血液管理工具：监测系统
Haemovigilance的发展与应用思考

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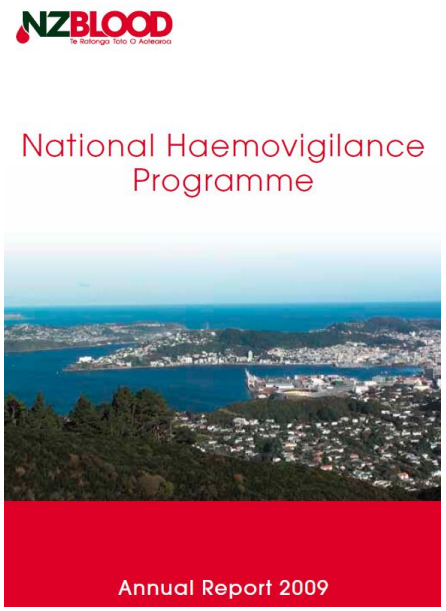
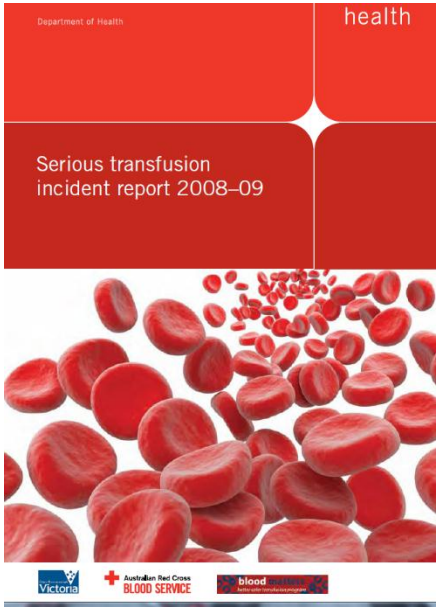
赣州市血液管理、医学检验质量管理工作暨学术交流会议

2023年6月29日，赣州

主要内容

- HV基本概念
- HV的发展
- HV应用
- 思考





管理工具与绩效考核（1）

编号	管理工具名称	应用范围
1	客户关系管理（Customer Relationship Management，CRM）	献血者管理、供血医院
2	全面质量管理（Total Quality Management，TQM）	体系管理
3	顾客细分（Customer Segmentation）	献血者管理
4	外包（Outsourcing）	委托检验、宣传
5	企业核心能力（Core Capability of Enterprise）	
6	供应链管理（Supply Chain Management ，SCM）	
7	战略规划（Strategic Planning）	机构发展规划
8	业务流程再造（Business Process Reengineering，BPR）	确认再确认
9	知识管理（ Knowledge Management，KM）	KE
10	使命书和愿景书（Mission and Vision）	
11	平衡记分卡（Balanced Score Card，BSC）	个人绩效考核
12	作业导向管理 (Work Oriented Management)	SOP
13	忠诚度管理 (loyalty Management)	献血者保留
14	六西格玛（6σ）	成分科、实验室管理
15	战略联盟（Strategic Alliance）	

管理工具与绩效考核（2）

编号	管理工具名称	应用范围
16	标杆（基准）管理（Benchmarking management）	机构绩效考核、卓越绩效管理体系GB/T19580
17	变革管理计划（Change Management）	
18	增长战略（Growth Strategies）	
19	经济附加值增值分析（Economic Value Added，EVA）	
20	价格优化模型（Price Optimization Models）	
21	开放市场创新(Open Market Innovation)	
22	规模定制（Mass Customization，MC）	献血纪念品
23	情景设定和突发计划（Scenario Planning）	
24	海外经营 (Overseas Management)	
25	五常法（5s整理法）	采血环境管理
26	Reporting and Learning Systems（RLS)	HV
27	SWOT分析法（Strength,Weakness,Opportunity,Threat)	
28	企业识别系统（Cooperation Identity System)	血站文化建设
29	5W2H(Why,when,where,who,what,How,How much)	SOP编写
30	Risk-based Decision	风险管理、持续改进

Reporting and Learning Systems (RLS)

- The ability to learn from adverse events and near misses is a cornerstone for improving safety in different high-risk areas, such as the aviation and oil industries.

- Commercial passenger aviation has become extremely safe partly due to extensive use(RLS).

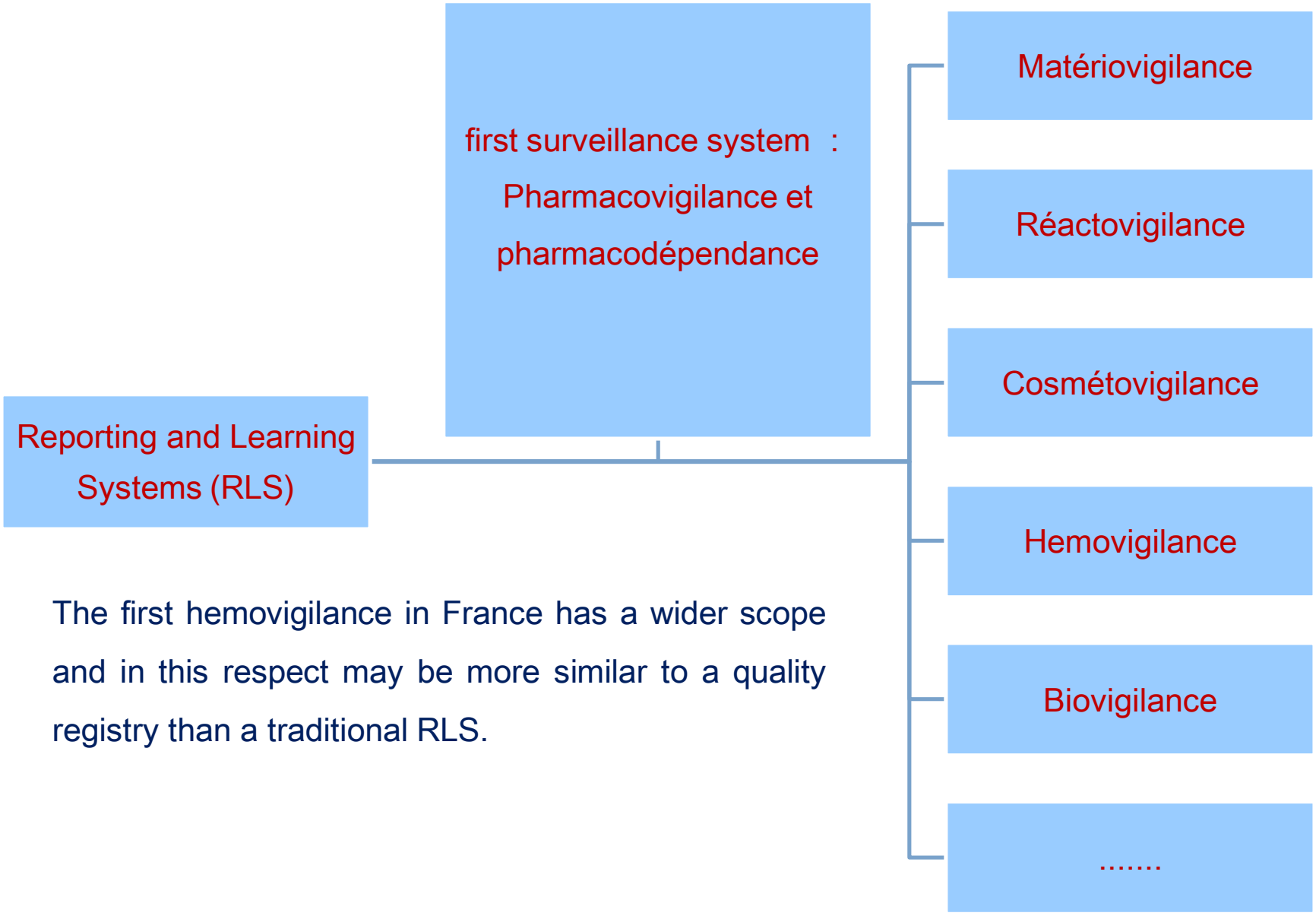
RLS 运行基本原则

Adverse events and near misses were analyzed by an independent organization with enough competence：

- The agency that receives reports must be capable of disseminating information.
- Feedback to the reporter was given in a timely manner.
- Making recommendations for changes, informing the development of solutions and given the suggestions on how to improve the system.
- The healthcare system is open for suggestions for system.

WHO guideline on RLS

- The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the healthcare system（从错误中学习）
- Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill effects from reporting. The system is non-punitive.（免责无惩罚不良事件收集）
- Reporting is of value only if it leads to a constructive response.
  - ✓ **At a minimum, this entails feedback of findings from data analysis（反馈数据分析的结果和发现）（有反馈能分享的信息数据才有意义）**
  - ✓ **Ideally, it also includes recommendations for changes in healthcare procedures and systems（有能改变程序和体系的建议和措施）**
- Meaningful analysis, learning, and dissemination of lessons learned require expertise and other human and financial resources. The agency that receives reports must be capable of disseminating information, making recommendations for changes, and informing the development of solutions.（改进措施和政策导向）



The first hemovigilance in France has a wider scope and in this respect may be more similar to a quality registry than a traditional RLS.

RLS in Medicine

- Pharmacovigilance focus on reporting only new or very serious complications
- Biovigilance (reporting systems for cells and tissues) focus on product-related problems.
- HV is a recent development in transfusion safety and has a wider scope and in this respect may be more similar to a quality registry than a traditional RLS.
  - Gain information from the investigations and data from donation to transfusion.
  - Identify trends in adverse reactions and events
  - Target areas for corrective and preventive actions, ,raise awareness of transfusion hazards, minimize the potential risks
  - Assist in the formulation of guidelines, and improve standards, systems and quality of the entire process in practice
  - Stimulate research
  - Be an early warning of new thing

2003 CoE（European Blood Safety Directive）	• 诣在系统收集血液制品采集和临床治疗应用中发生的可预期和不可预期的副反应信息的一系列监控程序
2009-now: International HV Network， IHN	• **HV is defined as surveillance procedures covering the whole transfusion chain, from collection of blood and its components to 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**
ISBT-WP Hémovigilance Definition	• **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 transfusion effects to prevent their occurrence or recurrence.**
WHO Hémovigilance Definition	• **HV is required to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient.** • **The system should include monitoring, identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.**

Haemovigilance

HV是涵盖整个输血链即从静脉到静脉，从献血者到受血者的一系列追踪监测程序；通过对献、输血反应（Adverse reaction, AR）和全过程不良事件（Adverse event, AE）进行监测识别收集、调查、分析和报告，以预防其发生和再次发生的血液监测系统。涉及到献血人群流行病学（markers rates of TTIDs、RR）、输血服务、临床输注、实验室、输血委员会、法规和其他卫生健康当局。

·临床输血专栏·

高岩，邱艳. 血液质量管理的有效工具Haemovigilance[J]. 中国输血杂志，2015，28（9）：1154-1158.

Haemovigilance的发展现状及思考

邱艳

Haemovigilance一词最早用于描述监控输血不良反应的系列相关活动，在国内有人曾翻译为血液预警系统，并解释其内容包括对输血所产生的不良、意外反应的信息进行查寻、收集和分析等。2003年

应，截至 2005年，快速反应事件已发生 30起。多年来 EHN致力于同欧洲各国合作，2004年发展到 20个成员国，EHN 还几次召开大会讨论 Haemovigilance定义，并启动了 Haemovigilance工作过程的标

HV工作范围

- 产品范围:取决于各国的法律法规
  - 全血、成分血：欧洲
  - 全血、成分血、血浆制品：加拿大
- 相关利益者（stakeholders）：
  - blood transfusion service
  - hospital clinical staff and transfusion laboratories
  - hospital transfusion committees
  - regulatory agency
  - national health authorities
- 地域范围：
  - Local：BJ
  - National
  - Regional：EHN
  - International: ISBT
  - Global: WHO

HV工作内容

- 献血者：收集献血者延迟献血因素、献血反应信息，分析对献血者的损伤原因；献血人群的流行病学研究
- 血液产品：生产工艺的确认和过程控制,差错管理，评价血液残余风险度
- 血液输注和患者血液管理（自体输血的监控），指导临床“合理用血”，评估临床输血治疗的“效益与风险比”
- 受血者：收集输血反应信息，监控输血副反应。在英国只针对严重输血事件，如SHOT系统，在法国监测所有输血副反应，追踪溯源鉴别经血传播疾病的发生。监测新类型的输血反应和新成分血在临床使用，如：病毒灭活血浆（法国发现亚甲蓝灭活血浆的过敏反应发生率高于INTERCEPT，停止亚甲蓝病毒灭活血浆的供应）
- 紧急风险评估、干预和决策支持（预警）。如，采血使用旁路留样袋，降低了表皮消毒不彻底造成细菌污染的风险；临床输注男性献血者血浆，降低了TRALI的发生率等
- 制定报告程序、报告表等，开展了输血差错事件的研究
- 观察输血后的长期作用，如输血相关的免疫调节、存活率、肿瘤复发率、住院期

Haemovigilance 工作程序

HV是一个收集、分析和评价输血链数据的质量监控管理系统。

①不良事件识别（除非每袋血液都要监测）

②依据事件描述，选择标准化的分类表，填报统一报告表（信息一定要充分）

③根据指南等相关程序和格式，登记报告

④用预判方案编制收集的信息，转换数据

⑤用公认标准和技术分析和处理数据，包括分类、严重程度和相关性判断；

⑥发生原因或再次发生的原因分析，可以借助已有的方法，如SHOT推荐使用的 toolkit

⑦风险评估，包括潜在危害和再次发生的可能性。推荐使用高风险行业使用的risk matrix或者prospective risk assessment，如儿科紧急输血（pediatric emergency ）采用Healthcare Failure Mode and Effect Analysis (HFMEA) 方法分析，或者UK Civil Aviation Authority的Bowtie method 做prospective analysis

⑧ 反馈结果和推荐整改方案，包括对输血链的具体操作，进行干预或制定和修改相关法规等，发布报告（包括快速预警，匿名或强制）

⑨持续的报告发布，达到持续完善的作用，符合差错管理的纠正措施实施验证原则和PACD

History and Current Status of Haemovigilance

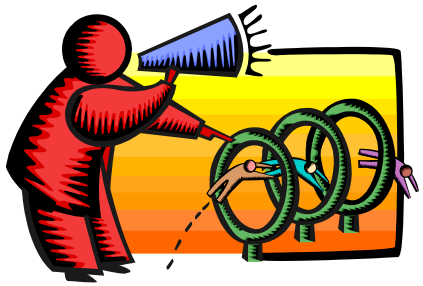
发展历史和现状

Haemovigilance发展历史

- 1991：基于艾滋病事件，pioneer work on HV started in France
- 1992：法国第一个建立血液监控系统Centre National d'Hémovigilance
- 1993：Agence Française du Sang (loi du 04.01.93)开始要求书面形式上报输血反应信息和建立100%的血液溯源机制，此时也萌发出现不同的HV 定义
- 1994: Organisation de l'hémovigilance成立（le décret 94-68 du 24.01.1994）
- 19950602：欧洲理事会在其决议文件首次提出建立地区HV，分享信息，保证血液安全
- 1995：ISBT Venice 第5次地区大会(4th欧洲)首次组织了HV 研讨会"Haemovigilance procedures in Transfusion Medicine"提出HV是血液质量管理的一部分

Haemovigilance发展历史

- 1996：欧盟委员会在Adare, Ireland召开正式部长会发布“Blood Safety and Self-Sufficiency: an Agenda for the European Community”确定HV是保证“血液安全和自主供应”的6个行动领域之一。
- 1996：英国基于临床输血的一项研究，开始利用SHOT（Serious Hazards of transfusion）系统自愿上报输血反应信息。
- 1997：在法国波尔多召开首届欧洲HV研讨会，同年在法国里昂召开第二届欧洲HV研讨会。
- 1998：比利时、法国、卢森堡、荷兰和葡萄牙五国组成EHN（European Haemovigilance Network）。目的在成员国之间：
  - ✓ 一是共享信息
  - ✓ 二是加强应急反应能力
  - ✓ 三是促进合作
  - ✓ 四是联合举办培训活动



Haemovigilance发展历史

- 1999：EHN开通了www.ehn-org.net网站完成上述工作，其次建立应急系统（Rapid alert system，RAS ）提高快速反应。如输注某一类成分血后出现广泛输血反应或耗材、仪器、试剂出现问题时，其他成员国会被提醒迅速做出反应。1999-2005年，快速反应事件发生30起
- 1999：欧洲委员会发布了HV network的可行性报告(the Haeman Report)
- 2000/2001: the 3rd and 4th European Seminars on HV systems (voluntary or compulsory), the required data types(blood donors, usage of blood components or also plasma derivatives), definitions, materio-vigilance, RAS and website

HV发展历史

- 2001：丹麦开始启动收集献血反应数据，当年献血者反应报告为有3/10万，严重反应共23例

- 20030127：欧洲委员会(European Commission)-Directive 2002/98/EC 在修订Directive 2001/83/EC. L33. 基础上，在Article 15和29明确提出按规定程序报送输血链上发生的严重不良事件。基于此，欧盟 (European Union，EU)决定通过 EU Blood Safety Directives 立法,在欧洲的国家实施HV

HV发展历史

- 2004：ISBT成立了WP-HV,同ENH共同成立Working Group on Complications Related to Blood Donation (DOCO)，启动了HV标准化工作，为欧洲血液指令的实施奠定基础
- 2004：ISBT爱丁堡大会上有3篇报道关于严重献血反应，ISBT-HV-WP决定开始启动献血反应的调查工作
- 20050930：European Commission-Directive 2005/61/EC 要求实施 European Parliament-Directive 2002/98/EC中 traceability requirements and notification of serious adverse reactions and events (Text with EEA relevance)
- 2005：ISBT雅典地区大会提出了献血反应定义、分类和诊断标准的建议

HV发展历史

- 2006：欧洲委员会(European Commission)在2003和2005年通过的一系列血液指令（EU Blood Safety Directives）的基础上，立法强制要求欧盟各国实施HV,并通过政府当局上报严重输血反应，欧洲成为血液监控系统种类最多的地区，这些为世界范围内HV的推进实施奠定了基础。
  - The key role of HV in blood transfusion safety is reflected in the EU Blood Directive 2002/98/EC.26
  - The technical details are further laid down in the so-called daughter directives:
    - ✓ 2004/33/EC (Directive on donations, donors, and blood components);
    - ✓ 2005/61/EC (Directive on traceability and notification—HV)；
    - ✓ 2005/62/EC (Directive on a quality management system).

HV发展历史

- 2006年9月：南非开普敦召开的第29届国际输血大会上批准采纳ISBT-WP提出的献血反应定义、分类和诊断标准。为不同的HV系统治疗、预防、反应分级和处理的统一标准化，以及世界范围内数据共享和可比性迈出了第一步
- 2006年：美国首次启动HV的理念的运用
- 2007年6月9-11日：WHO在加拿大Ottawa召开血液安全咨询会Universal Access to Safe Blood Transfusion期间，鉴于与会专家提出应建立全球HV的建议，启动了HV的全球倡导工作，指出HV是输血相关不良事件（AE）和输血反应（AR）的监控系统，包括监测、识别、报告、调查与分析。Urges Member States “to ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma-derived medicinal products, including TTI”

HV发展历史

- 200802 : The EHN Established Database for the Surveillance of Adverse Reactions and Events in Donors and Recipients of Blood Components (ISTARE) and capture the aggregated data on transfusion adverse reactions, errors, and failures as well as donor adverse reactions。

- 2008：ISBT WP-HV和EHN，在人们充分认知的各类献血反应的分类和诊断标准基础上，颁布STANDARD FOR SURVEILLANCE OF COMPLICATIONS RELATED TO BLOOD DONATION ，发展疑难献血反应的判断标准。

2009： 在1998成立的EHN（European Haemovigilance Network）基础上成立IHN (International Haemovigilance Network，www.ihn-org.com），会员是以国家的形式参加,目前有29个国家。

IHN成员国

Australia
Austria
Belgium
Brazile
Canada
Croatia
Denmark
Finland
France
Germany
Greece
Iceland
Ireland
Italy
Japan

Luxembourg
Malta
Netherlands
Norway
New Zealand
Portugal
Singapore
Slovenia
South Africa
Spain
Sweden
Switzerland
UK
USA

IHN: What we do

- 建立初期继续秉承EHN的目的促进：
  - 一是成员国之间重要信息交流（exchange of importance information ）
  - 二是成员国之间应急反应能力（a swiftly functioning alarm or warning system ）
  - 三是举办国际研讨会（international scientific semin）制定术语定义（developing definitions），分析数据用于对标（benchmarking）最佳执业，到2023年HIS召开第25届IHN Seminar
  - 四是通过联合举办培训活动，支持各国HV的建立与发展
- Much progress has been achieved in haemovigilance over the past 20 years, but there is still a lot to do

International Haemovigilance Network

VISION

Health services around the world will have effective HV systems in place

MISSION

To promote HV internationally to improve outcomes for donors and patients

To support HV systems worldwide

To be the leading international HV resource

IHN shall be a financially sustainable organisation

The governance structure shall be aligned to pursue IHN's mission and meet its strategic goals

Strategic goals:

1. Promote appropriate, consistent and effective data collection & validation, analysis and recommendations

2. Develop innovative short- and longer-term HV outcome measures

3. Develop objective indicators for demonstrating the effectiveness of HV

Strategic goals:

4. Be a forum for networking/exchange for HV professionals

5. Have an effective engagement strategy for the various HV stakeholder communities

Strategic goals:

6. Be the global source and advocate of best definitions and analytic systems for donation and transfusion-related adverse events

7. Fulfill educational needs of members and other stakeholder groups

HV发展历史

- 2010：World Health Assembly Resolution WHA63.12 on ‘Availability, safety and quality of blood products’- “to develop a global haemovigilance, surveillance and alert network, which would provide a platform to countries for sharing key information on blood safety and availability issues and build a timely response in addressing emerging threats.”

- 201107：ISBT-WP-HV在总结已有HV的经验上，综合各国的HV，颁布STANDARD DEFINITIONS FOR NON INFECTIOUS ADVERSE TRANSFUSION REACTIONS输血反应的分类和诊断标准，发展疑难输血反应的判断标准。

HV发展历史

- 20121220: WHO联合United Arab Emirates、IHN和ISBT，召开全球HV咨询会，150 participants from 47 countries。

- Developing developed countries,
- including those with established systems (different models of haemovigilance systems will be highlighted) and
- those with plans to start haemovigilance.

- European Directorate for the Quality of Medicines European Commission,
- United States Centers for Disease Control and Prevention,
- Africa Society for Blood Transfusion,
- Latin American Association of Transfusion Medicine.
- Asia Pacific Blood Network,
- Arab Society of Blood Transfusion Services,
- International Society of Surgery,
- Safe Blood for African Foundation,
- South Asian Association of Transfusion Medicine
- …..

HV发展历史

- 2012：WHO 国家HV评估标准
  - ✓ International level-WHO,IHN,ISBT
  - ✓ Regional
  - ✓ National level
  - ✓ Local
  - ✓ Hospital/Institutional level
  - ✓ Blood transfusion services

HV发展历史

- 2014： ISBT、IHN和aaBB WHO published guidance on establishing national HV-User guide for navigating resources on stepwise implementation of HV systems. User guide established the principles and provides examples of basic tools to get start, such as the Deming cycle for continuous improvement(Plan, Do, Check, Act)
- 201407:对《非传染性输血反应标准定义》中输血相关肺损伤进行了修订
- 20141211 ： ISBT-WP-HV 、 EHN 和 aaBB 更 新 了 STANDARD FOR SURVEILLANCE OF COMPLICATIONS RELATED TO BLOOD DONATION.

HV发展历史

- 2015:WHO 国家HV备忘录
- 2016 : WHO published guidance on establishing national HV-User guide for navigating resources on stepwise implementation of HV systems. User guide established the principles and provides examples of basic tools to get start, such as the Deming cycle for continuous improvement(Plan, Do, Check, Act)
- 202002 : WHO published the Action frame work to advance universal access to safe, effective and quality assured blood product 2020-2023. (effective surveillance, HV and pharmacovigilance, supported by comprehensive and accurate data collection system)

我国HV发展进程

- 2002：东北地区输血管理研讨会，奥斯邦公式报告血液监控与预警系统

- 20030127:中国输血协会龚邦建在浙江省血液中心—医学论坛血液知识栏目发表“血液预警系统（Haemovigilance）”“血液预警系统”是近年来在一些比较发达的国家和地区出现的为保障血液安全而建立的信息反馈系统。根据田兆嵩教授提供的资料（摘自2001年第7版欧洲血液成分手册），将血液预警系统的内容做一翻译和介绍。有错误之处，敬请指正。

- 20070312：卫生部医药卫生科技中心举办培训班报告-From Hemovigilance to Biovigilance

我国HV发展进程

- 2009:HV是涵盖整个输血链即从静脉到静脉，从献血者到受血者的一系列追踪监测程序；通过对献、输血反应（Adverse reaction, AR）和全过程不良事件（Adverse event, AE）进行监测识别收集、调查、分析和报告，以预防其发生和再次发生的血液监测系统。涉及到献血人群流行病学（markers rates of TTIDs、RR）、输血服务、临床输注、实验室、输血委员会、法规和其他卫生健康当局。

北京医学 2009年第 31卷第 2期 · 111 ·

· 临床输血专栏 ·

Haemovigilance的发展现状及思考

邱艳

Haemovigilance一词最早用于描述监控输血不良反应的系列相关活动，在国内有人曾翻译为血液预警系统，并解释其内容包括对输血所产生的不良、意外反应的信息进行查寻、收集和分析等。2003年应，截至2005年，快速反应事件已发生30起。多年来EHN致力于同欧洲各国合作，2004年发展到20个成员国，EHN还几次召开大会讨论Haemovigilance定义，并启动了Haemovigilance工作过程的标

我国HV发展进程

20-22，Sep.2012： HV in China, WHO Global Consultant on HV

3.3 Haemovigilance in Republic of China – Dr J Dandan

China has a population of 1.3 billion in 32 provinces, with 439 blood transfusion services There is currently no integrated haemovigilance programme but several mechanisms are in place for monitoring blood quality and adverse reactions to transfusion. The Blood System framework consists of central government which oversees the provinces, the Red Cross society and the Ministry of Health (MOH). The role of the MOH is to set up legal systems, technical standards and procedures. Since 1999 it has managed blood services, collected and analysed data and set up quality control. The Blood Transfusion Service is responsible for quality management and bi-directional traceability. Hospitals implement clinical guidelines, monitor adverse reactions and set up transfusion committees.

Challenges: although multiple strategies have been set up there is no national collation of data. There is concern about the meaning of 'non-punitive' and the atmosphere of 'learning from errors' has not been established, leading to fear and resultant inhibition of reporting. There is a shortage of funds and human resources, and a lack of structure at the state level.

我国HV发展进程

- 2013年WHO主办的“China-WHO Haemovigilance Consultation”在上海举行，讨论如何在中国开展HV
- 2015: 高岩，邱艳. 血液质量管理的有效工具Haemovigilance[J]. 中国输血杂志，2015，28（9）：1154-1158.
- 2017：中国输血协会血液安全监测委员会成立
- 20180319：血液预警联盟由“输血不良反应发生机制与干预”协同创新团队发起成立，受中国医学科学院“医学与健康科技创新工程”资助，依托中国医学科学院输血不良反应重点实验室，联合采供血系统与医疗机构、教学和科研平台，建立国家输血不良反应预警系统。
- 202106：中国输血协会血液安全监测委员会成立发布《全国血液安全监测报告》
- 20211223：国家卫健委发布的《全国血站服务体系建设发展规划（2021-2025）》开展血液安全监测和风险预警工作。建立机制，选择哨点，监测TTIDs及RR、ADs

HV的应用

Standard for Surveillance of Complications Related to Blood Donation

Working Group on Complications Related to Blood Donation

International Society of Blood Transfusion
Working Party on Haemovigilance

European Haemovigilance Network

- only given for the most common complications (occurrence >1% of all complications) and
- not for the rare events associated with blood donation (<1% of all complications).
- Add Allergic reaction

2008

International Society of Blood Transfusion

International Haemovigilance Network

Advancing Transfusion and Cellular Therapies Worldwide

Standard for Surveillance of Complications Related to Blood Donation

Working Group on Donor Vigilance
of the
International Society of Blood Transfusion
Working Party on Haemovigilance

in collaboration with

The International Haemovigilance Network
The AABB Donor Haemovigilance Working Group

December 11, 2014

These definitions have been formally endorsed by
The European Blood Alliance

献血反应分类

A. Complications mainly with local symptoms.

A 1. Complications mainly characterized by the occurrence of blood outside vessels

- Haematoma
- Arterial puncture
- Delayed bleeding

A 2. Complications mainly characterized by pain

- Nerve irritation
- Nerve injury
- Tendon injury
- Painful arm

A 3. Other complications with local symptoms

- Thrombophlebitis
- Allergy (local)

B. Complications mainly with generalized symptoms.

- Immediate Vasovagal reactions
- Immediate Vasovagal reaction with injury
- Delayed Vasovagal reaction
- Delayed Vasovagal reaction with injury

C. Complications related to aferese

- Citrate reaction
- Haemolysis
- Generalised allergic reaction
- Air embolism

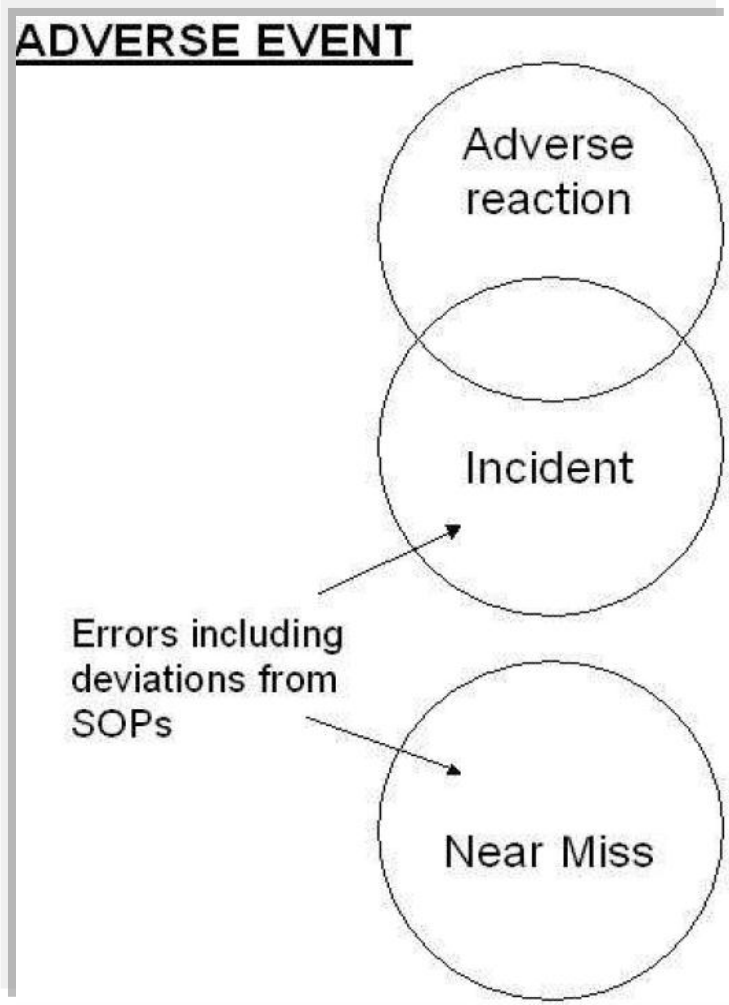
D. Other donation complications

2011年7月-ISBT WORKING PARTY ON HAEMOVIGILANCE

STANDARD DEFINITIONS FOR NON INFECTIOUS ADVERSE TRANSFUSION REACTIONS

- 目的：监控输血反应,并使不同的 **haemovigilance** 体系可比。
- 用途：非严格的诊断标准，但可将不良输血事件（**adverse transfusion events**）分类。
- 适用范围: 成人。 儿童和新生儿需要医疗机构依此自定。
- **2014**年**7**月又对《非传染性输血反应标准定义》中输血相关肺损伤进行了修订

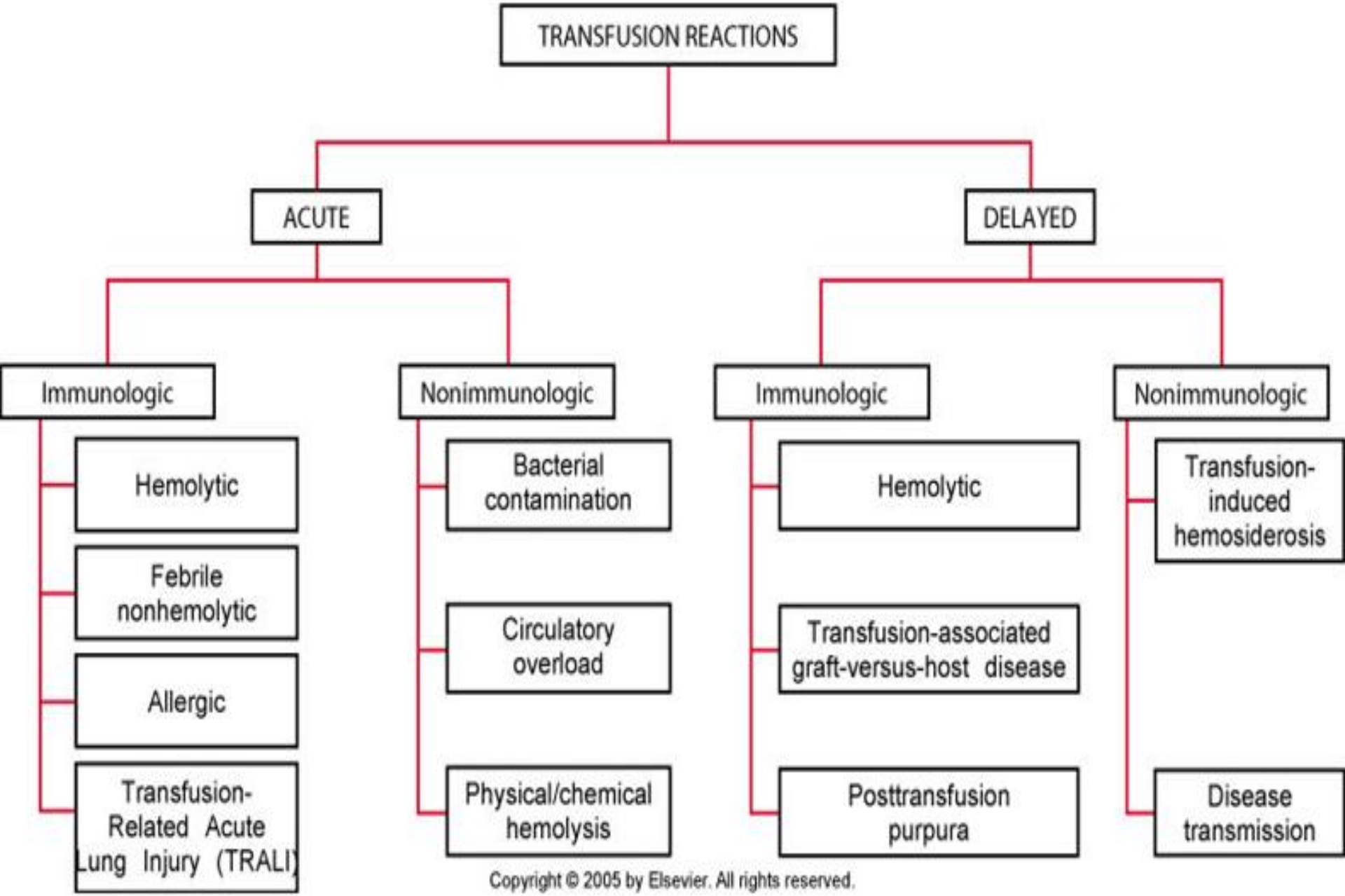
不良输血事件分类



- 不良输血事件（adverse transfusion events，ATE）：输血前、中和后发生的可能与输血相关的非预期事件，可能由差错或事故造成，受血者可能或不出现不良输血反应。
- 输血反应（reactions）：由输血导致病人的非预期反应，它可以由事故造成，也可能与差错事故无关。
- 事故（incidents）：指病人接受了不正确的输血治疗，包括不满足输血指证、违反操作规程或不合理的医院输血指南等 ，可能或不出现输血反应。
- 临界失误（near misses）：输血前发现的能够造成错误输血或发生输血反应的差错或违反操作规程的行为。

输血不良反应的分类（高等医学统编教材P204）

	急性反应（≤24小时）	迟发反应（> 24小时）
免疫性反应	发热反应 过敏反应 溶血反应 输血相关的 急性肺损伤	溶血反应 移植物抗宿主病 输血后紫癜 血细胞或血浆蛋白 同种异体免疫
非免疫性反应	细菌污染反应 循环超负荷 空气栓塞 出血倾向 枸橼酸中毒 非免疫性溶血反应 电解质紊乱 肺微血管栓塞	含铁血黄素沉着症 血栓性静脉炎 输血传播疾病



英国NISHOTs

免疫介导的：

- 溶血性输血反应（HTR）
- 非溶血性发热性输血反应(FNTR)
- 过敏性输血反应
- 输血相关急性肺损伤(TRALI)
- 输血后紫癜(PTP)
- 输血相关移植物抗宿主病(TA-GVHD)
- 微嵌合体
- 输血相关免疫调节(TRIM)
- 同种异体免疫

非免疫介导的：

- 脓毒血症输血反应
- 非免疫性溶血
- 错误输血
- 输血相关循环超负荷(TACO)
- 代谢紊乱
- 大量输血致凝血紊乱并发症
- 红细胞贮存损伤引起的并发症
- 输血过量或不足
- 铁超负荷

1 HEMOLYTIC TRANSFUSION REACTIONS

1.1 Acute hemolytic transfusion reaction (AHTR)

1.2 Delayed hemolytic transfusion reaction (DHTR)

1.3 Delayed serologic reaction (DSTR)

2 NON HEMOLYTIC TRANSFUSION REACTIONS

2.1 Febrile non hemolytic transfusion reaction (FNHTR)

2.2 Allergic reaction

2.3 Transfusion-related acute lung injury (TRALI)

2.4 Transfusion associated circulatory overload (TACO)

2.5 Hypotensive transfusion reaction

2.6 Transfusion associated dyspnea呼吸困难 **(TAD)**

2.7 Post transfusion purpura (PTP)

2.8 Transfusion associated graft-versus-host disease (TA-GVHD)

2.9 Other transfusion reactions

a) Haemosiderosis含铁血黄素沉着病

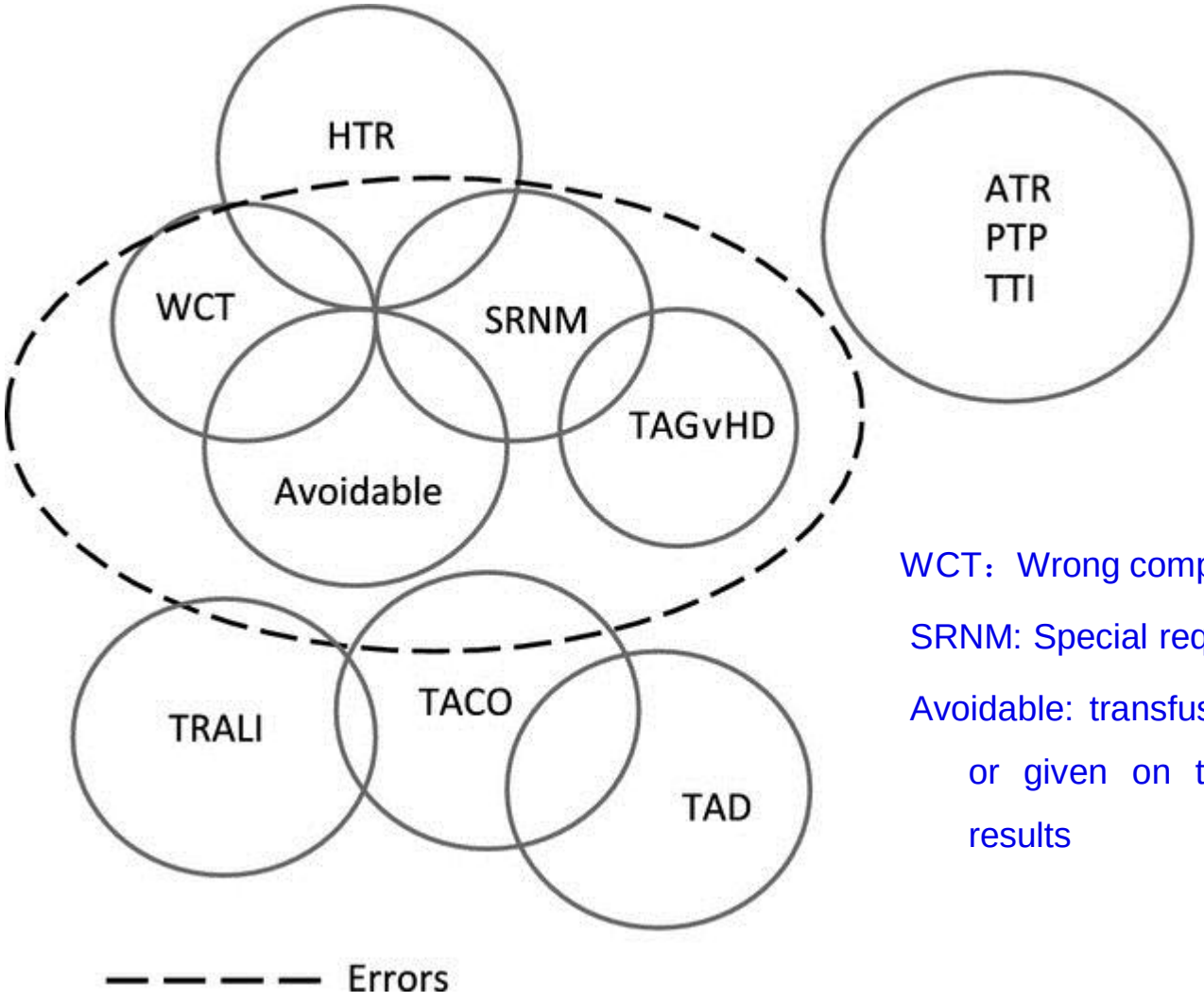
b) Hyperkalemia

c) Unclassifiable Complication of Transfusion (UCT)

- **Transfusion related Immune modulation**
- **Hypothermia**
- **Citrate toxicity**
- **Electrolyte imbalance**
- **Embolism**
- **Metabolic derangements in pediatric and massive transfusion**

3. 诊断标准

interrelationships between different adverse incidents



WCT：Wrong component transfused

SRNM: Special requirements not met

Avoidable: transfusions that are unnecessary or given on the basis of wrong blood results

相关度（Imputability）

标准还规定了在输血不良事件调查后，对其发生与输血的相关度的评价规则：

- 肯定相关（Definite（certain））：输血反应调查证据证明不良事件由输血引起，不存在质疑。
- 很可能相关（Probable（likely90%）:证据明确支持不良事件由输血引起。
- 可能相关（Possible（70%））：证据不能确定不良事件由输血引起或存在其他原因。
- 可能无关（Unlikely（doubtful））：证据表明不良事件不仅仅由输血引起还有非输血因素引起。
- 肯定无关（Excluded）：证据排除不良事件疑由输血引起。

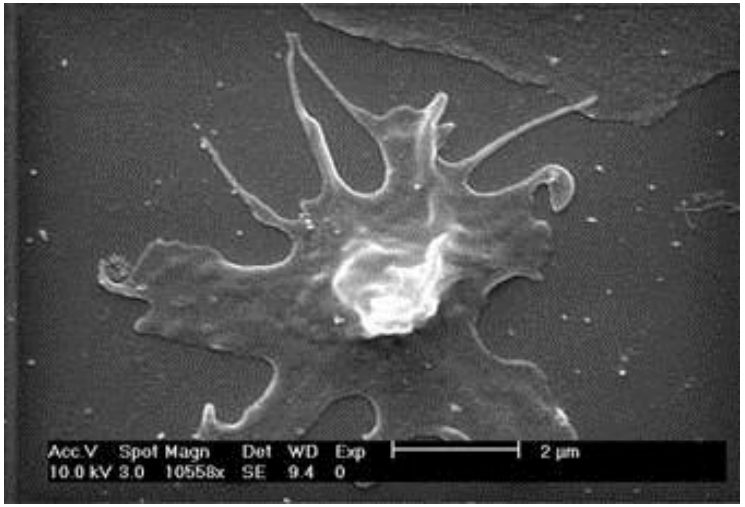
Only possible, probable and definite cases should be used for international comparisons.

输血反应严重程度（Severity ）-4级

- 1非严重 (Grade 1 Non-Severe)：受血者可能需要医疗干涉（消除症状），但不实施医疗干涉不会导致永久性的机体或功能的损伤。
- 2严重(Grade 2 Severe)：由于输血不良事件直接导致病人需要住院治疗或延长住院期；和/或导致长期或明显残疾或功能丧失；或需要医疗或外科干预解除持久的机体或功能的损伤。
- 3威胁生命(Grade 3 Life-threatening)：受血者需要充分的医疗干预（（血管加压（vasopressors），插管（intubation），转运至ICU（transfer to intensive care））以预防死亡。
- 4死亡(Grade 4 Death)：受血者死于输血不良反应。*4级只适用于死亡与输血的相关度为可能（possibly），很可能（probably）或肯定（definitely），如果病人死于其他原因，反应的严重程度应该分为1, 2 or 3。*

输血相关急性肺损伤

Transfusion-related Acute Lung Injury TRALI



Recognized in early 1970's， named Non -Cardiogenic Pulmonary Edema (NCPE)

输血相关急性肺损伤预防措施
TRALI risk-reduction strategies

1. 严格掌握输血适应证,在条件允许的情况下，自身输血。
2. Donor qualification:妊娠史其血液制剂慎用,供血者宜为男性。
3. HLA antibody testing considerations and donor re-testing: 供者受者HLA或中性粒细胞特异性抗体检测和鉴定,阳性献血者供者不宜继续成为献血者（defer donors）。
4. 有明确适应证时，尽可能选择少血浆的血液制品，如洗涤RBC。若抗体来自受血者，应考虑输用少白细胞成分血,The use of PAS for Plts
5. Inventory management

The 25th Regional Congress of the ISBT
London, UK from June 27 - July 1, 2015
Scientific programme
Pulmonary Adverse Effects

GOOD BYE TRALI, HELLO TACO

Then TAD

International Society of Blood Transfusion

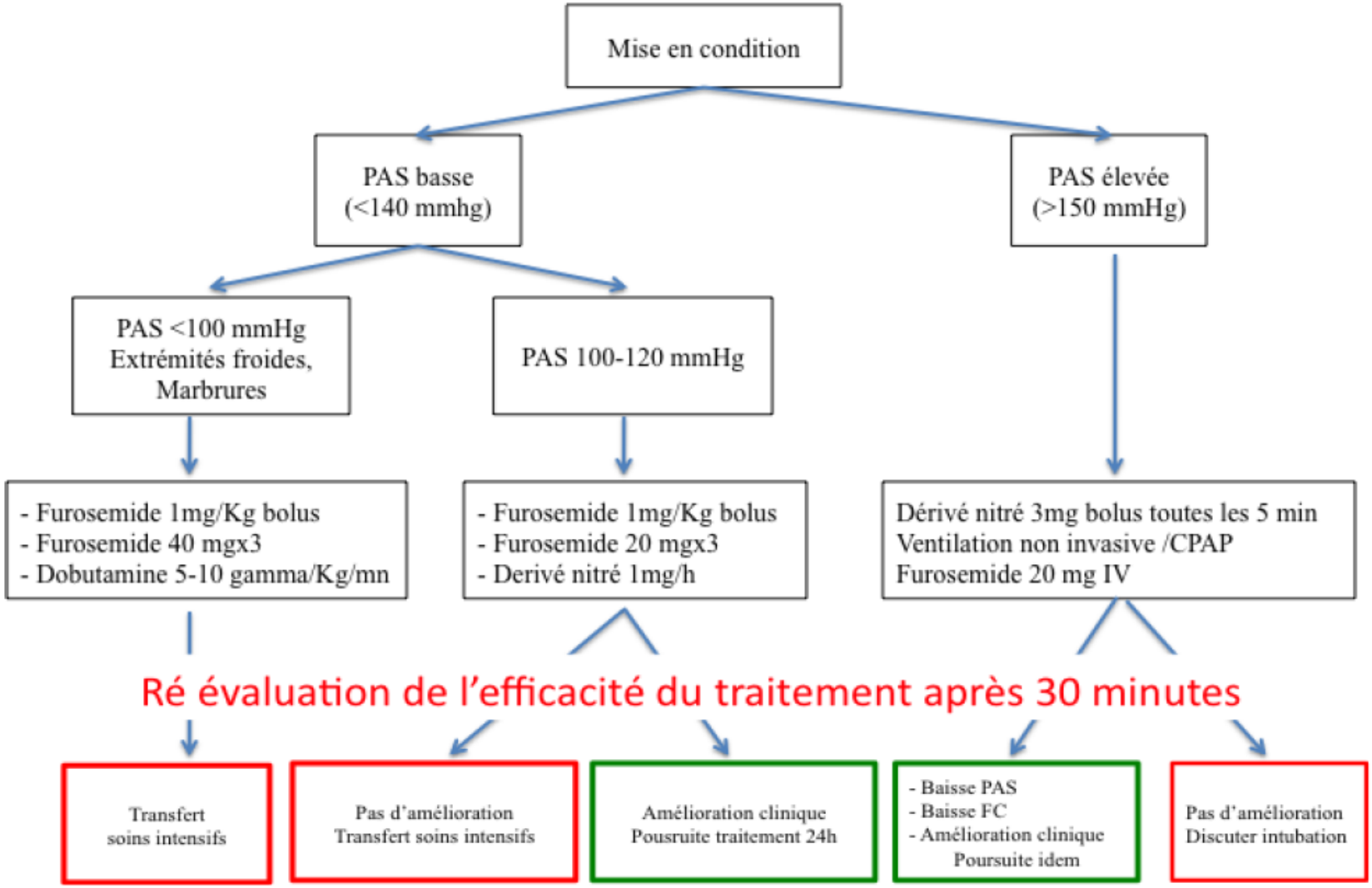
TACO诊断标准

Tableau II : Critères diagnostiques (d'après [10-13])

Signes cliniques	Dyspnée et orthopnée, expectoration mousseuse Angoisse intense Tachycardie Râles crépitants pulmonaires Pression artérielle plutôt élevée Amélioration rapide sous diurétique / vasodilatateur
Signes biologiques	concentration plasmatique des peptides natriurétiques de type B (BNP, NT Pro BNP) élevée * Ratio [protéines] liquide d'oedème / plasma < 0,65
Signes radiologiques	Index cardiothoracique > 0,5 Elargissement des pédicules vasculaires aux hiles Œdème alvéolaire à prédominance péri-hilaire
Signes échographiques	Dysfonction systolique VG (FEVG < 40%) Dysfonction diastolique VG (rapport E/A>1 ou rapport E/Ea>15)
Cathétérisme pulmonaire	Pression Artérielle Pulmonaire d'Occlusion (PAPO) > 18 mmHg

TACO处理措施和流程

Figure 2 : Arbre décisionnel de la prise en charge du TACO, adapté selon ref 14



CPAP : Continuous positive airway pressure
FC : fréquence cardiaque
PAS : pression artérielle systolique

Recommendations

- All measures must be taken to reduce the risk of transfusion-associated circulatory overload (TACO). These include pre-transfusion clinical assessment to identify patients at increased risk of TACO, in whom particular consideration should be given to the appropriateness of transfusion, the rate of transfusion and diuretic cover. Careful attention to fluid balance is essential and must be documented.

  Action: Transfusion practitioners, Hospital Transfusion Teams (HTTs), Hospital Transfusion Committees (HTCs)

- Prothrombin complex concentrate should be used for warfarin reversal in accordance with national guidelines[19], and should be immediately available in all Trusts/Hospitals/Health Boards.

  Action: HTTs, Hospital Transfusion Laboratory Managers

- Blood transfusion is not an appropriate treatment for iron deficiency and puts patients, particularly the elderly, at risk of TACO. Iron deficiency should be diagnosed and appropriately corrected with iron supplements, and the underlying cause established and treated.

  Action: General Practitioners, hospital doctors, Medical Schools, HTTs

The impact of revised definitions for transfusion-associated circulatory overload and transfusion-related acute lung injury on haemovigilance reporting

Yin Yuan, Peta M. Dennington, James Daly, Shoma Baidya, John-Paul Tung

First published: 18 January 2023 | https://doi.org/10.1111/vox.13402 | Citations: 1

- Objectives: TACO and TRALI are serious adverse transfusion reactions. Standardized surveillance definitions are important to ensure consistent reporting of cases. Recently, revised definitions have been developed for TACO and TRALI, the latter of which has not yet been widely implemented. This study aimed to assess the impact of the new TACO and TRALI definitions on haemovigilance reporting.
- Materials and Methods : The Australian Red Cross Lifeblood Adverse Transfusion Reaction database was accessed to identify all cases of suspected or confirmed TACO and TRALI referred from 1 July 2015 to 30 June 2019. Cases were assessed against both the former and new definitions and the results were compared.
- Results: A total of 73 cases were assessed. There were 48 TACO cases identified. Only 26 of 48 cases strictly met the former 2011 SBT definition of TACO; 6 cases did not meet the definition and 16 cases lacked sufficient clinical details. In comparison, 46 cases met the revised 2018 ISBT definition, with only 2 cases having insufficient details. There were 24 cases of TRALI according to the existing 2004 Canadian Consensus Conference (CCC) definition compared with 25 cases according to the proposed 2019 revised definition.
- Conclusion:The revised TACO definition captured more cases than the former definition. No significant differences were observed in the number of TRALI cases under the proposed new definition. This is the first study to provide validation data for the revised TRALI definition.

HV尚在解决的问题

- Infectious transfusion complications: Definitions and criteria for TTIDs are challenging to standardize
  - ✓ the differences between the diseases and their epidemiology
  - ✓ different standards and methods of testing between countries.
  - ✓ Work is being pursued by the ISBT-TTID-WP in collaboration with the HV-WP.
  - ✓ To date, no international definitions have been adopted by the IHN or ISBT.
- Errors, failures, and incidents: A number of types of sentinel event have been defined by the ISBT and IHN. Nevertheless, the very term adverse event is used differently in different organizations, and notably the EU legislation defines serious adverse event differently from international pharmacovigilance legislation.

血液生产和输注过程的HV

- 20120619：draft proposal of new error classification was sent for review and comments to WP-QM members
- 20120704：to the members of WP-HV.
- 201207：ISBT congress in Cancun WP-QM presented *new Version 1* classification of errors in transfusion medicine, covering 3 major areas of activities (those in blood establishments, hospital blood banks and clinical wards applying transfusion therapy).
- 201305：ISBT Amsterdam, WP-QM agreed to continue the work on this project。
- 201412：*new Version 2* of error classification in the field of blood establishment (BE) activities , in hospital blood banks and clinical wards applying transfusion therapy.

思考

临床输血 ⟹ 精准个体化

临床用血生产 ⟹ 自动化、标准化

血液管理 ⟹ 信息化

- 2001年7月，中国药品不良反应（ADR）监测信息网络系统正式开通
- 在输血服务行业？建立一个不良事件报告系统？

1-监测内容要与血液管理体系一致

血型的流行病学

筛查试剂

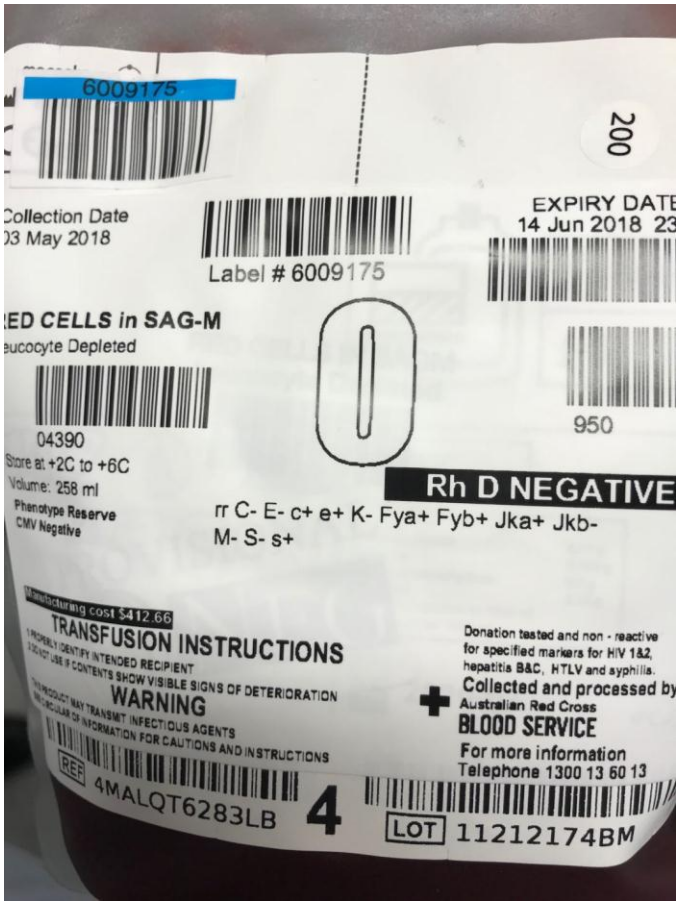


表 3 献血不良反应和输血不良反应监测内容

监测类别	监测内容
献血不良反应	血管迷走神经反应（VVR）即发型/迟发型
	枸橼酸盐反应
	溶血反应
	空气栓塞
	过敏反应
	血肿
	迟发型出血
	神经损伤/刺激
	血栓形成
输血不良反应	输血传播病毒感染
	输血传播细菌感染
	输血传播寄生虫感染
	输血传播其他病原体感染
	过敏反应
	溶血性输血反应
	迟发性血清学输血反应
	非溶血性发热反应
	输血后紫癜
	输血相关移植物抗宿主病
	输血相关急性肺损伤
	输血相关呼吸困难
	输血相关循环超负荷
	输血相关性低血压

例1：迟发型血清反应

Delayed serologic reaction (DSTR)

定义：输血后出现已知的有临床意义的红细胞抗体且无溶血的临床表现和实验室特征。 DSTR与同种免疫同义。

SHOT: Alloimmunisation is defined as demonstration of clinically significant red cell antibodies after transfusion, which were previously absent (as far as is known), when there are no clinical or laboratory signs of haemolysis.

Tableau 19 : Répartition des anticorps anti-érythrocytaires non ABO dans l'allo-immunisation isolée déclarée d'imputabilité 2 à 3, 2015

Anticorps anti-érythrocytaire non ABO *	Effectif	%
JK1	385	17,01%
KEL1	375	16,57%
RH3	374	16,53%
FY1	231	10,21%
RH1	142	6,27%
LU1	116	5,13%
RH4	95	4,20%
JK2	92	4,07%
MNS3	89	3,93%
RH2	89	3,93%
KEL3	68	3,00%
MNS1	58	2,56%
RH8	45	1,99%
FY2	20	0,88%
RH5	17	0,75%
CH/RG1	16	0,71%
LE1	15	0,66%
MNS4	12	0,53%
LE2	7	0,31%
P1	6	0,27%
LU2	2	0,09%
MNS2	2	0,09%
CO2	1	0,04%
FY3	1	0,04%
KEL7	1	0,04%
LW1	1	0,04%
RH6	1	0,04%
SC1	1	0,04%
XG1	1	0,04%
Total	**2263**	**100%**

** seul le 1er anticorps est pris en compte pour le calcul d'effectif*

例2：细菌污染性输血反应

Bacterial Contamination Reaction

(Transfusion Transmitted Sepsis)

细菌污染性输血反应

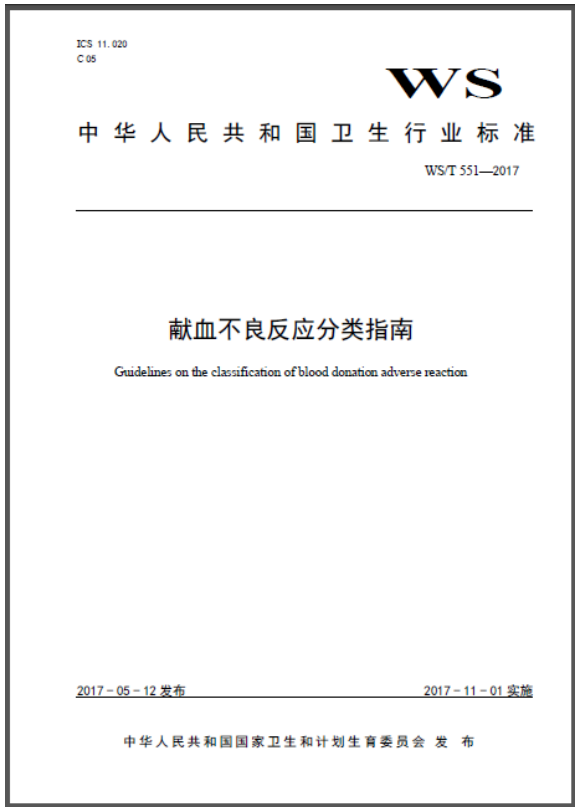
- 供者在献血时处于菌血症期（有局部感染灶）
- 保存液、采血和输血器具消毒不严，血袋有破损
- 细菌可以通过静脉穿刺过程中进入血袋（消毒不严格或皮肤碎屑）
- 血液成分制备过程中无菌操作不严格
- 血液在贮存或运输中冷链不符合要求
- 血液制剂细菌污染后产生的内毒素及细胞因子释放导致反应。
- 涉及的微生物广泛：多数G+及G-细菌在室温生长,如葡萄球菌、沙门菌属等。冰箱温度生长细菌： G-菌，如绿脓、肠杆菌属等
- 筛查处理程序
- 血小板库存时间

Tableau 28. : Les germes retrouvés – classement par type de PSL, nombre et ordre d'imputabilité décroissante – Période 2000 à 2011

		Nombre et %	Score d'imputabilité	
Type de germe	Familles PSL	Imputabilité 1 à 3	2	3
Germes avec des CGR				
Klebsiella pneumoniae	CGR	3 (100%)		2 (66,7%)
Bacillus (non précisé)	CGR	1 (100%)		1 (100%)
Bacillus cereus	CGR	1 (100%)		1 (100%)
Klebsiella oxytoca	CGR	1 (100%)		1 (100%)
Yersinia (non précisé)	CGR	1 (100%)		1 (100%)
Yersinia enterocolitica	CGR	1 (100%)		1 (100%)
Propionibacterium acnes	CGR	3 (100%)	2 (66,7%)	
Staphylococcus (non précisé)	CGR	11 (100%)	1 (9,1%)	
Escherichia coli	CGR	4 (100%)	1 (25%)	
Candida (non précisé)	CGR	1 (100%)	1 (100%)	
Citrobacter (non précisé)	CGR	1 (100%)	1 (100%)	
Proteus mirabilis	CGR	1 (100%)	1 (100%)	
Serratia marcescens	CGR	1 (100%)	1 (100%)	
Clostridium perfringens	CGR	1 (100%)		
Corynebacterium (non précisé)	CGR	1 (100%)		
Enterobacter cloacae	CGR	3 (100%)		
Gram - sans précision	CGR	1 (100%)		
Listeria monocytogenes	CGR	1 (100%)		
Micrococcus (non précisé)	CGR	1 (100%)		
Proteus morganii (Morganella morganii)	CGR	1 (100%)		
Pseudomonas aeruginosa	CGR	1 (100%)		
Staphylococcus à coagulase neg.	CGR	1 (100%)		
Staphylococcus epidermidis	CGR	3 (100%)		
Stenotrophomonas maltophilia (Pseudomonas maltophilia)	CGR	1 (100%)		
Streptococcus (non précisé)	CGR	6 (100%)		
Streptococcus groupe A (S. pyogenes)	CGR	1 (100%)		
Bactérie non listée	CGR	8 (100%)	2 (25%)	3 (37,5%)
Germes avec des plaquettes				
Staphylococcus (non précisé)	Plaquettes	17 (100%)	6 (35,3%)	8 (47,1%)

2-标准的制订专家的共识-循证医学

- 等同等效采纳不是适合所有的领域


ICS 11.020
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WS

中华人民共和国卫生行业标准

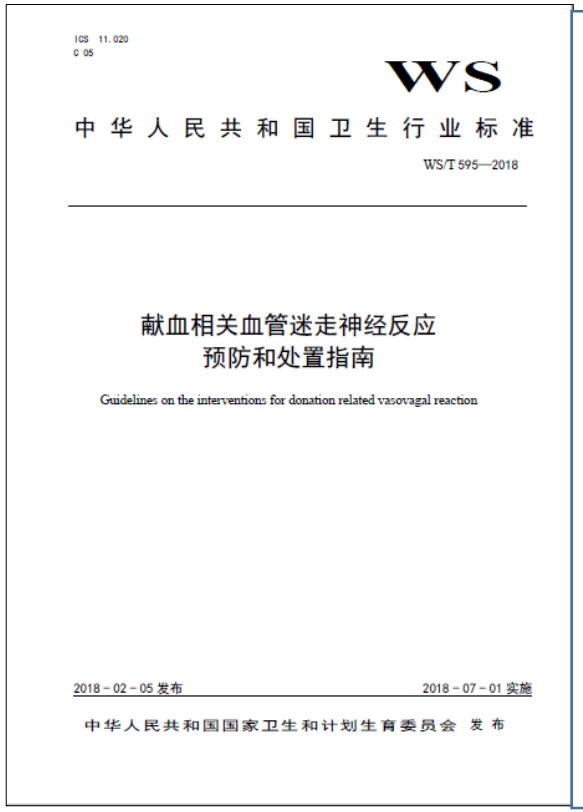
WS/T 551—2017

献血不良反应分类指南

Guidelines on the classification of blood donation adverse reaction

2017-05-12 发布　　2017-11-01 实施

中华人民共和国国家卫生和计划生育委员会 发布


ICS 11.020
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WS

中华人民共和国卫生行业标准

WS/T 595—2018

献血相关血管迷走神经反应
预防和处置指南

Guidelines on the interventions for donation related vasovagal reaction

2018-02-05 发布　　2018-07-01 实施

中华人民共和国国家卫生和计划生育委员会 发布


ICS 11.020

T/CSBT

中国输血协会团体标准

T/CSBT 001—2019

血液安全监测指南

Guideline for Haemovigilance

2019-04-12发布　　2019-04-12实施

中国输血协会发布

献血不良反应监测预防处置相关标准

发布时间	发布机构	性质	名称
2000	法国l'Afssaps	HV报告	rapport national d' hémovigilance
2007	法国l'Afssaps	国家法规	Décision du 7 mai 2007 fixant la forme, le contenu et les modalités de transmission de la fiche de déclaration d' effet indésirable grave survenu chez un donneur de sang (FEIGD)
2008	ISBT/EHN	国际标准	Standard for Surveillance of Complications Related to Blood Donation
2014	ISBT/IHN/ABO/EBA/AABB	国际标准	Standard for Surveillance of Complications Related to Blood Donation
201705	国家卫生计生委	行业推荐标准	《献血不良反应分类指南》WS/T551-2017
2018	国家卫生计生委	行业推荐标准	《献血相关血管迷走神经反应预防和处置指南》WS/T595-2018
2019	中国输血协会	团体标准	《血液安全监测指南》T/CSBT 001—2019

Donor Haemovigilance-Singapore

- Hematoma/Bruising
- Vasovagal reactions
- Nerve Injury
- Pain
- Citrate toxicity
- Thrombophlebitis

血管迷走神经反应临床表现

Vasovagal reaction (VVRs)

轻度血管迷走反应仅有主观的症状，主要表现为晕厥先兆症状，无意识丧失；

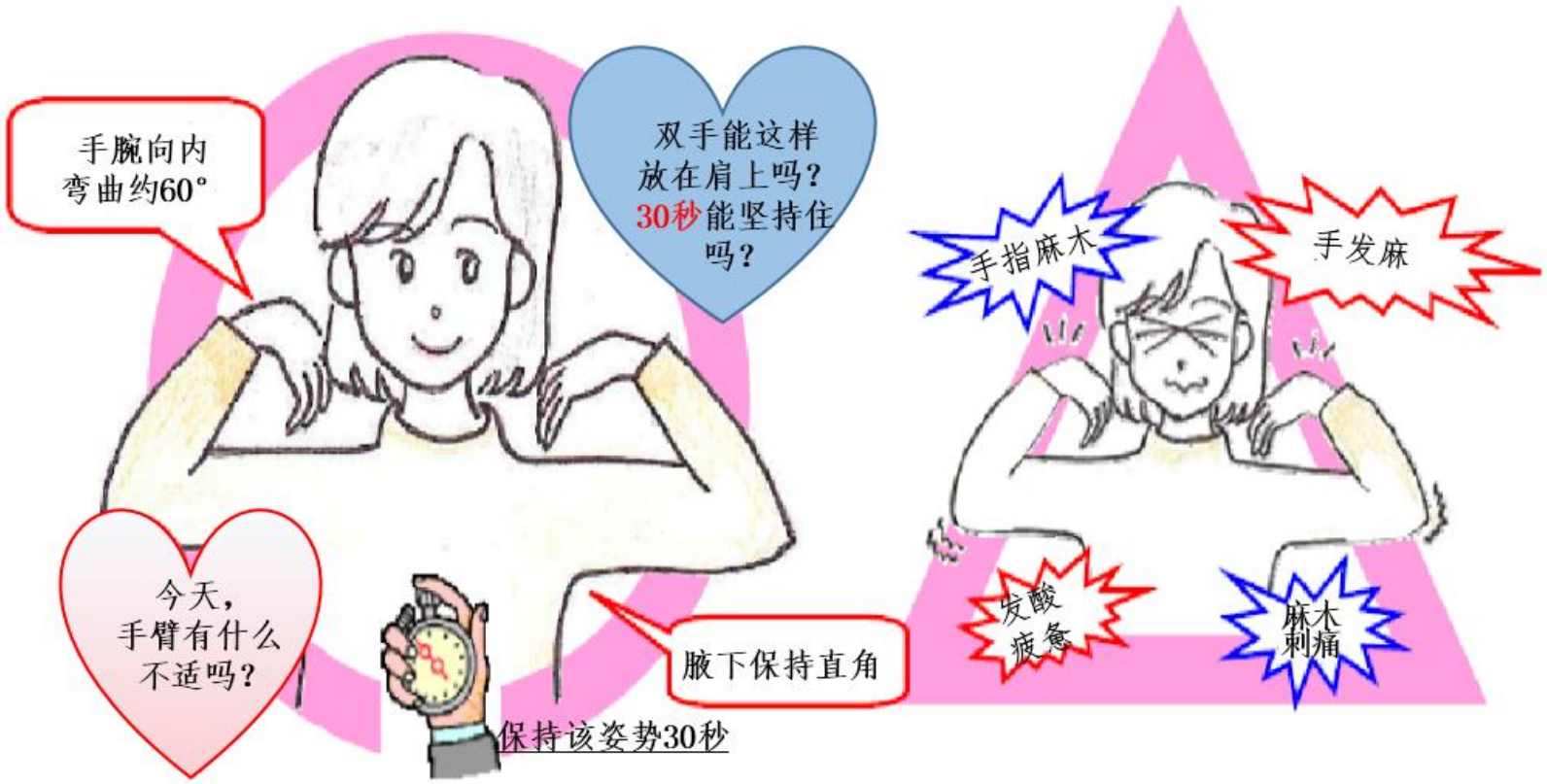
中度的血管迷走反应，会表现为意识丧失，伴或不伴呕吐，不能自制、抽搐，意识丧失小于1钟。

55例VVRs临床症状分布情况

临床症状	合计例数n（%）
头晕（dizziness）	30(54.55)
虚弱乏力/疲惫（weakness）	18(32.73)
全身性不适(discomfort)	15(27.27)
意识丧失/昏厥（consciousness loss/faint)	15(27.27)
头痛（headache）	7(12.73)
恶心（nausea）	7(12.73)
胸闷（chesttightness）	6(10.91)
胸痛（thoracodynia）	5(9.09)
心动过缓/心慌（bradycardia）	5(9.09)
呕吐（vomiting）	5(9.09)
腹部不适/腹泻腹痛(abdominal discomfort）	5(9.09)
出汗（sweating）	3(5.45)
面色苍白（pallor）	3(5.45)
焦虑（anxiety）	2(3.64)
抽蓄（convulsions）	2(3.64)
呼吸增强/过度换气（hyperventilation）	2(3.64)
口干嘴唇发麻	2(3.64)
感冒	2(3.64)
眼睛不舒服	2(3.64)
浑身酸痛/脖子痛	2(3.64)
全身麻木	1(1.82)
咳嗽	1(1.82)
耳鸣	1(1.82)
流鼻血	1(1.82)

3-提出建议和推荐

例： 日本献血者SAEFPT检查



日本推荐的leg muscle tension exercise

2013年7月启动研究　2015年10 全国应用

<Exercise-1> during the donation.

1. Cross your legs and tense muscles on both legs.

2. Stretch your ankles and count five.

3. Release tension as crossing legs. Relax and count five.

4. Repeat 2 and 3 five times.

5. Re-cross your legs and repeat five times in the same way.

Perform above in sets of 1 to 5

<Exercise-2>

Additional two sets after donation.

<POINTS>

- **Tense your abdominal and gluteal muscles with legs**
- **Keep breathing**
- **Keep the rhythm**

献血前教育和教育材料

Understanding, Managing, and Preventing

Blood Donor Reactions in Teenagers

DEVELOPED BY A WORKING GROUP OF THE ABC SCIENCE, MEDICAL, AND TECHNICAL COMMITTEE

Jerry Gottschall, MD

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Mary Townsend, MD

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4-HV的运行管理

- 注意力不应该集中于数据收集方面，不明白发生的真正原因，HV的核心是发现问题，反馈
- 纠正和预防措施是HV的目标
- 高层管理人员的接受与支持，保证持续的HV运行
- 人力保障，专业人员的支持
- 愿意与合作者分享信息
- 财力支撑和数据的安全


thank you
danke
謝謝
ngiyabonga
teşekkür ederim
спасибо
dank je
gracias
tesekkur ederim
mauruuru
bedankt
hvala
mochchakkeram
dziękuję
go raibh maith agat
sukriya
kop khun krap
obrigado
arigato
dakujem
grazie
merci
terima kasih
감사합니다
спасибо