Hemovigilance in NL

Transfusion and transplantation reactions in patients

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and TRIP national medical coordinator, 16th March 2021

Disclosures

I have no conflicts of interest to declare.

My jobs at TRIP (28 hours/week) and Sanquin (8 hours/week) are separate.

I am a member of Vigilance Expert Subgroup of the European expert group of national competent authorities for blood, tissues and cells; contracted by the European Commission as a vigilance expert to support vigilance improvement work in 2021.

Views expressed in this seminar are personal and do not necessarily reflect those of organisations with which I am associated.

Outline

Situation in 2001-2

Development of national hemovigilance (HV) reporting (recipients)

Donor hemovigilance

Traceability

HV in 2021: strengths, weaknesses and challenges

Discussion

HV: adverse events and reactions in clinical transfusion

2001-2002: scene setting for national HV reporting

1. Two wrong blood fatalities in 2000; healthcare inspectorate report (2001) mandates hospital blood transfusion committees
2. TRIP Foundation created by professional bodies in 2001, project subsidy granted (2002) by Ministry
3. 2002-4 professional guideline revision mandates reporting to TRIP as the norm
4. 2003: Inspectorate quality indicators “Do you report to TRIP? If not, how do you ensure safety in the transfusion chain?”

Launch: letter to hospitals

HV officer in each hospital: laboratory lead or hematologist

HV assistant (transfusion safety officer)

- laboratory, nursing or quality background
- collect information about transfusion reactions or incidents
- teaching, updating protocols, audit
- Works under HV officer and blood transfusion committee

Definitions!

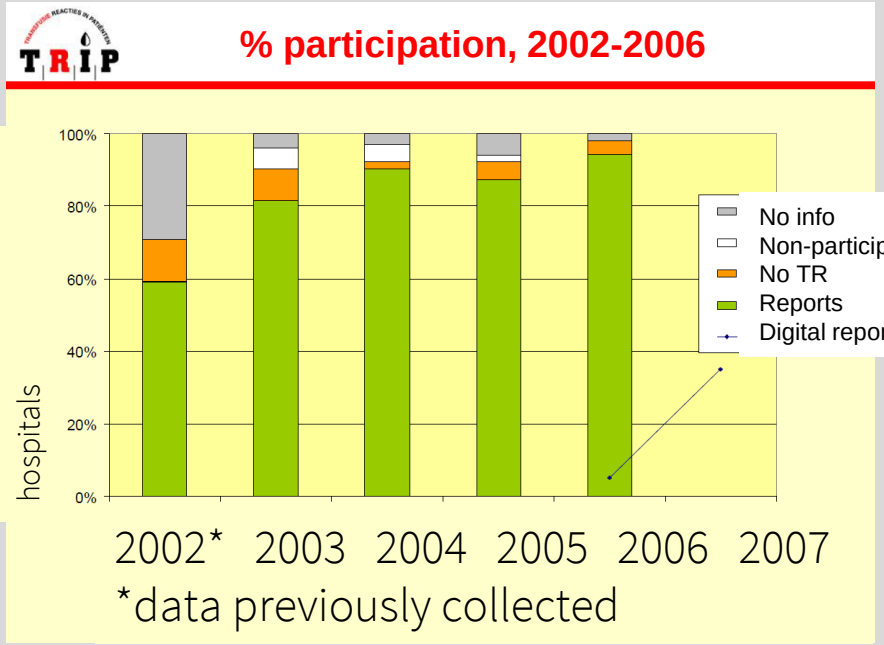
Transfusion reactions and incidents (errors, failures)
All severity levels reported
Based on ISBT-International Haemovigilance Network definitions
Possibly related to product quality: report urgently to Sanquin
Paper -> online reporting system (2006)

TRIP verification of submitted reports
Expert advisory board

Ramp-up phase

Regional data sharing about transfusion reactions (TR) before TRIP

From 2006 >90% participation every year



Forging the network

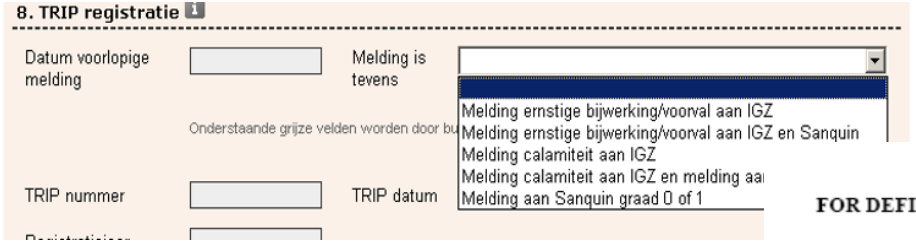
Hospital visits
Lectures on request
Annual report
Symposium

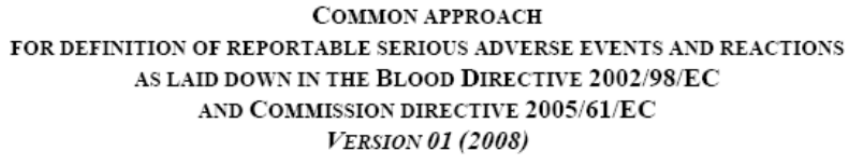
EU legislation: mandatory reporting

Hospitals informed

Serious adverse reaction/event: forward to Inspectorate in TRIP digital reporting system

First annual SARE submission: 2007 data



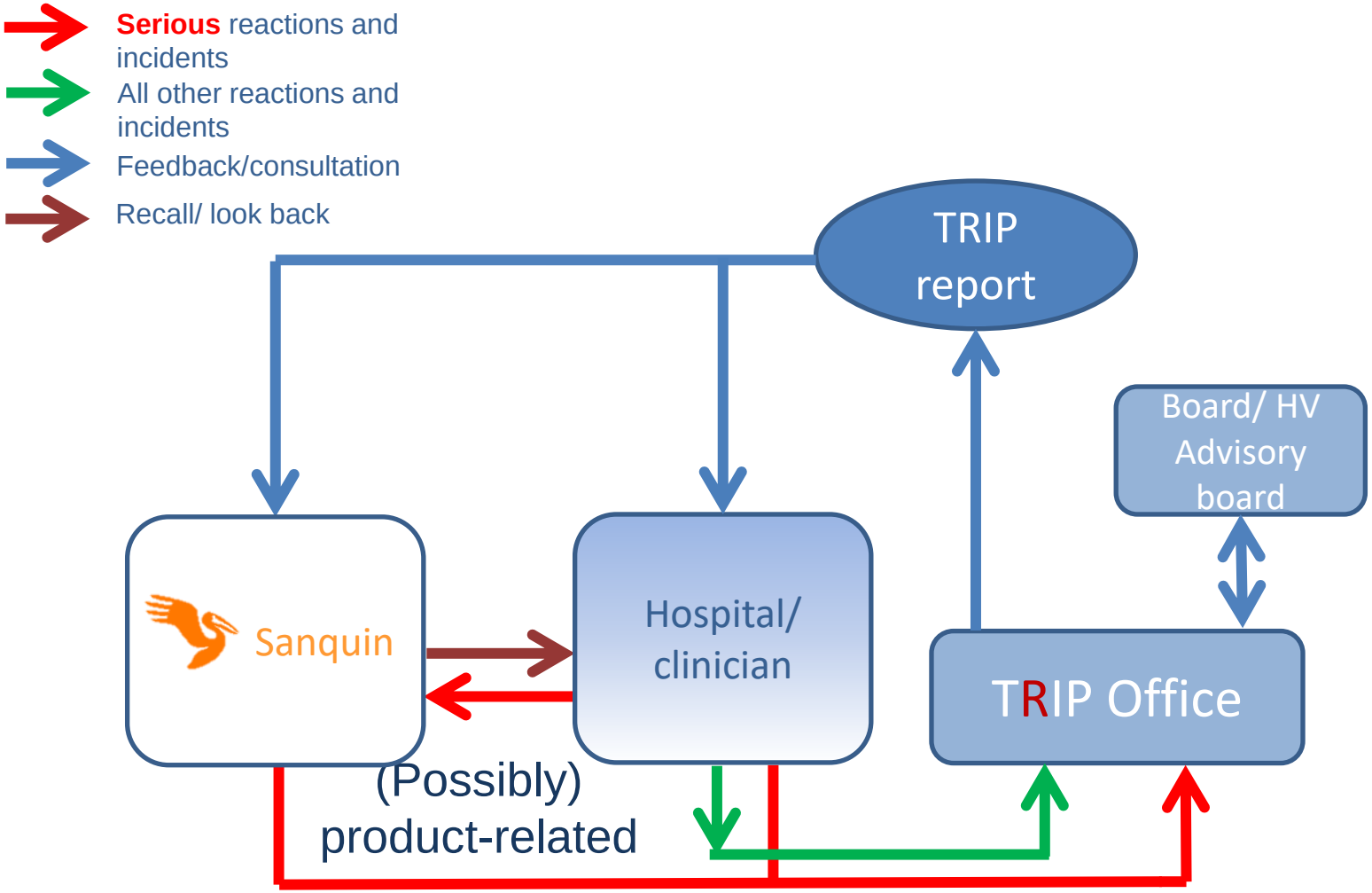

COMMON APPROACH
FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS
AS LAID DOWN IN THE BLOOD DIRECTIVE 2002/98/EC
AND COMMISSION DIRECTIVE 2005/61/EC
VERSION 01 (2008)

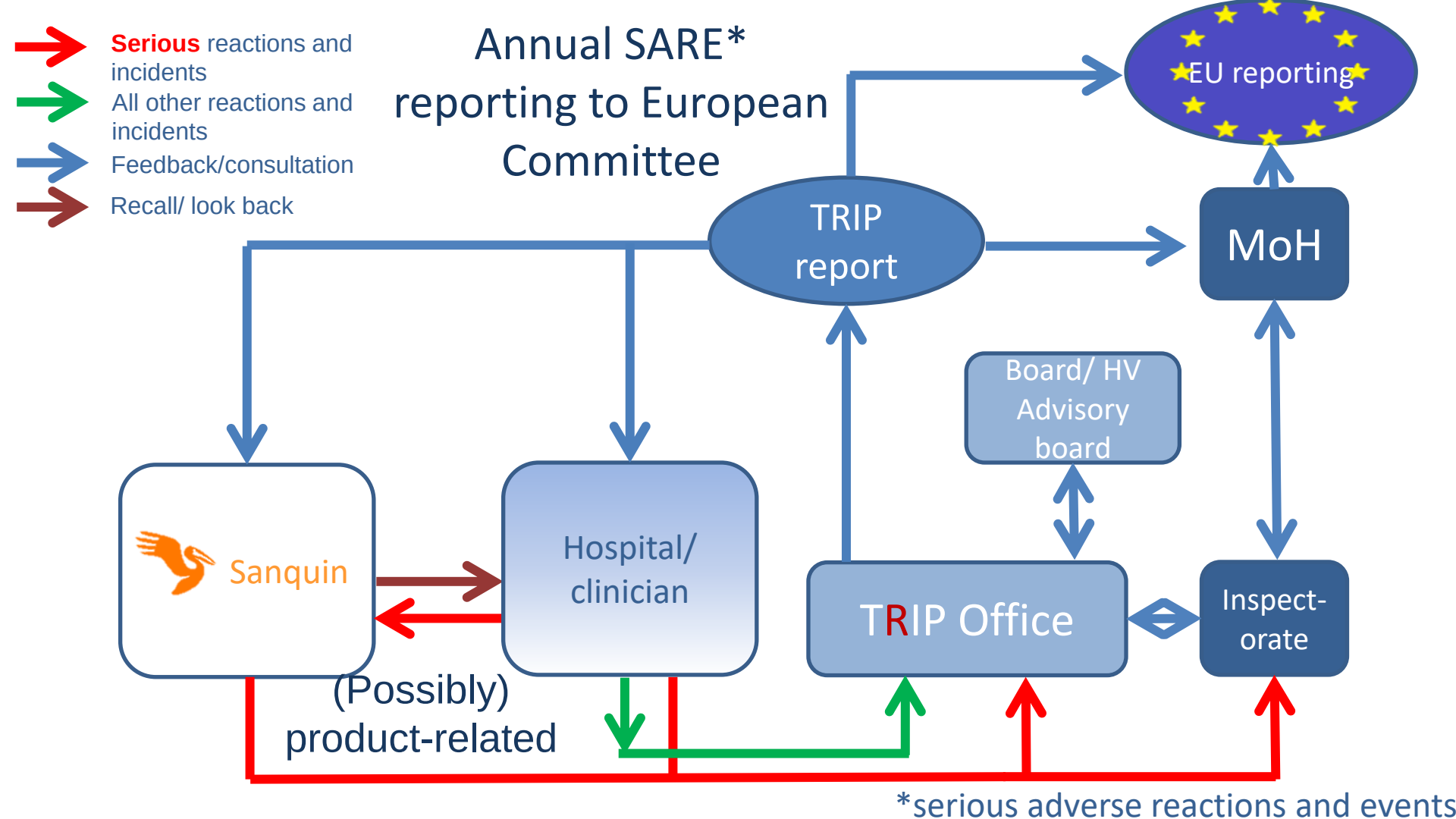
Blood Transfusion committee

- Blood users, laboratory, nursing lead…

- Audit, protocols (e.g. patient identification; massive transfusion protocol)
- Patient blood management
- Oversight of staff training on transfusion

- Does the committee meet?
- NL recommendation: 4x per year


Serious reactions and incidents
All other reactions and incidents
Feedback/consultation
Recall/ look back
TRIP report
Board/ HV Advisory board
Sanquin
Hospital/ clinician
TRIP Office
(Possibly) product-related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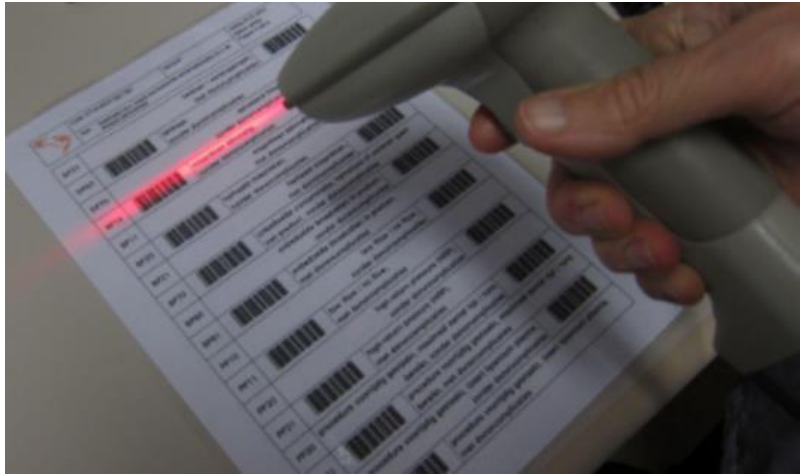
Donor hemovigilance



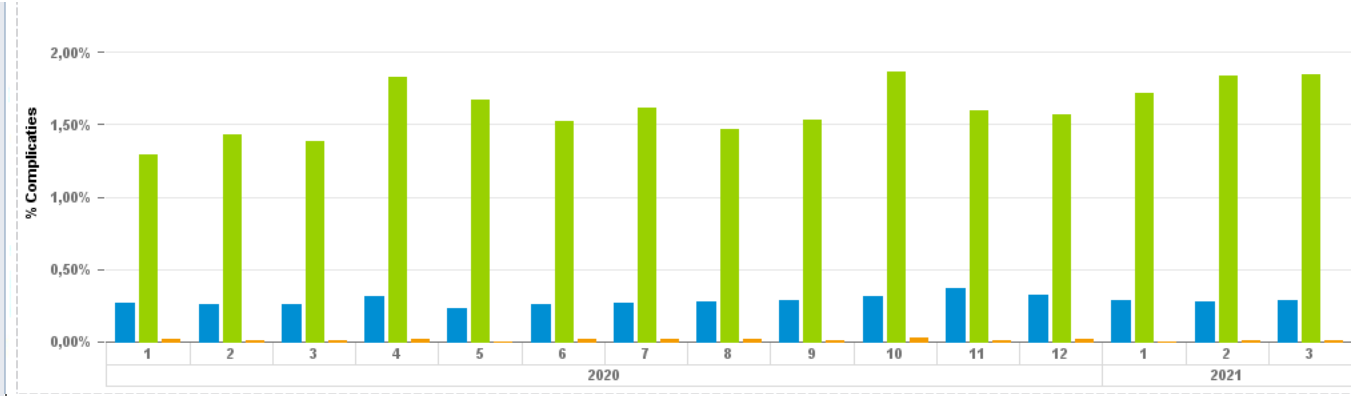
Sanquin's responsibility

- All levels of donor adverse reactions recorded (eProgesa)
- Serious cases, or if third parties involved (e.g. general practitioner), reported in "Trackwise"
- Serious adverse reactions in donors reported annually to Healthcare Inspectorate
- Voluntary reporting to European Commission by MoH
- Currently not reported publicly

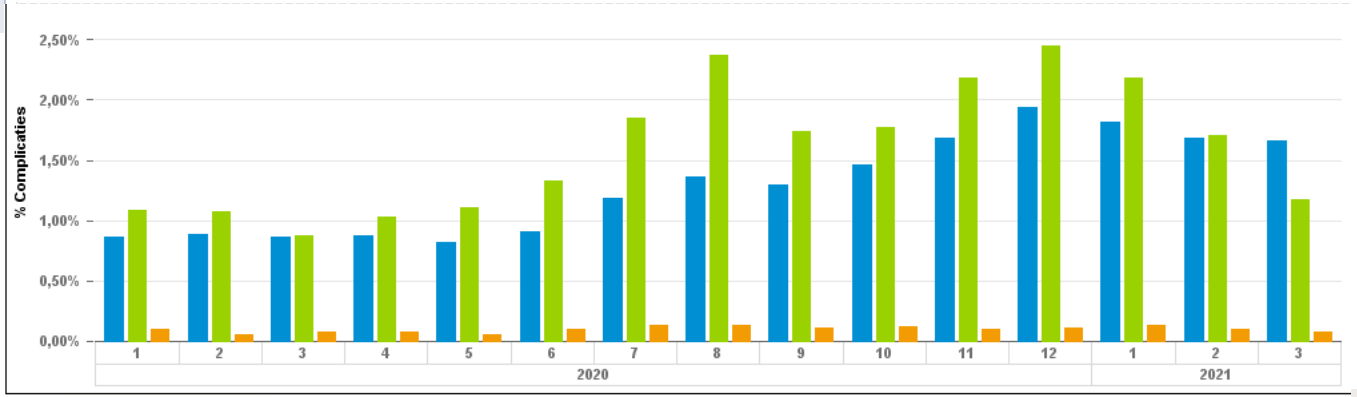
Monitoring rates of complications

Local (vp-related
Vasovagal
Other

Whole blood donation



Plasmapheresis



Evidence for a preventive measure

NNT 23 novice donors to avoid a self-reported VVR

8300 participants (73% female, 41% first donation)

6921 (83%) responded to questionnaire

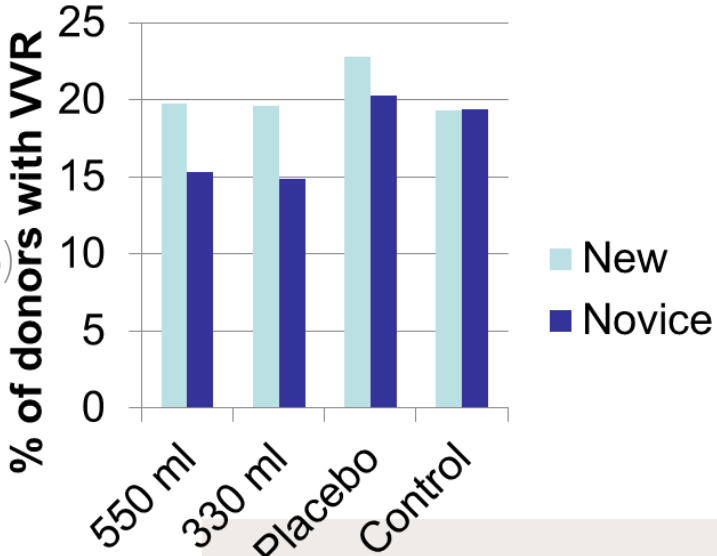
23% reduction of self-reported vasovagal reactions (VVR)

(OR 0.77; 0.63-0.94) in novice donors

No difference between 330 and 500 ml water

No effect in new donors

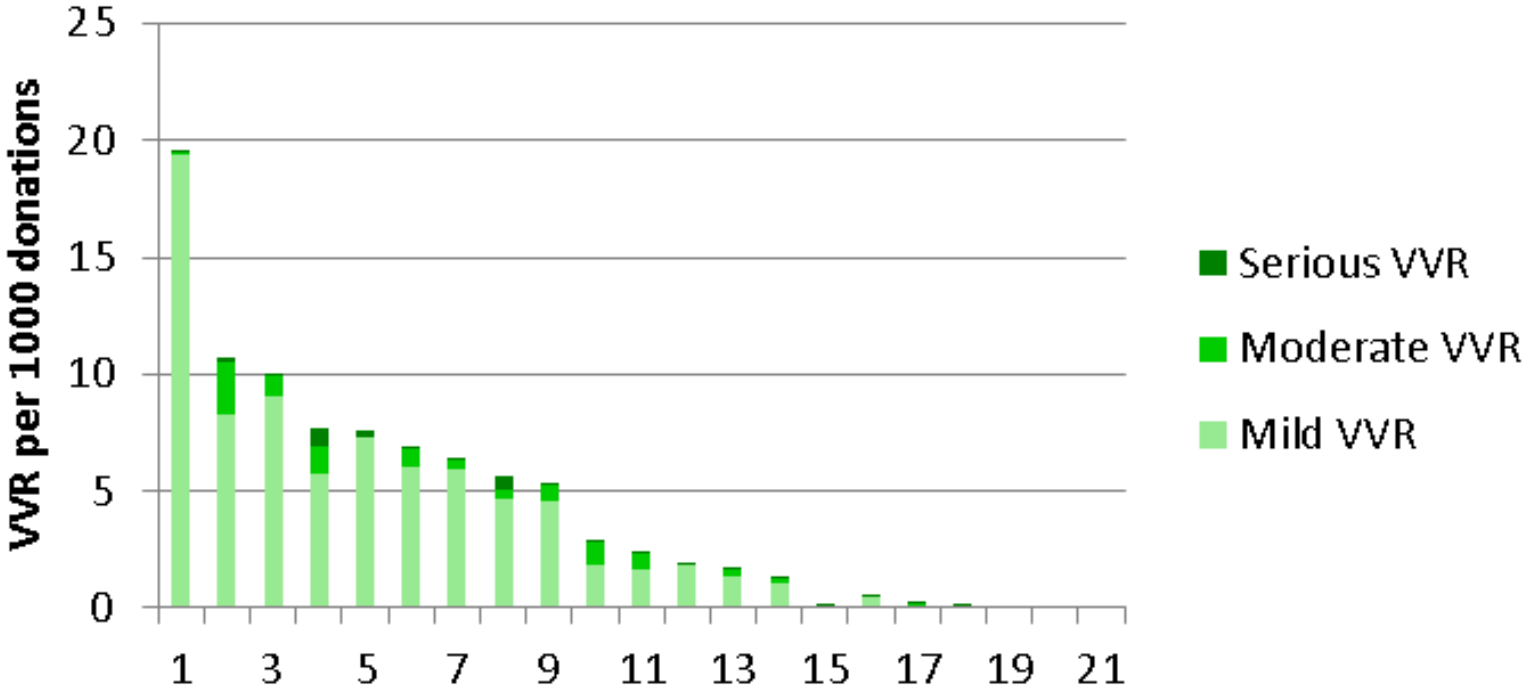
(Transfusion 2018; doi:10.1111/trf.15065)



ISTARE
INTERNATIONAL SURVEILLANCE OF TRANSFUSION-ASSOCIATED REACTIONS & EVENTS

Country rates of VVR (average over each country's years with data)

Lack of comparability between systems



Wiersum-Osselton et al.
Vox Sang 2020

Donor hemovigilance

- Ethical responsibility of blood establishments
- Extra preventive care at next donation
- Monitor trends in reactions, improve quality of care
- EBA endorsed international definitions (2014) and severity assessment tool (2020)
- Challenges
  - maintaining good recording
  - poor comparability of data between jurisdictions
  - not systematically reported by EU member states

Discussion

Traceability

Traceability (blood establishment)

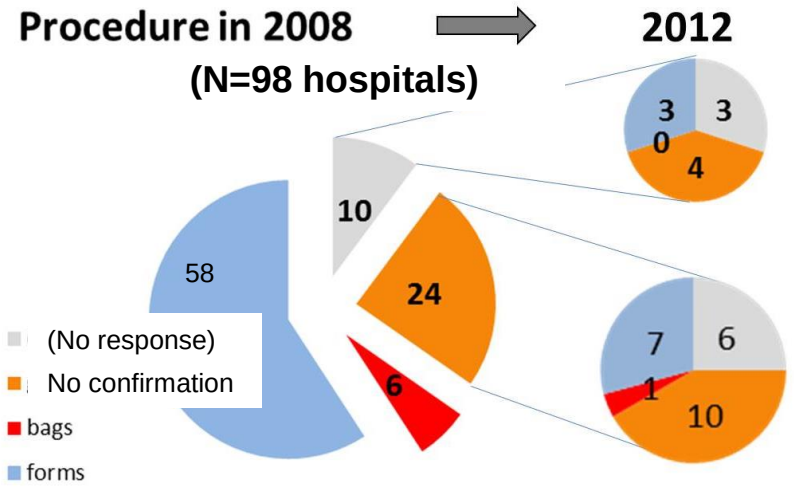
Blood establishment: Donor
->donation (testing, processing)
->units prepared
->to which hospital?
(or unit destroyed)
100% (eProgesa)

Requirement: 30 years data storage, readable medium

Traceability (hospitals)

Hospital transfusion laboratory: which unit to which patient?

- Laboratory computer system
- Link selected component(s) to patient, issue (or expiry/destroyed)
- Is transfusion confirmed?
  - In 2012 74/98 hospitals responded to TRIP survey
    - 15 hospitals: no confirmation
    - 53 hospitals: forms returned
    - 5: bags returned
    - Median returned: 99.5%
    - 1: electronic scan however not yet able to confirm transfusion
  - Improvement from 2008 survey



Follow-up of donors and recipients after adverse events or reactions

RECALL, LOOK-BACK

Post-donation information (donor rings; or at next attendance)

Positive bacterial screening of platelet concentrate – hospital informed

Seroconversion of repeat donor – previous donations – hospital informed

REVERSE LOOK-BACK (TRACEBACK)

Following report of transfusion reaction (sepsis, TRALI, hepatitis B/C)

- Donor investigations

Sanquin

TRIP
Hemo- en biovigilantie

Hemovigilance in 2021: strengths, weaknesses and challenges

Characterising haemovigilance systems

Scan of 7 established HV systems (online annual reports), 2020

22-210 pages

Both mandatory and “voluntary”/professionally mandated

Recipient adverse reactions median 236/100,000 blood components (range 18-418)

5/7 also report on donor adverse reactions

3/7 (prominently) include recommendations for safety improvement; others include information on safety measures taken/ongoing

Data quality issues

- Cases reviewed, but information may be inadequate; 1x no classification possible for 20% of reports
- 2x incomplete participation, education needed
- 3x unexplained (within-country) variation in numbers of reports in relation to blood use
- Decline in reports
  - Safety improvement
  - Competing activities, reporting fatigue

?

SHOT (UK): holistic non-punitive approach needed to improve patient safety

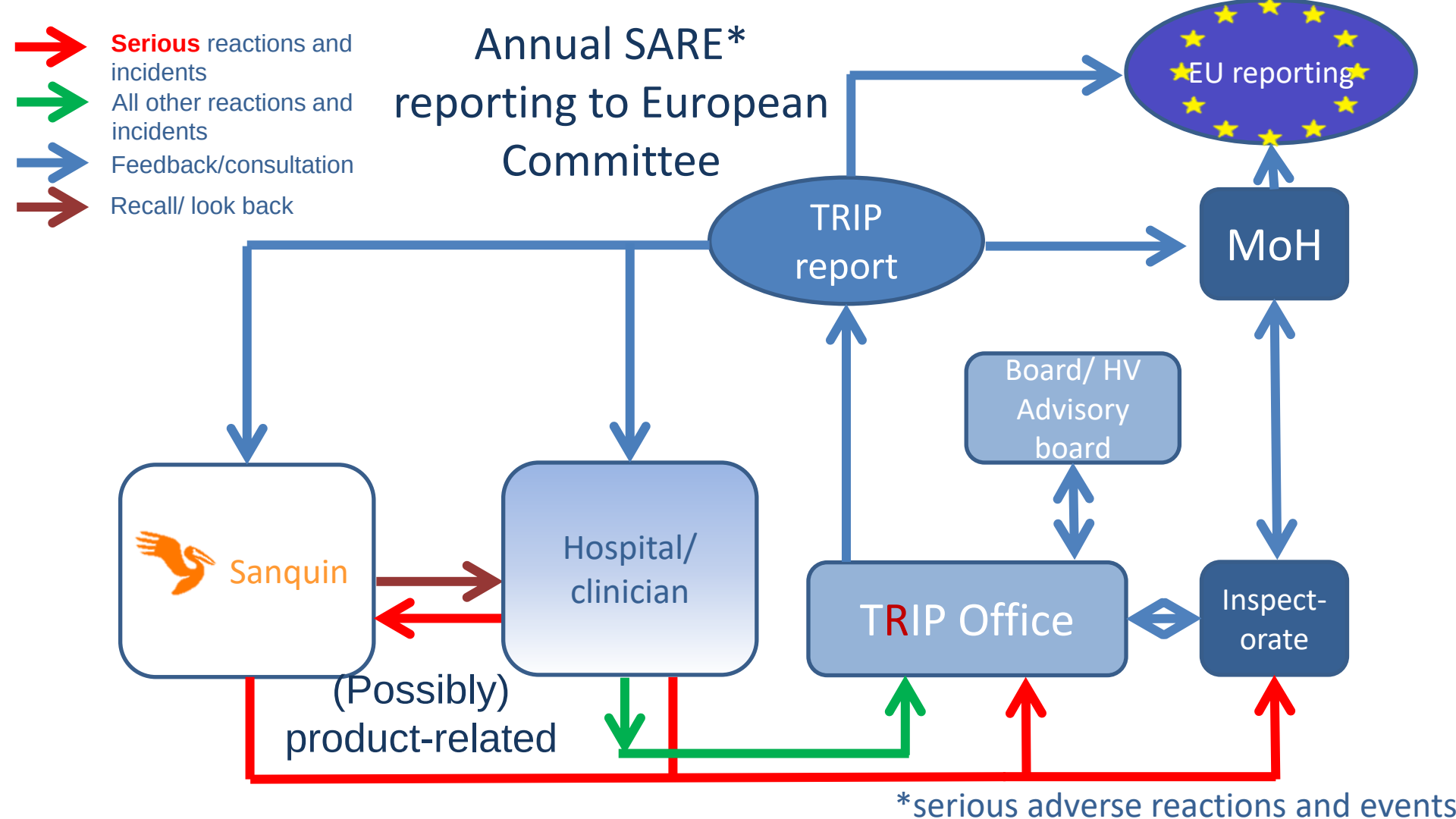
Challenges, opportunities

Definitions (continuing journey)

- Comparability of data
- Include long term complications
  (e.g. iron)
- Indicators
- New insights, new products

EU legislation – shortcomings – revision launched

Together: strengthen HV so that it brings about improvement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Conclusions

First steps bottom-up process starting with professionals

Alignment with EU directives

Present situation:

- Web-based system with evaluation of reactions
- MoH (inspection) reponsible for oversight, receives SAE/SAR reports
- TRIP provides the data reported by Hospitals and Sanquin
- MoH responsible for reporting to EU

Acknowledgements

TRIP and Sanquin colleagues

Hospital HV officers and Transfusion safety officers in The Netherlands

Ministry of Health representatives

International partners

Discussion