

Integrating Directive 2002/98/EC into Dutch hemovigilance

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- Introduction: the ‘stakeholders’
- Role of TRIP and how compliance will be achieved
- Additional factors
 - patient safety movement
 - tissue vigilance
- Potential positive impact

The stakeholders

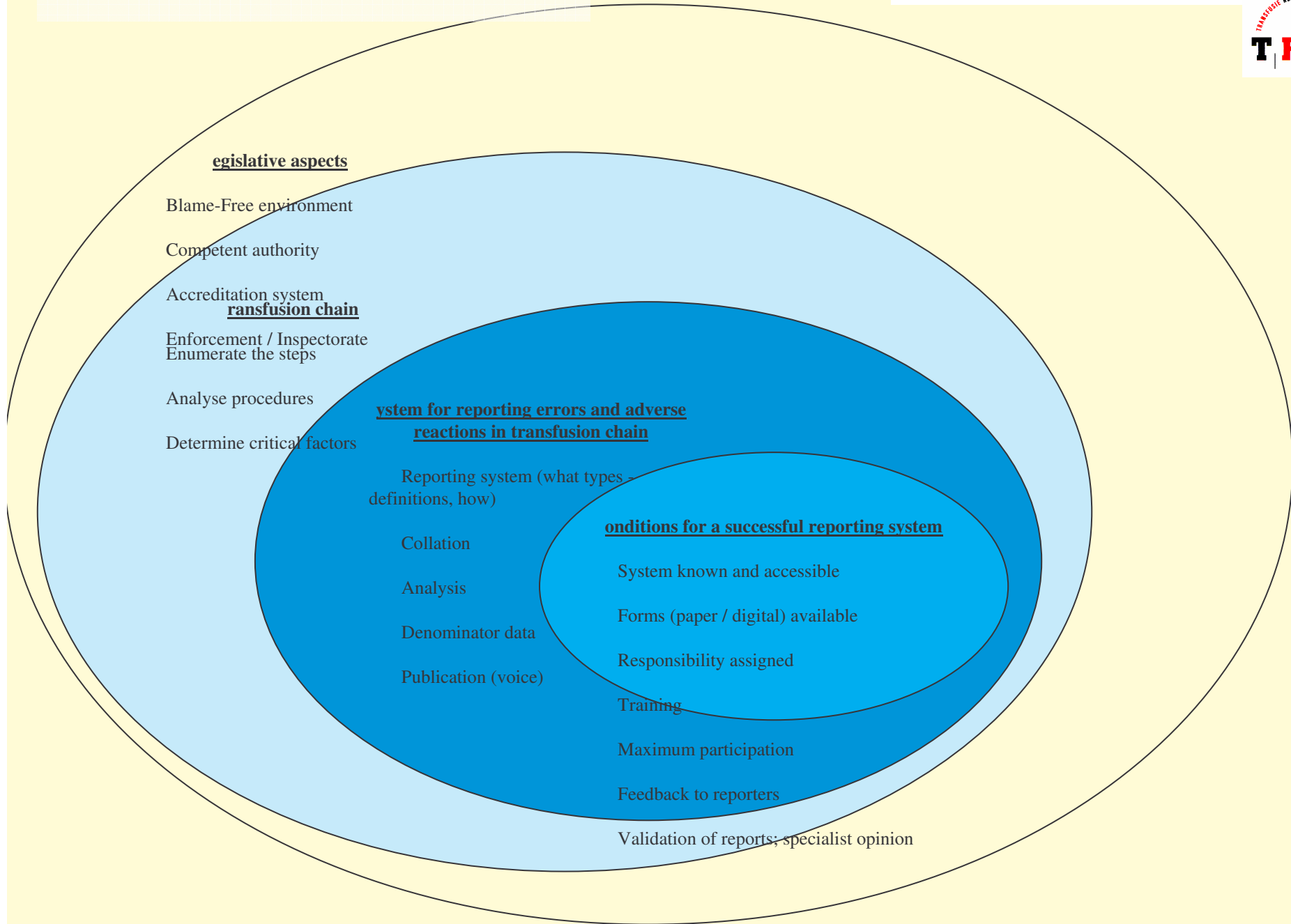
**Ministry /
Healthcare
Inspectorate**

**EU: blood
component
safety**

**TRIP: safety in
the whole
transfusion chain
(working through
professionals)**

**Sanquin
blood supply
foundation**

Hospitals



Legislative aspects

Competent authority

Who or what?

Accreditation system

Blame-Free environment

Enforcement / Inspectorate

!



System for reporting errors and adverse reactions in transfusion chain

Reporting system (what types -

definitions, how

Unclear what is required; comparison between countries will be useless without common definitions

Collation

Analysis

Denominator data

Publication (voice)

Inspectorate reports lack detail and are little read by those who actually work in the transfusion chain



Conditions for a successful reporting system

System known and accessible

Forms (paper / digital) available

Responsibility assigned

Training

Maximum participation

Feedback to reporters

Validation of reports; specialist opinion

The reporter is responsible for submitting to the Authority

All reports should follow the same route

Transfusion chain

Enumerate the steps

Analyse procedures

Determine cr

The Inspectorate has separate departments for health care establishments + patient safety and blood

ply

Can recommendations be made for improving safety?

How do we as professionals (help to) make it useful?

and mitigate any negative impact?



Role of TRIP and how compliance will be achieved



Who or what is the competent authority?

- Ministry of Health or the Health Care Inspectorate?
- Not TRIP!
 - a) legally not possible
 - b) we don't have the manpower
 - c) nor would we wish to assume a regulatory or enforcement role which could undermine professionals' confidence
- It has been stated that the Inspectorate will receive the reports on behalf of the Ministry

What are we talking about?

In 2005:

- 89 reports of serious transfusion reactions (60 of certain or probable or possible imputability) and only 18 of these involved possible infectious hazards (no certain or probable viral TTI).
 - In many serious transfusion reactions (listed as compulsory in the Directive) there is no reason for a hospital to report to the Authority
- 3 reports of incidents where a product fault could have led or did lead to serious consequences
- 39 reports of platelets units which after transfusion screened positive for bacterial growth (no clinical consequences reported)

In The Netherlands

- The Netherlands is fortunate to have a near-optimal blood supply.
- TRIP is already doing the work and can continue to provide scientific analysis and comment
- The Inspectorate is chiefly interested in information which they have to act upon and isn't interested in receiving some 100 extra reports where there is no real product safety issue.



TRIP's position

- Impartial (independent from blood supplier and hospitals)
- Experience and expertise
- Over 90% voluntary participation by hospitals: our interest is to continue to receive **all** reports!
- Public reporting of anonymous information
- Ongoing funding committed (since 2006)



The solution

- TRIP online reporting database will generate automatic e-mail with pdf attachment to Inspectorate if reporter indicates that the report is an 'EU report' or 'calamity' (=very serious safety incident)
- A new e-mail will be generated when the report is confirmed and is accepted by TRIP as complete
- Meanwhile the Inspectorate can log on at any time and view all mandatory reports
- Cross-referencing between systems to remove double reports

What actually will be subject to the mandatory reporting under Directive 2002/98/EC?

- concentrate on the minimum scenario, adjust if necessary on the basis of jurisprudence
- inform hospitals and blood supply organisation of the mechanism, offer no 'interpretation' of the Directive



Additional factors

patient safety movement

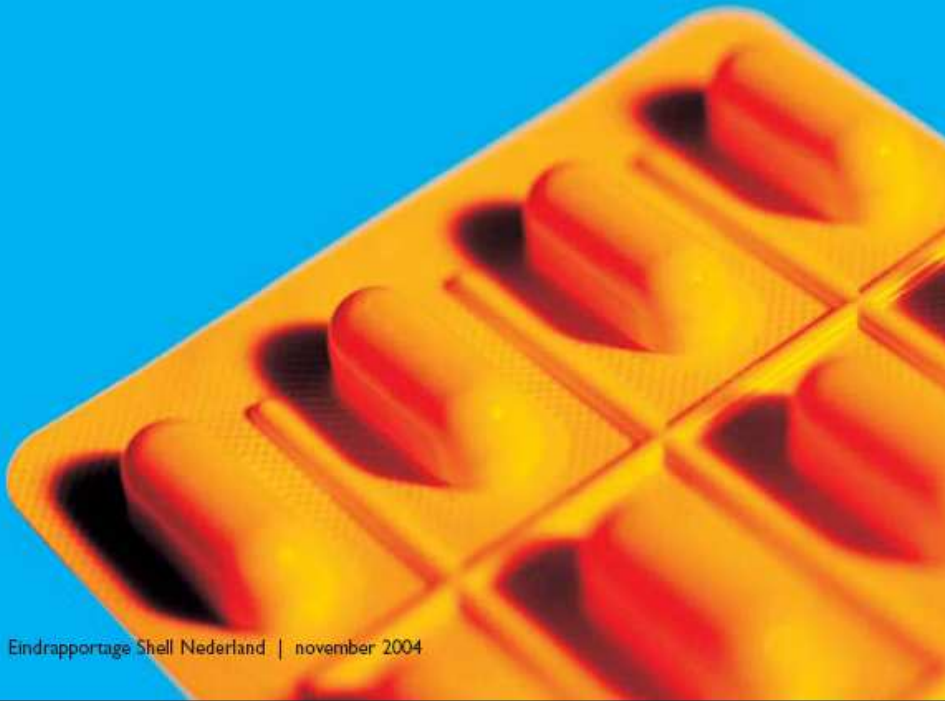
tissue vigilance



Patient safety movement

Hier werk je veilig,
of je werkt hier niet

Sneller Beter - De veiligheid in de zorg



Eindrappor tage Shell Nederland | november 2004

All hospitals must
implement a risk
management system by
1st January 2008



Patient safety movement (2)

- Commercial activity
- One department of a hospital doesn't know what another is already doing
- Challenge to TRIP to ride this wave and turn it to the advantage of hemovigilance

Tissue vigilance

- Directive 2004/23/EC
- TRIP asked to set up compliant tissue vigilance system
 - read more about this on our poster
- We are convinced that linking hemovigilance with tissue vigilance (and maybe later with organ vigilance??) will lead to mutual benefit.

Potential positive impact

By collaboration between TRIP and the regulator:

- scientifically validated data using agreed definitions
- more complete, speedier information
- user-friendly system (no need for paper reports)

Potential positive impact (2)

- strengthening of (international) scientific ties, learning from each other
- not just product focus, but chain-wide approach
- use of TRIP network of contacts to make findings available to professionals in the transfusion chain and guideline-writers

