CENTRO NAZIONALE SANGUE

Istituto Superiore di Sanità

Challenges of the SoHO oversight system: VES point of view

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Rome, April 8th 2025

Presentation

- History of VES

- New opportunities under the regulation
- Challenges

- Supporting each other

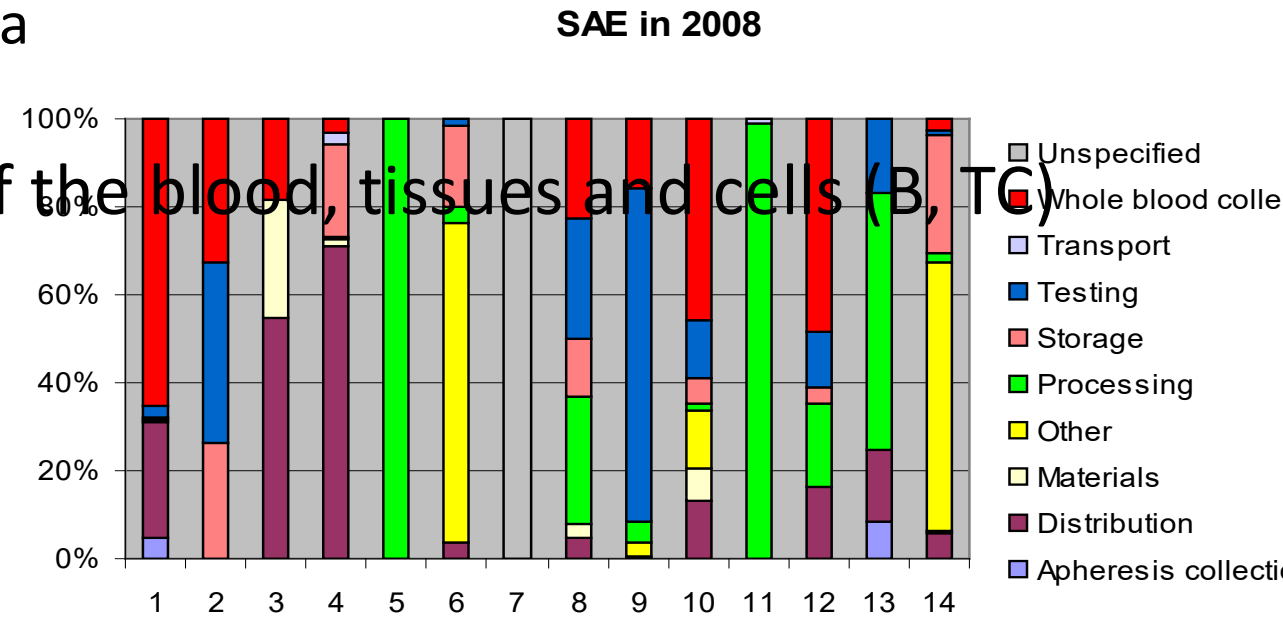
Introduction

Are you

a) Involved in *national level* vigilance work, i.e. do you assess reported individual (S)AR/(S)AE?
b) Professionally involved in the work of a SoHO establishment?
c) A past VES member or a newly nominated V&T member?

VES History

- 2007 onwards: haemovigilance (HV) working group
  - Heartfelt plea from SHOT and other HV systems: don't just pick out the 'cherries'
  - Common Approach; SARE (serious adverse reactions and events) reporting "a learning exercise"
  - "quality check", queries to verify data
  - SAE: lack of harmonization
- 2017: vigilance expert subgroup of the blood, tissues and cells (B, TC) competent authorities, "VES"
  - Terms of reference, rapporteurs
- 2018: organs included



VES work in subgroups

SARE reporting improvement - improve classification of reported SARE and provision of denominators

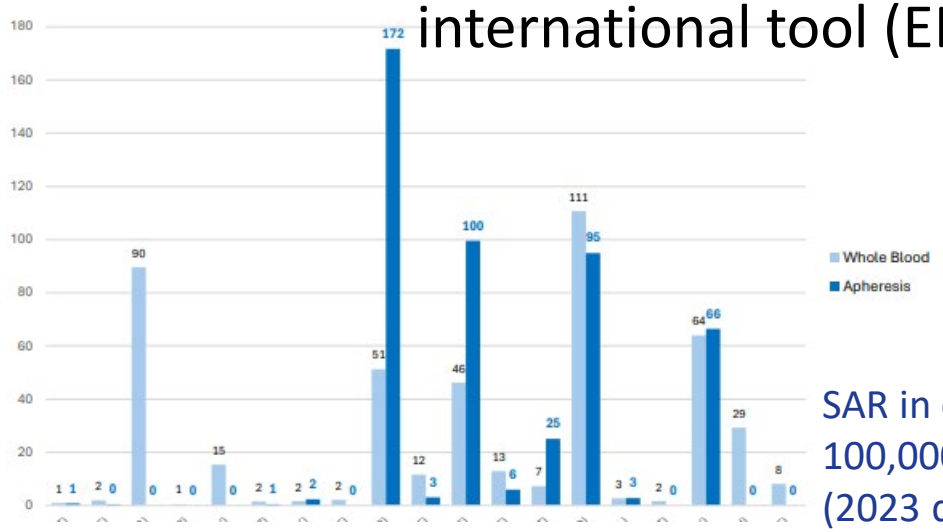
Rapid alert “RAB/RATC” review

VES-IES cross fertilization

Organs: survey of organ vigilance arrangements and pilot of EU level reporting of SAR/SAE

SARE reporting improvement

- Annual revision of Common Approach (B, TC)
- Reduce cases classed as Other (specific SAR types, drop down menus)
- Reduce SAE specified as Human error (new: System failure)
- Improve assignment to activity steps
- Blood donor SAR seriousness assessment: pilot using international tool (EBA endorsed) in 2024



SAR in donors per 100,000 collections (2023 data)

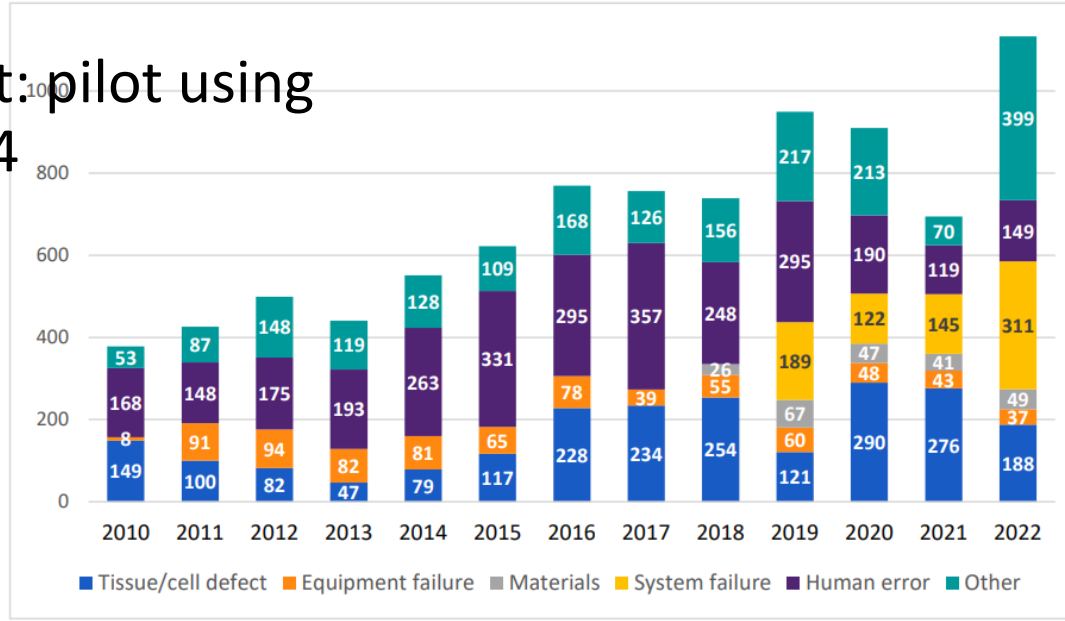


Figure 35. Distribution of SAE by type/specification; 2010-2022 data

Vigilance wish list during revision of legislation

- Vigilance should extend beyond Q/S of the products
  - Include transfusion/application
  - Efficacy monitoring
- Seamless vigilance
  - To where SoHO is transferred to different EU legislative framework
  - When new SoHO / SoHO product is introduced
- Harmonise definitions between B and TC
- Mandate reporting of SARE affecting donors even if there was no impact on Q/S
- Retain
  - reporting of no harm events
  - reports of SARE affecting children born from MAR

Vigilance wish list (2)

- Results of vigilance reporting may be used as input for risk-based inspections
- Consider audit of SoHO vigilance work at NCA level (e.g. peer audit)
- Autologous treatments: efficacy data should be evaluated …. appropriate consent (…)
- Reference to guidance produced by expert bodies e.g. EDQM, ECDC, VES
- Continue to refer to international definitions for donor adverse reactions.

- Change term (serious) adverse event X

Definitions

(43)‘adverse reaction’ means any incident which could be reasonably associated with the **quality or safety of SoHO**, or their **collection from a SoHO donor** or human **application to a SoHO recipient**, that caused harm to a living SoHO donor, to a SoHO recipient or to offspring from medically assisted reproduction;

(44)‘adverse event’ means any incident or error **associated with SoHO activities** that can affect the quality or safety of SoHO in such a way that implies a risk of harm to a living SoHO donor, to a SoHO recipient or to offspring from medically assisted reproduction;

Regulation 2024/1938, Article 3

(45) **'serious adverse reaction'** or 'SAR' means an adverse reaction that results in any of the following:

(a) **death**;

(b) **life-threatening, disabling or incapacitating** condition, including transmission of a pathogen or of a toxic substance that might cause such condition;

(c) transmission of a **genetic disorder** that:

(i) in the case of medically assisted reproduction *with third-party donation*, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction; or

(ii) in the case of medically assisted reproduction in the context of *within-relationship use*, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction, due to a **pre-implantation genetic test error;**

(d) **hospitalisation** or prolongation of hospitalisation;

(e) the need for a **major clinical intervention** to prevent or reduce the effects of any of the results referred to in points (a) to (d);

(f) **prolonged sub-optimal health** of a SoHO donor following single or multiple SoHO donations;

(46)**'serious adverse event'** or 'SAE' means an adverse event that poses a risk of any of the following:

(a) inappropriate SoHO distribution;

(b) a defect posing a risk to SoHO recipients or SoHO donors is detected in one SoHO entity that would have implications for other SoHO recipients or SoHO donors because of shared practices, services, supplies or critical equipment;

(c) loss of a quantity of SoHO that causes human applications to be postponed or cancelled

(d) loss of highly matched SoHO or SoHO for autologous use;

(e) a mix-up of reproductive SoHO in such a way that an oocyte is fertilised with sperm from a person other than the intended person, or reproductive SoHO are applied to a SoHO recipient other than the intended SoHO recipient;

(f) **loss of the traceability of SoHO**

Regulation 2024/1938, Article 3

SoHO activities

->V&T: SARE denominators

SoHO donor registration;
SoHO donor history review and medical examination;
testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationshi
collection;
processing;
quality control;

SAE denominators?

Also dataset for monitoring selfsufficiency emergency preparedness

storage;
release;
distribution;
import;
export;
human application;
clinical-outcome registration.

Making the change

- “Everything” about vigilance and traceability has to be written into **SCB best practices**
- Adapted SoHO Common Approach guidance with forms and information materials ready for use in MS

Don’t throw out the baby with the bathwater

- At national level
  - Adapt (paper/digital) systems for wider scope
  - Restictions re staff conflicts of interest
  - Assessing adequacy of investigations, advice, timely communication
  - Public annual report

Opportunities
to be seized

(A selection)

Building on our experience

Broadened scope = new actors

Donor protection, new requirements

Protection of MAR offspring

Better quality vigilance data, authority-level verification of investigation results

Vigilance in SoHO product authorisation

Harmonisation across member states

New SoHO

Thinking beyond borders

- Rapid alerts
- Import and export
- Feeding ECDC, public health
- Learn other “languages”
  - WHO
  - IHN, ISBT
  - Safety science
  - Pharmacovigilance

Support for each other

NUDGE

SCB

↕

Member state NCA, competent authorities, delegated bodies

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Entities

Conclusion

- Opportunities
- Vigilance: starting where we are, stepwise improvement
- A lot of work
- Worth it!

Thank you

- Best wishes and success in your area of work
- Thank you for your attention