AACC
Better health through laboratory medicine.

PEARLS OF LABORATORY MEDICINE

Hemovigilance: A Quality Tool for Blood Transfusion

Matthew S. Karafin, MD MS

Versiti Wisconsin

DOI: 10.15428/CCTC.2019.312827

Introduction

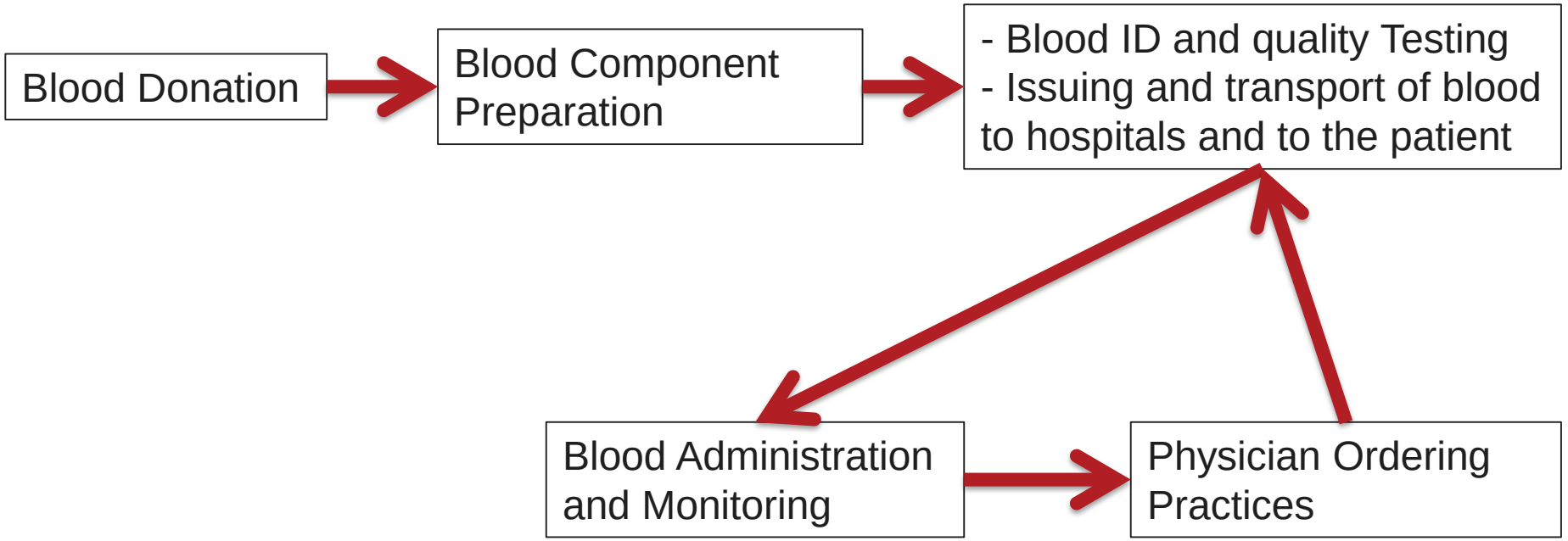
Hemovigilance

- Haema: Greek for “blood”
- Vigilans: Latin for “watchful”

According to the International Hemovigilance Network:

- “A set of surveillance procedures covering the whole transfusion chain, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurence or recurrence.”

The Transfusion Chain



Hemovigilance should be everywhere

Hemovigilance is a quality system that can exist at 3 levels.

- Local
- National
- International

Any Hemovigilance system, at any level, needs to:

- Document any issues with a blood transfusion chain
- Use lessons learned to reduce these issues

Hemovigilance is not everywhere

Current Challenges:

- Delays in entry and reporting
- Limited data granularity
- Limited system flexibility
- Limited system breadth and depth
- Resource and financial pressures

Examples of hemovigilance success: TRALI reduction using all male plasma donors

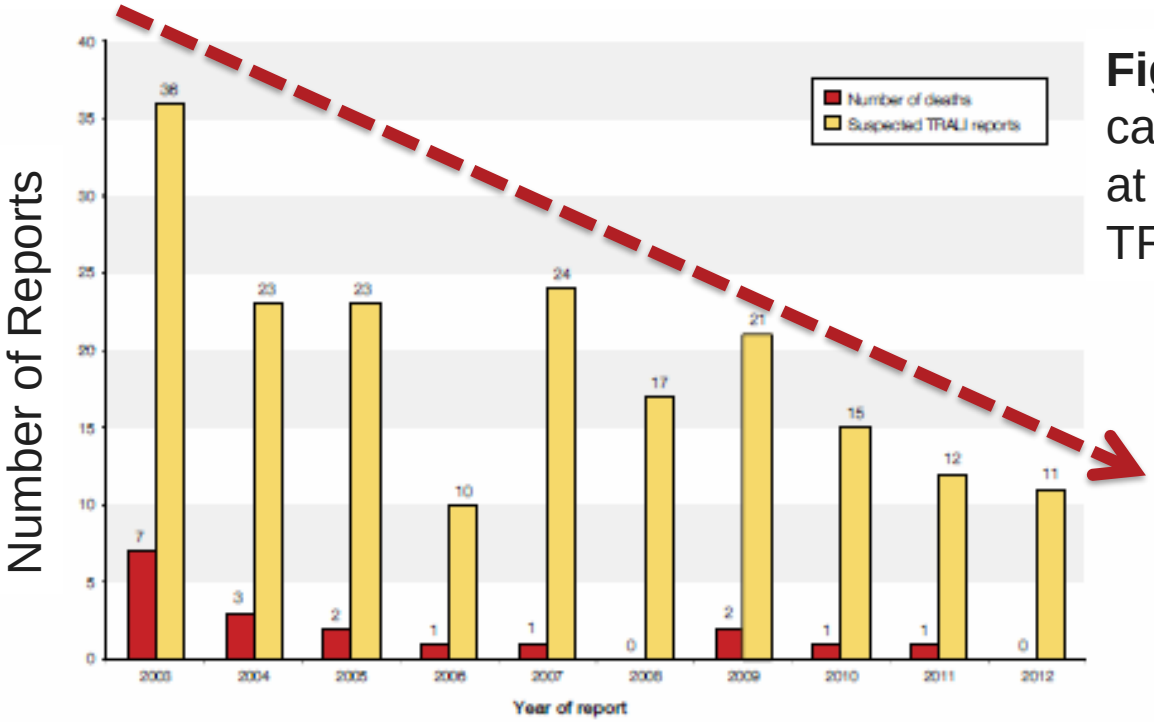


Figure: Number of suspected cases (yellow) and deaths (red) at least possibly related to TRALI by year or report

Bolton-Maggs, P., Poles, D., Watt, A., Cohen, H. & Thomas, D.; on behalf of the SHOT Steering Group. (2013) The Annual SHOT Report 2012. Available at: http://www.shotuk.org/wp-content/uploads/2013/08/SHOT-Annual-Report-2012.pdf

Organized National Hemovigilance Networks

Established and centralized hemovigilance networks around the world (not exhaustive).

- Europe
  - France (1994)
  - United Kingdom (1996)
  - Netherlands (2003)
  - Ireland (1999)
- Africa
  - Namibia (2010)
  - South Africa (2010)
- North America
  - Canada (2007)
  - United States (2006)
- Asia
  - Japan (1993)
  - Singapore (2003)
  - India (2012)
- Australia (2007)

National Hemovigilance Networks: United States

Mandatory Hemovigilance Reporting:

- US Food and Drug Administration
  - Transfusion-related fatalities
  - Product deviations

Table: Transfusion-Associated Fatalities by Complication FY2013-FY2017

Complications	FY13 No.	FY13 %	FY14 No.	FY14 %	FY15 No.	FY15 %	FY16 No.	FY16 %	FY17 No.	FY17 %	Total No.	Total %
Anaphylaxis	-	0	2	7	2	5	5	12	3	8	12	6
Contamination	5	13	1	3	5	14	5	12	7	19	23	12
HTR (ABO)	1	3	4	13	2	5	4	9	1	3	12	7
HTR (non-ABO)	5	13	4	13	4	11	1	2	6	16	20	11
Hypotensive Reaction	-	0	1	3	1	3	1	2	0	0	3	2
TACO	13	34	5	17	11	30	19	44	11	30	59	32
TRALI	14	37	13	43	12	32	8	19	9	24	56	30

Table from *https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/transfusiondonation-fatalities*

National Hemovigilance Networks: United States

Reporting is **not mandatory** for anything else:

- Non-fatal transfusion reactions (infectious and non-infectious, acute and delayed)
- Non-fatal donor reactions
- Process or procedure errors that do not lead to product deviations

…So, how do we learn and monitor anything nationally???

National Hemovigilance Networks: United States

The National Healthcare Safety Network (NHSN).

- Started in 2010 by the CDC
- Secure, free, web-based reporting system
- Collects data about transfusion-related adverse events: incidents (e.g., errors and near misses) and patient adverse reactions
- Created standardized definitions to allow for the potential to compare between sites
- Allows hospitals to monitor their own data, and to share data with external groups at the individual hospitals discretion
- As of 2016, 277/4600 (6.0%) of hospitals were enrolled

National Hemovigilance Networks: United States

The National Healthcare Safety Network (NHSN).

Reaction Type	Case-definition	Severity	Imputability
1. Transfusion-associated circulatory overload (TACO) 2. Transfusion-related acute lung injury (TRALI) 3. Transfusion-associated dyspnea (TAD) 4. Allergic reaction 5. Hypotensive transfusion reaction 6. Febrile non-hemolytic transfusion reaction (FNHTR) 7. Acute hemolytic transfusion reaction (AHTR) 8. Delayed hemolytic transfusion reaction (DHTR) 9. Delayed serologic transfusion reaction (DSTR) 10. Transfusion-associated graft vs. host disease (TAGVHD) 11. Post-transfusion purpura (PTP) 12. Transfusion-transmitted infection (TTI)	Varies…	1. Non-severe 2. Severe 3. Life-threatening 4. Death 5. Not determined	1. Definite 2. Probable 3. Possible 4. Doubtful 5. Ruled Out 6. Not Determined

National Hemovigilance Networks: United States

The National Healthcare Safety Network (NHSN).

Transfusion-related adverse reactions reported to the National Healthcare Safety Network Hemovigilance Module, United States, 2010 to 2012

Alexis R. Harvey, Sridhar V. Basavaraju, Koo-Whang Chung, and Matthew J. Kuehnert

Transfusion-Transmitted Infections Reported to the National Healthcare Safety Network Hemovigilance Module

Kathryn A. Haass [a,*], Mathew R.P. Sapiano [b], Alexandra Savinkina [a,c], Matthew J. Kuehnert [a], Sridhar V. Basavaraju [a]

…It's working, and we are learning stuff!

National Hemovigilance Networks: United States

Other National Monitoring options.

- AABB
  - Center for Patient Safety (no longer available)
  - Donor Hemovigilance and Reporting Tool (DonorHART)

- Collaborative independent research initiatives
  - American Red Cross
  - Blood Systems Research Institute
  - NIH - Retrovirus Epidemiology Donor Study (REDS-II)
  - NIH - Recipient Epidemiology and Donor Study (REDS-III)

National Hemovigilance Networks: United States

The future...

…is up to us.

National Hemovigilance Networks: United States

Conclusions.

- Hemovigilance efforts are critically important
- Public health initiatives informed by national hemovigilance monitoring activities has saved lives
- The US hemovigilance system is still emerging, and is showing promise

Suggested References

1. Chung KW, Harvey A, Basavaraju SV, Kuehnert MJ. How is national recipient hemovigilance conducted in the United States? Transfusion. 2015;55(4):703-7.
2. Haass KA, Sapiano MRP, Savinkina A, Kuehnert MJ, Basavaraju SV. Transfusion-Transmitted Infections Reported to the National Healthcare Safety Network Hemovigilance Module. Transfus Med Rev. 2019;33(2):84-91.
3. Bolton-Maggs PHB. Serious hazards of transfusion - conference report: celebration of 20 years of UK haemovigilance. Transfus Med. 2017;27(6):393-400.

Disclosures/Potential Conflicts of Interest

Upon Pearl submission, the presenter completed the Clinical Chemistry disclosure form. Disclosures and/or potential conflicts of interest:

- **Employment or Leadership**: No disclosures
- **Consultant or Advisory Role:** No disclosures
- **Stock Ownership:** No disclosures
- **Honoraria:** No disclosures
- **Research Funding:** No disclosures
- **Expert Testimony:** No disclosures
- **Patents:** No disclosures

Thank you for participating in this *Clinical Chemistry* Trainee Council Pearl of Laboratory Medicine.

Find our upcoming Pearls and other Trainee Council information at www.traineecouncil.org

Download the free *Clinical Chemistry* app on iTunes today for additional content!

Follow us: