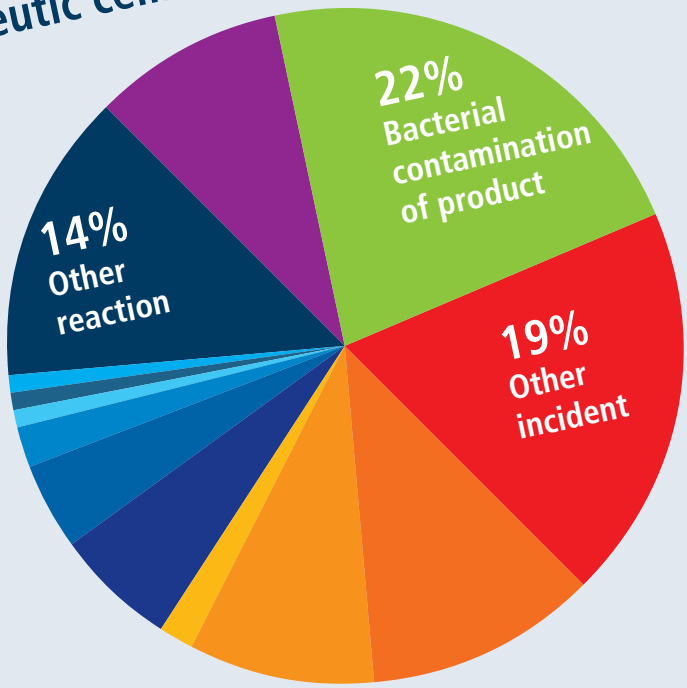
TRIP HIGHLIGHTS 2018

Biovigilance

TRIP
Hemo- en biovigilantie

3
reports of incorrect Single European Code

Hematopoietic stem cells and therapeutic cells 2006-2018 (258 reports)



96 reports

96% participation of organisations in biovigilance

517,448,000
17,218,000
3% of EU citizens

317,970
39,796
12% of tissue/cell recipients
Data from 21 EU Member States

96% overall participation by organisations with a role in biovigilance in 2018

100%

105
Tissue establishments

98%

79/81
Hospitals

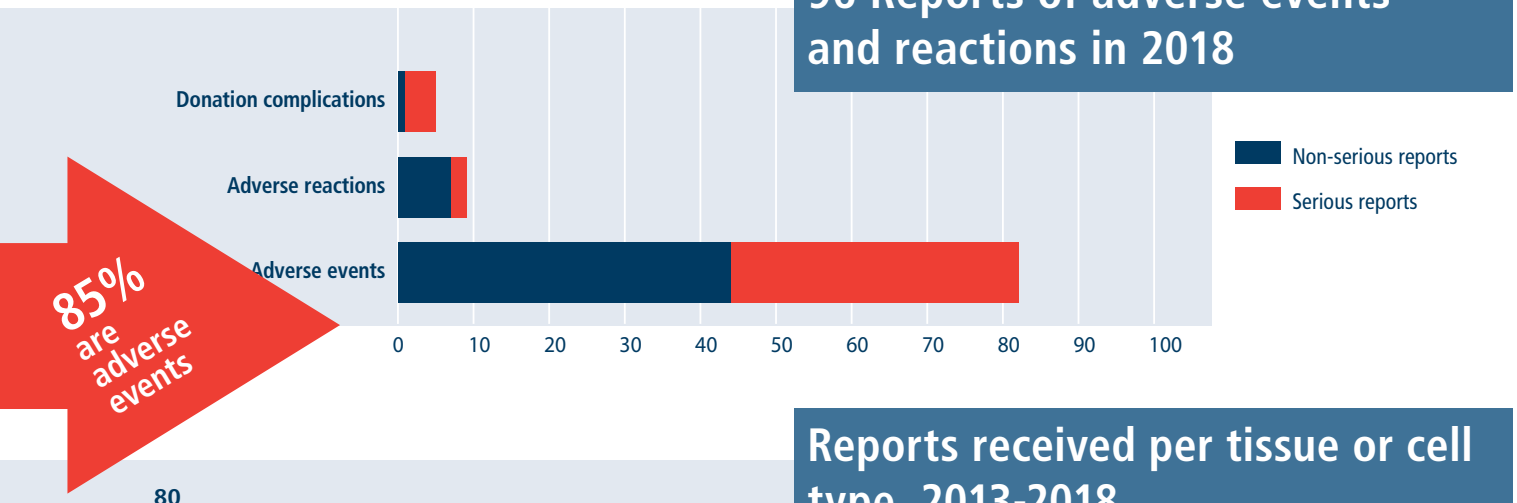
93%

14/15
Clinics

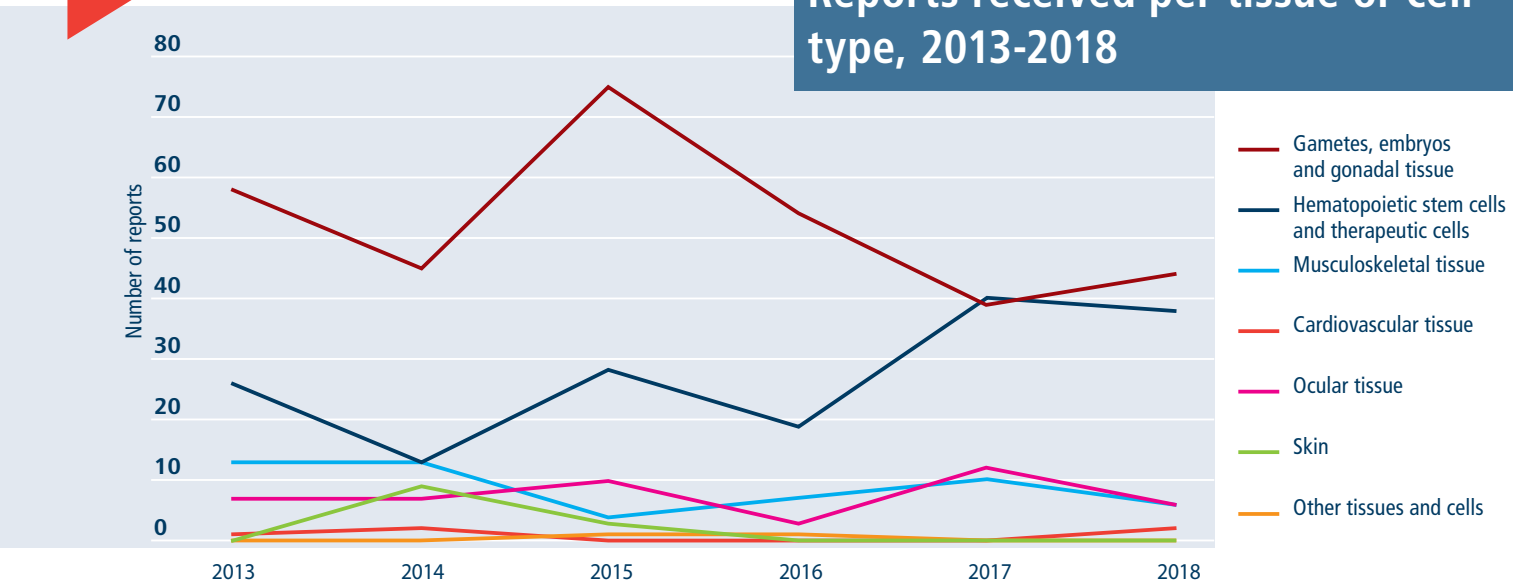
91%

52/57
Oral implantology practices

96 Reports of adverse events and reactions in 2018



Reports received per tissue or cell type, 2013-2018



High standard of biovigilance data in The Netherlands

517,448,000
17,218,000
3% of EU citizens

317,970
39,796
12% of tissue/cell recipients
Data from 21 EU Member States

3% of EU reported serious adverse reactions came from NL

4% of EU reported serious adverse events came from NL

RECOMMENDATION 1

The validation of the Single European Code generation by a tissue establishment should be based on verification of both the eye-readable code and the bar or QR code.

Single European Code

01397-12/12D

SEC: XX000048000000S101397 E000002100120140802

3
reports of incorrect Single European Code

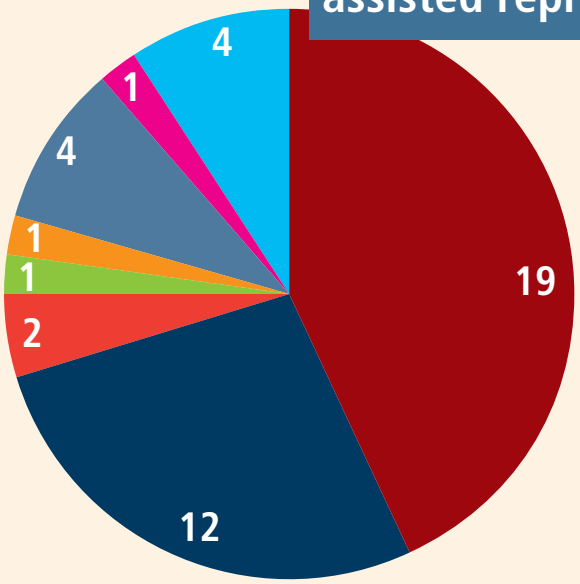
RECOMMENDATION 2

The reports of congenital abnormalities associated with medically assisted reproduction using donor gametes should be considered over a period of several years.
A distinction should be drawn between genetic and non-genetic abnormalities.

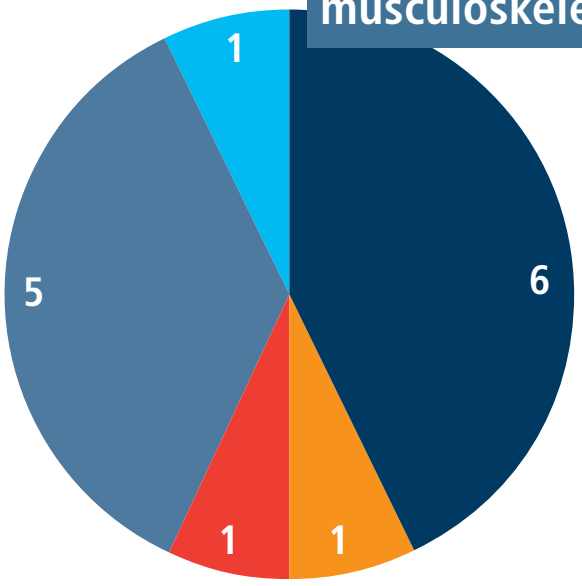
RECOMMENDATION 3

Identification errors associated with the application of gametes or embryos can potentially be further reduced by electronic verification of the correspondence between product and recipient or by an independent second check performed by a person not involved in the recipient's treatment.

Reports associated with medically assisted reproduction in 2018

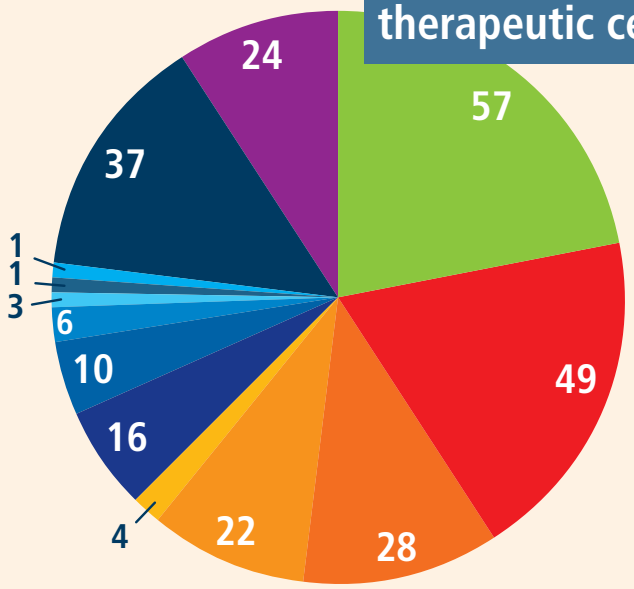


Reports associated with ocular, cardiovascular and musculoskeletal tissue in 2018



57 reports of bacterial contamination of product

Reports assiociated with hematopoietic stem cells (HSC) and therapeutic cells (TC), 2006-2018

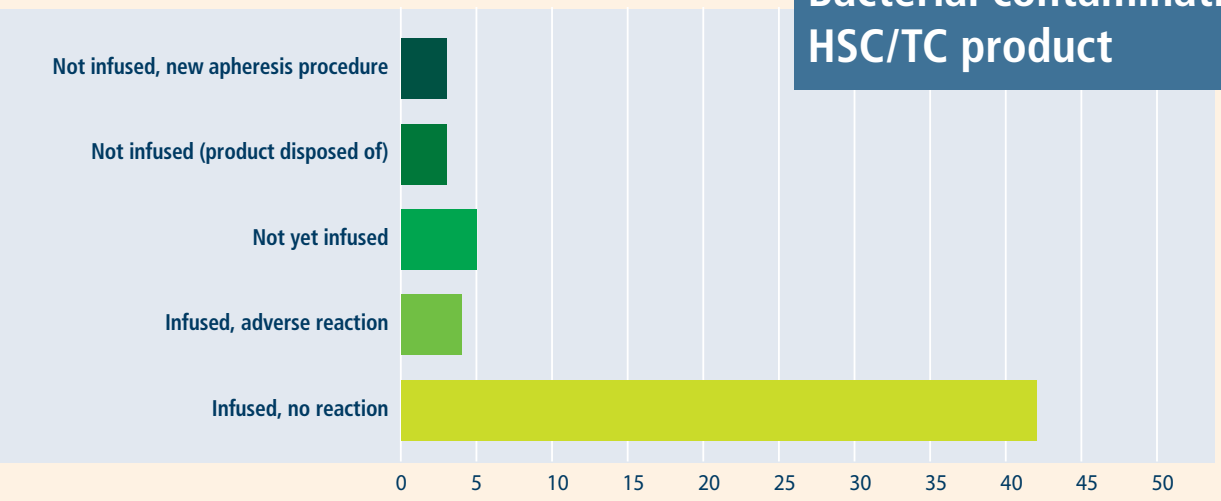


- Bacterial contamination of product
- Other incident
- Loss of cells
- Insufficient growth/engraftment
- Small categories of events
- Anaphylactic and other allergic reaction
- Hemolytic reaction
- Post-transplantion febrile reaction
- Circulatory overload
- Transfusion-related acute lung injury (TRALI)
- Post-transplantion bacterial infection
- Other reaction
- Donation complication

RECOMMENDATION 4

Reports of bacterial contamination of hematopoietic stem cell products should be analysed in depth by TRIP and the professionals, in order to reduce the number of adverse events leading to loss of cells and additional apheresis procedures.

Bacterial contamination of HSC/TC product



RECOMMENDATION 5

The hematopoietic stem cell reports classified as other reaction and as other incident should be reviewed by TRIP with a view to obtaining a breakdown into specific sub-categories where possible.

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The full TRIP report biovigilance 2018, extended version, will be published online as soon as possible.

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