	Reference Materials	Speakers and Panelists	Presentation (English)	Presentation (French)
Day 3 (moderated by Daniele Lagniez)				
14. **Case Studies – possible transfusion transmitted infection (e.g. HIV, HCV)** a. Determining causality		Nadia KHALDI	PDF	PDF
15. Bidirectional traceability of information a. Tracking from the donor to the recipient b. Tracing from the recipient to the donor c. Lookback activities for products and patients	PDF ISBT_Intro_to_traceability.pdf	Lisette Hauser	PDF	PDF
16. Case Studies – bidirectional traceability a. HIV Lookback i. Identification of at-risk units ii. Product retrievals iii. Medical notifications b. Hemolytic reaction in a transfusion recipient i. Investigating the basis of an incompatible transfusion		Lisette Hauser		
17. Understanding errors, accidents and system deficiencies a. Concept of root cause b. Concept of latent vulnerabilities c. Importance of addresing near miss events	PDF ISBT_2015_Sentinel_Errors_and_Accidents.pdf	Caroline Lefort	PDF	PDF

18. Assessment criteria for haemovigilance in the WHO Global Benchmarking Tool (GBT+Blood) for national regulatory systems	https://www.who.int/medicines/regulation/benchmarking_tool_plus_blood/en/	Washington Samukange		
19. Open Panel Discussion – Day 3				

Topic	Reference Materials	Speakers and Panelists	Presentation (English)	Presentation (French)
Day 4 (moderated by Jo Wiersum)				
20. Haemovigilance in the Hospital a. Use of surveillance and reporting tools b. Hospital Transfusion Committee i. Structure and composition ii. Roles and responsibilities c. Interactions with transfusing physicians (meetings, control points)	ISBT_IHN_TR%20definitions.pdf ISBT_2015_Sentinel_Errors_and_Accidents.pdf	Simonetta Pupella		
21. Haemovigilance in the Blood Establishment a. Role of the medical director b. Use of surveillance and reporting tools	ISBT_AABB IHN_Donor_AE_definitions_2014.pdf	Shruthi Narayan		
22. Haemovigilance Data Management a. Reporting mechanisms i. Monitoring rates of expected events ii. Identification of novel events b. Central haemovigilance unit c. Stepwise development of advanced tools i. Electronic databases ii. Automated vs. narrative reporting iii. Open access		Jo Wiersum		
23. **Regulatory responses to safety data (product and process issues)** a. Available regulatory actions i. Example of a product issue (e.g. faulty serologic test for a transfusion transmissible infection)		Øystein Flesland		

ii. Example of a process issue (e.g. male donation of plasma to prevent TRALI, use of blood filters to reduce allergic reactions)				
24. Next steps for development of haemovigilance in Zambia			N/A	
25. Next steps for development of haemovigilance in Burundi			N/A	
26. Open Panel Discussion – Day 4				
27. Closing remarks from WHO/AFRO				