Cells and tissues: reporting of SAE and SAR in The Netherlands

Jo Wiersum-Osselton

with

M.Schipperus, M. ten Dolle, P. Zijlker and A. van Tilborgh

Tissue vigilance

- Directive 2004/23/EC
- TRIP asked to set up compliant tissue vigilance system
- Links between hemovigilance and tissue vigilance activity will lead to mutual benefit.

Tissue vigilance:
introduction in The Netherlands

Law on Quality and Safety of human tissue (revised)

Revised Decree on human tissue, 2006

Law on Organ Donation defines organ centre, responsibilities etc.

Law on Medical Treatment Agreement

Quality Law for Health Care Establishments: includes requirement to report very serious safety incidents

The stakeholders

Ministry / Healthcare Inspectorate

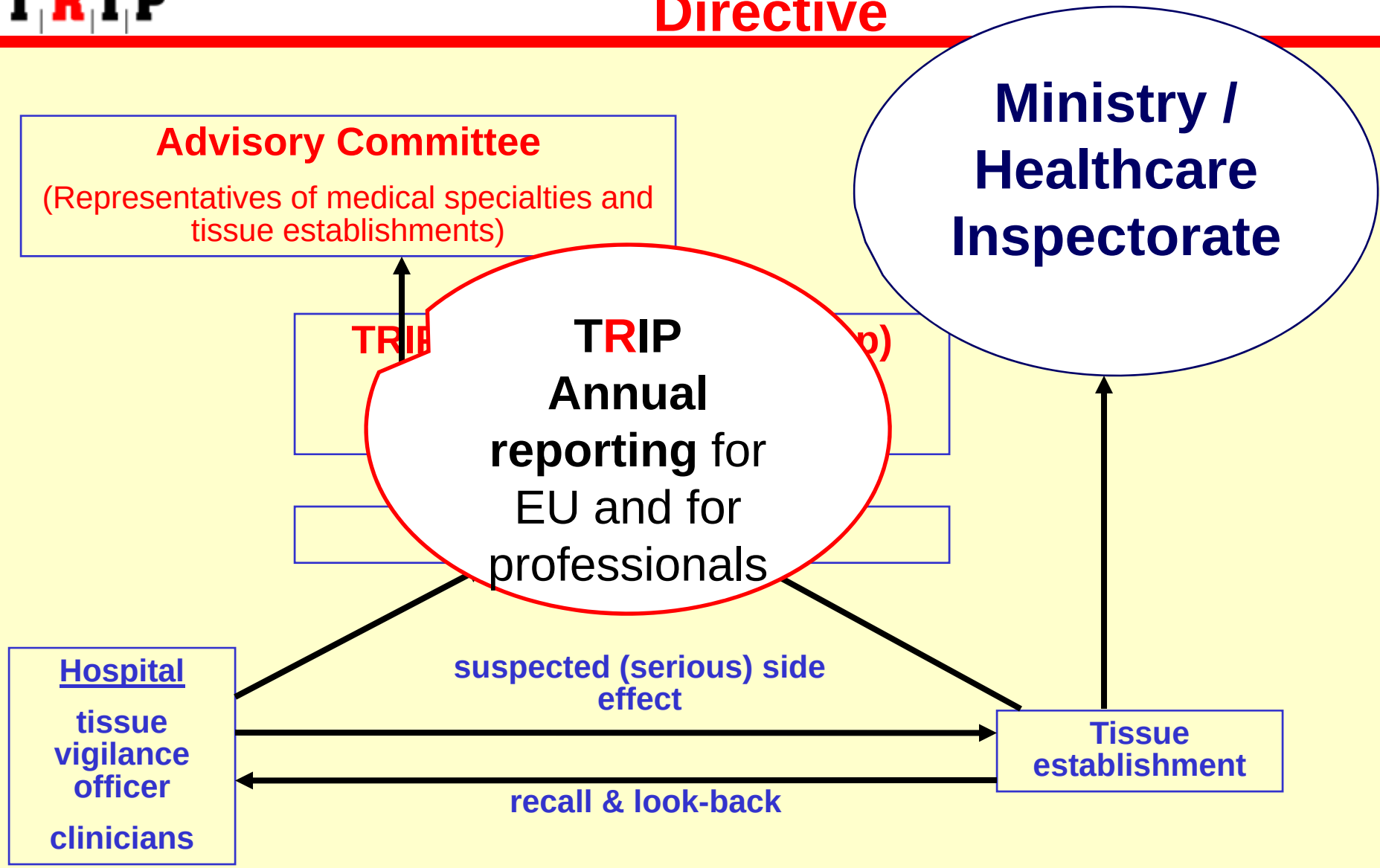
EU: tissue safety

TRIP: transfusion and transplantation safety - working through professionals

Tissue establishments

Hospitals

Tissue vigilance reporting under the Directive



Pilot launched in August 2006

- Contacts with tissue establishments and organ centres
- Hospitals informed, asked to designate **tissue vigilance officer**
- Request for numbers of units and for voluntary reporting
- Tissue establishments seeking accreditation from Ministry.

Initial experience: 2006 data

Type of tissue	Units or quantity
Skin	1971375 cm^2
Bone & cartilage	3100
Ocular tissue corneas scleras amniotic membrane	 1200 315 57
Auditory ossicles	37
Cardiovascular tissue	400 (valves, vessels, patches)
Hematopoietic stem cells (unrelated donors)	30 bone marrow 24 PBSC 16 umbilical cord blood
Hematopoietic stem cells (related donors and autologous procedures)	unknown
Reproductive cells	unknown
Other tissues: Pancreatic islet cells Ligaments, fascia, tendon, meniscus Foetal tissue	unknown

Initial experience: 2006 SAR and SAE

- 8 reports received
- 4 deemed serious
- one of ‘certain’ im-putability (M. tuberc.)

•donor’s prosthesis worked loose; specialist informed bone bank (16m after donation).

•recipient at same time: acetabulum working loose after 6 months.

•donor had not been aware of latent tuberculosis, had never been ill or treated.

Other reports

- Hemolysis after infusion of ABO incompatible cord blood unit

  not unexpected!

  Which adverse events are to be reported?
- Poor mechanical quality

  (problems suturing cardiac valve)
- Transient neurological deterioration after infusion of autologous stem cells
  - similar problem in different hospital!
- Minor reactions e.g. febrile reaction

Other reports (2)

- Bacteria screening of unit found positive after distribution
  - cornea
  - bone
  - autologous hematopoietic stem cells
  - also occurs in platelet units!
  - variable significance.

Many questions!

- Known side effects?
- Reporting to tissue-specific organisation (e.g. JACIE)

  does not obviate the need to report under the Directive!
- Which adverse events?
- Need for imputability assessment.
- Side effect which is not unexpected?

  e.g. knowingly transplanting infected unit.
- Cross-border traffic

  who should capture?

Advisory committee: manufacturers and users

- Current status=advisory (members will join TRIP board when tissue activity becomes permanent)
- Compile tissue-specific lists of side effects
- Specify in definitions: serious *unexpected* and *unintended* adverse reactions / events
- TRIP's task is to involve users.

Who ‘do’ tissue vigilance in the hospitals?

Difficult to find central point of contact!

– board of governors
– head of transfusion laboratory
– quality management department
– medical specialists
– donation officer (tissue vigilance is a separate task!)

– Tissue committee?

Weaknesses of TRIP system

- **Dependent on willingness of professionals to report**
- **Late reporting (‘cold’ vigilance)**
- **Difficult to contact staff in the hospitals**
- **“Polder model”: many people decide. Democratic, effective (we expect) but slow!**

Future strengths

- tissue-specific guidance generated by the specialists
- strengthening of (international) scientific ties, learning from each other
- not just product focus, but chain-wide approach
- findings available to professionals in the transfusion and transplantation chains
- development of professional standards.