Safeguarding public health

# REGULATORY HAEMOVIGILANCE: SABRE 2011

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- The MHRA – regulation of medicines and medical devices
- SABRE background – regulation and haemovigilance
- Relationship with SHOT
- Haemovigilance data 2005 - 2011 – UK
- Haemovigilance data from Europe
- Reporting trends for the South East Region
- Reporting issues/ areas for improvement
- Future plans for MHRA haemovigilance

## 2003 – MDA + MCA = MHRA

Medical Devices Agency merged with Medicine's Control Agency to form Medicines and Healthcare products Regulatory Agency

## Aims of the MHRA

'to enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe'

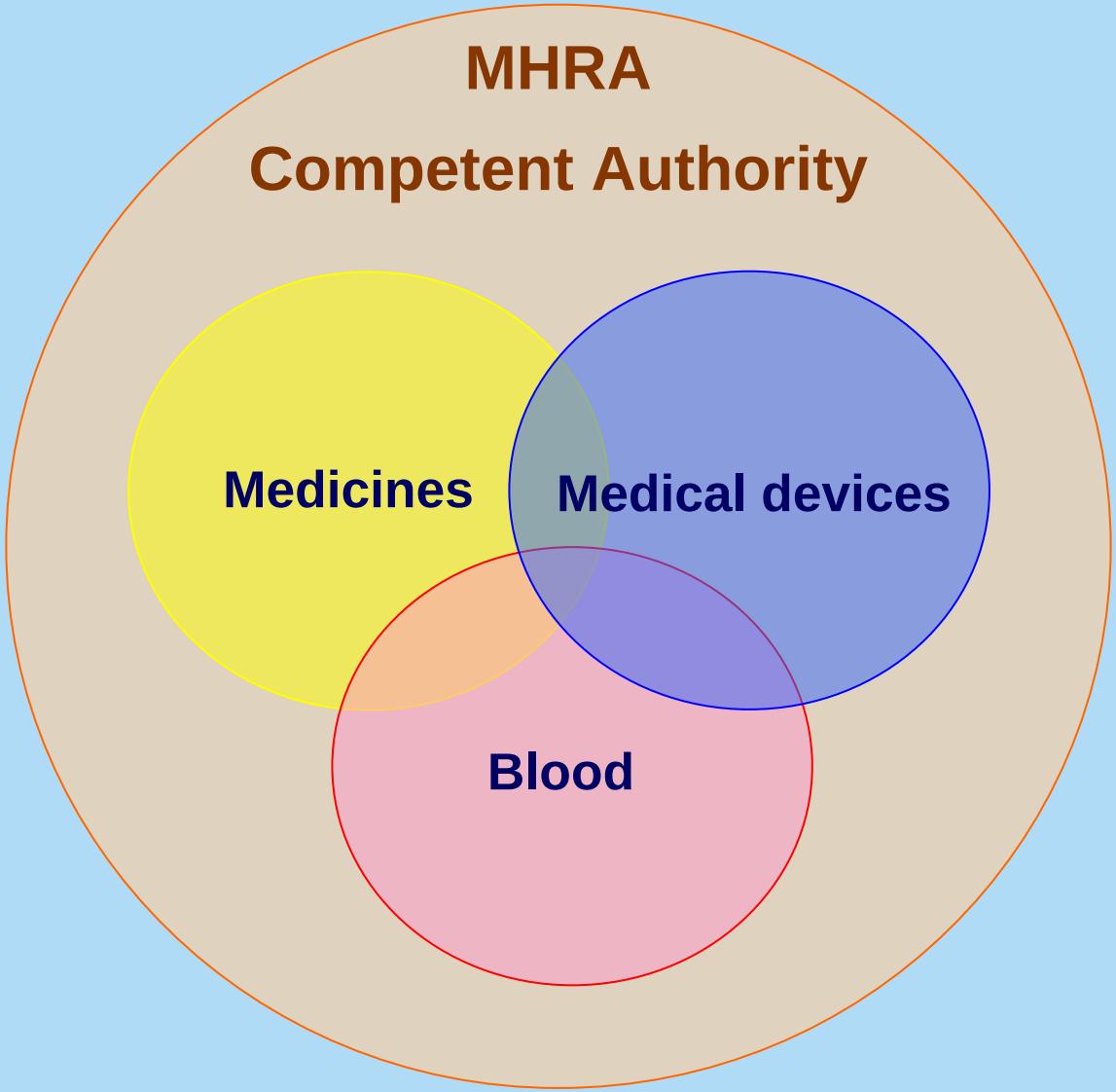
## Objectives

- safeguard public health through our primary role in ensuring that the products we regulate meet required standards, that they work and are acceptably safe
- carry out our communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public
- support research, ensuring through the application of Better Regulation principles that regulation does not stifle innovation
- influence the shape of the future regulatory framework through use of our effective European and International relationships

# MHRA now comprises 11 Divisions :

- **Support functions**
  - Ops and Finance/HR/IT/IM/Directorate
- **Licensing (medicines)**
- **Policy**
- **Vigilance and Risk Management of Medicines (VRMM)**
  - includes GPRD and yellow card scheme
- **Devices**
  - includes Adverse Incident Centre, MORE and SABRE
- **Inspection, Enforcement and Standards (IES)**
- **Communications**

# MHRA

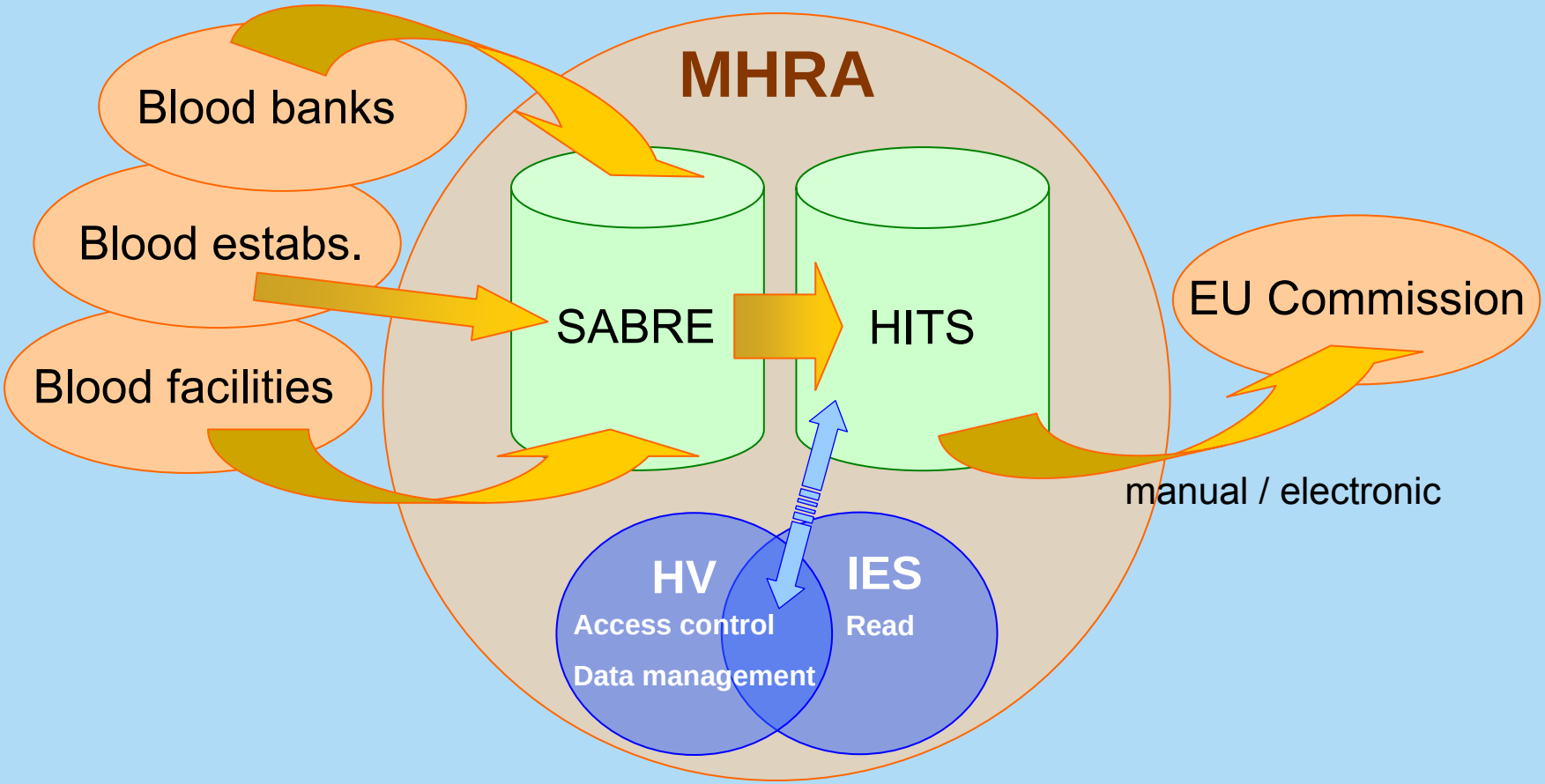


# MHRA: BSQ regulatory role:

Designated UK Competent Authority ensuring the effective implementation of EU Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components including:

- Vein to vein traceability
- Haemovigilance
- Compliance reporting and inspection
    - Funded through fees
    - Stakeholder engagement through MHRA Blood Consultative Committee

# UK BSQ haemovigilance:



# MHRA: Haemovigilance role

- Provision of system for collection of SAEs & SARs

- Annual summary reports
  - UK reporters
  - EU Commission

- Review of all reports
  - adequacy / quality
  - timeliness

- Liaison with inspectors
  - non-reporters
  - high risk reporters (late, high / low, repeat)
  - exceptions

# MHRA: Haemovigilance role:

- Reporting guidance
- SABRE Helpdesk
- Seminars and workshops
- Annual report
- MHRA Blood Consultative Committee
- support fee collection process

# Relationship with SHOT:

- ‘engaged’ since original implementation
- MHRA reporting is mandatory for Blood Establishments and hospital blood banks BUT is restricted to categories specified by EU Directive 2002/98/EC
- SHOT reporting is voluntary, but professionally mandated, applies to hospital practice rather than Blood Establishments and reporting categories can be developed according to incident trends
- Recent joint commitment to closer working
- Consideration of single reporting system/annual summary report

# SABRE Reporters by Country

| | |
|---|---|
| - England | 228 |
| - Scotland | 38 |
| - Wales | 14 |
| - N. Ireland | 9 |

# Non- reporters

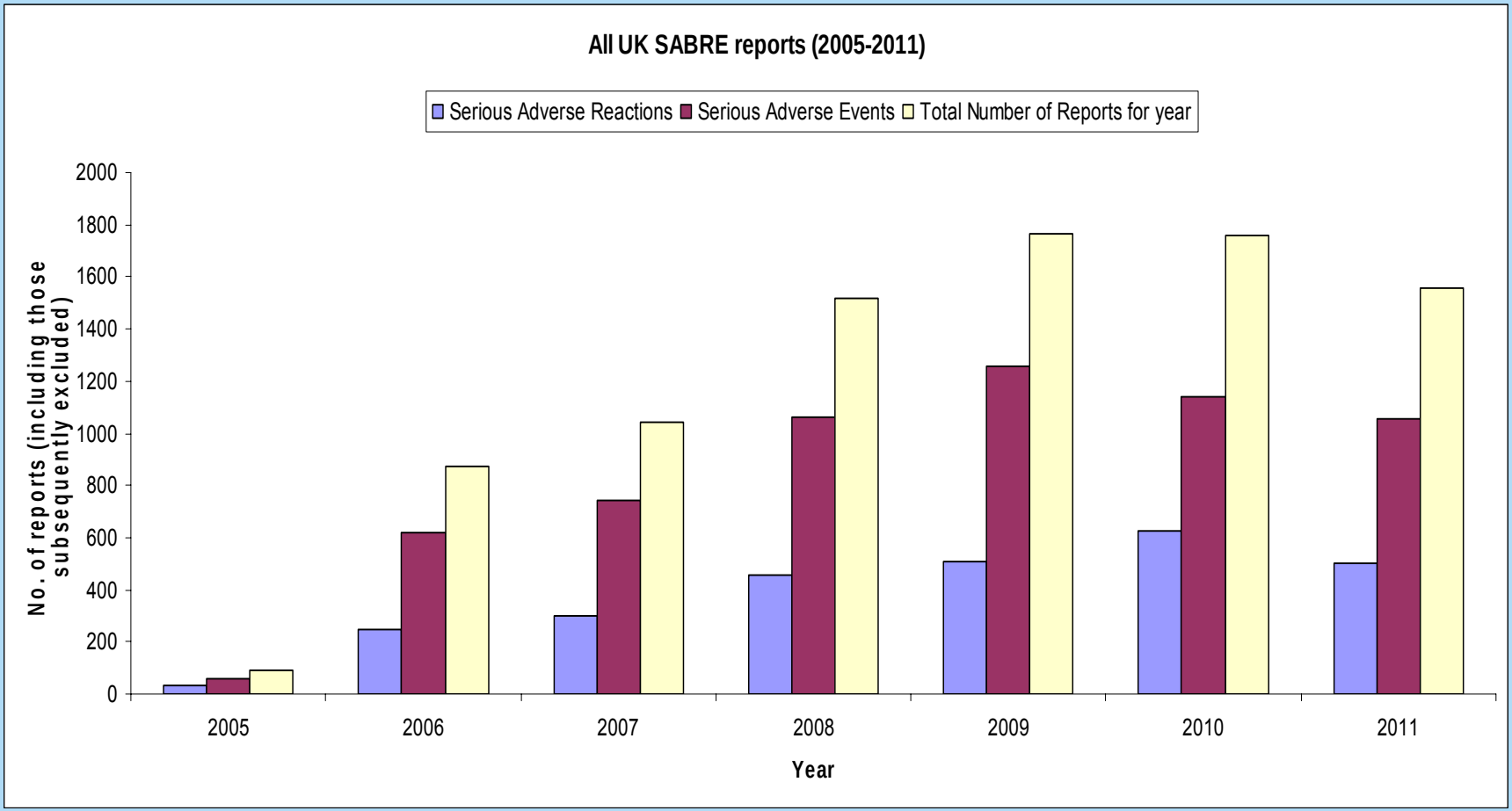
- No. of Registrants who have yet to report to SABRE = 25
- Several of these registrants are Facilities (blood component storage only)
- The others are small hospital blood banks all issuing less than 1000 units of blood and blood components per year

# All UK SABRE reports submitted 2005 – 2011:

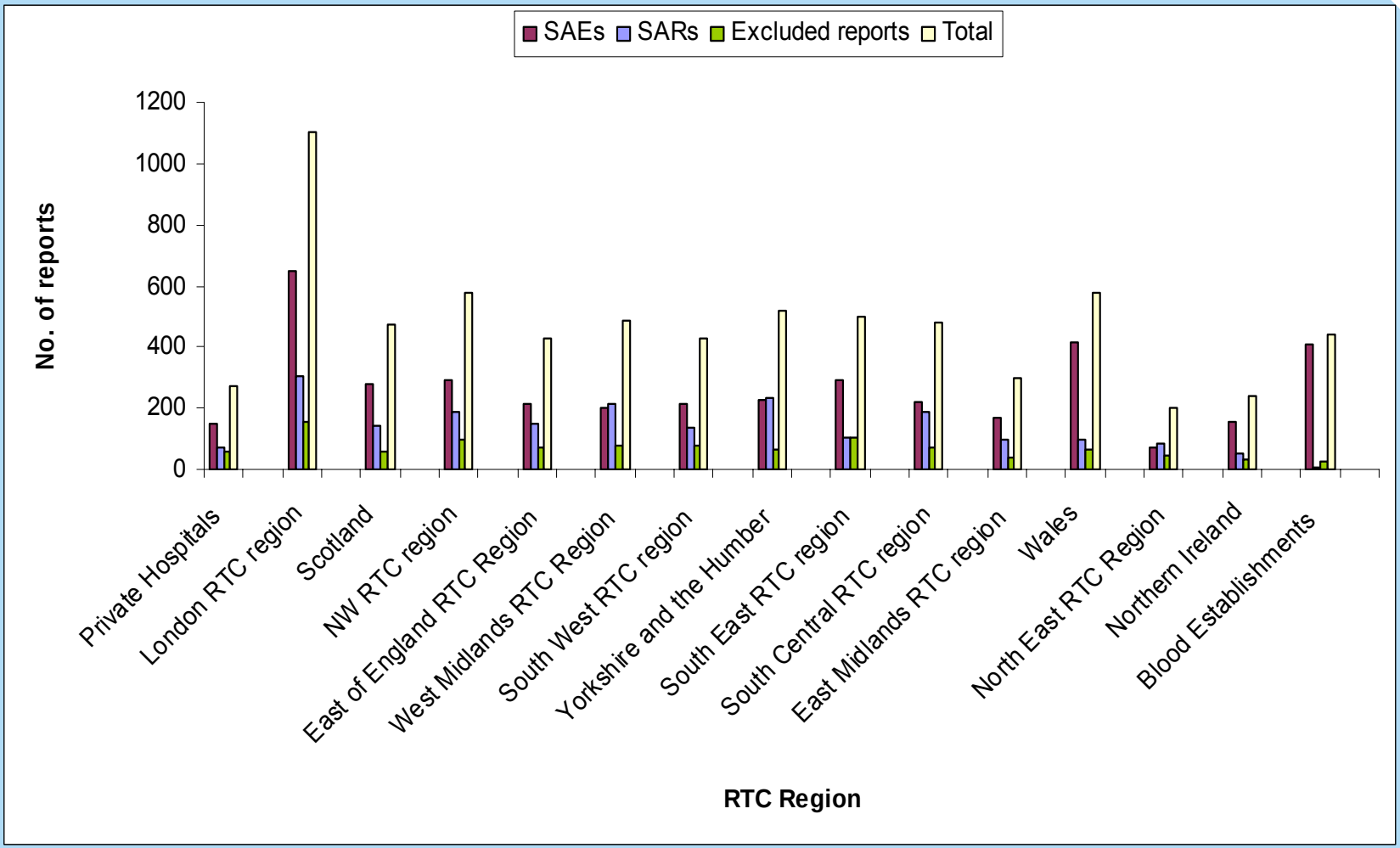
- Serious Adverse Events = 5936
- Serious Adverse Reactions = 2668
- Total = 8604

- Excluded reports = 1332
(did not meet EU reporting guidelines)

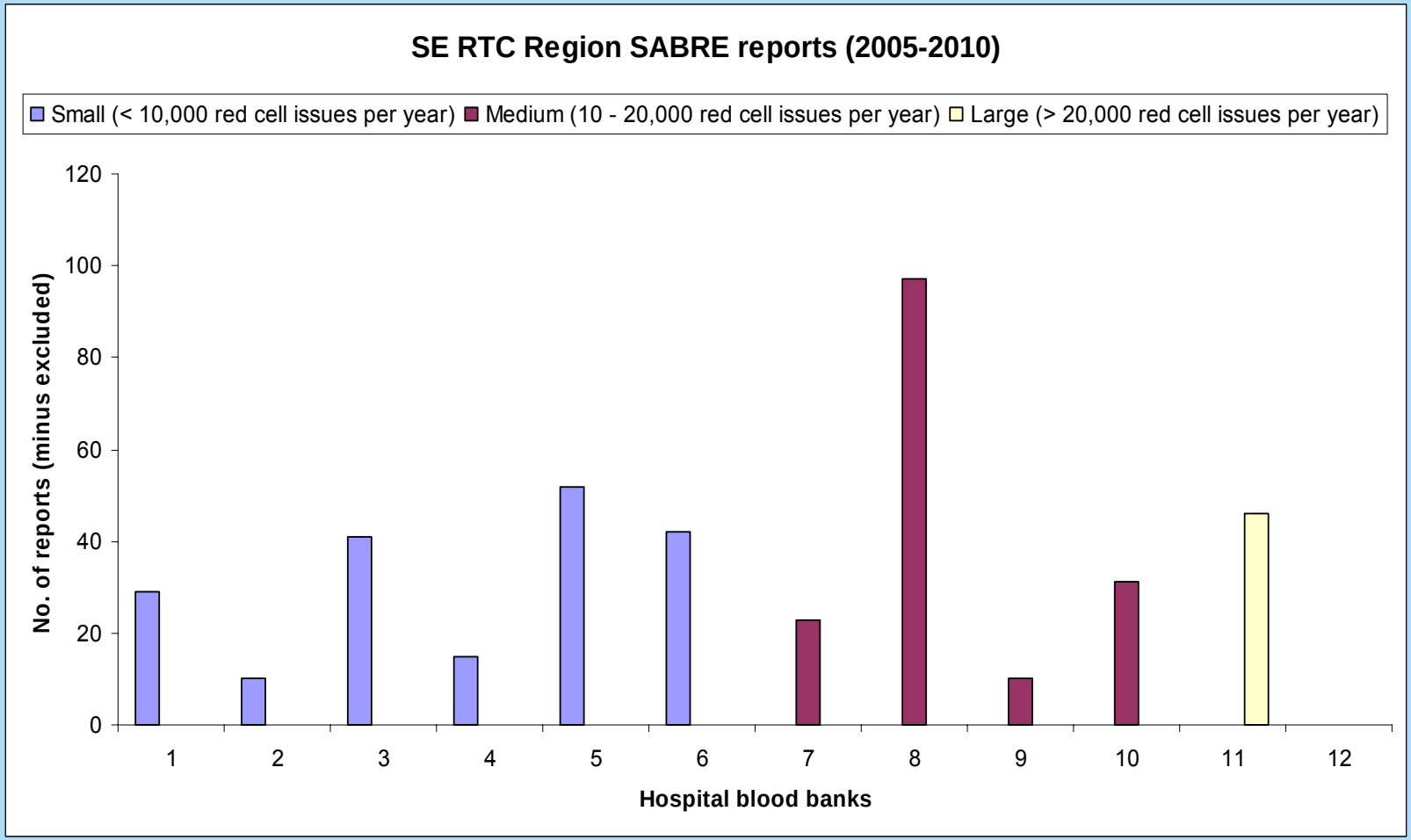
# All UK SABRE reports by year



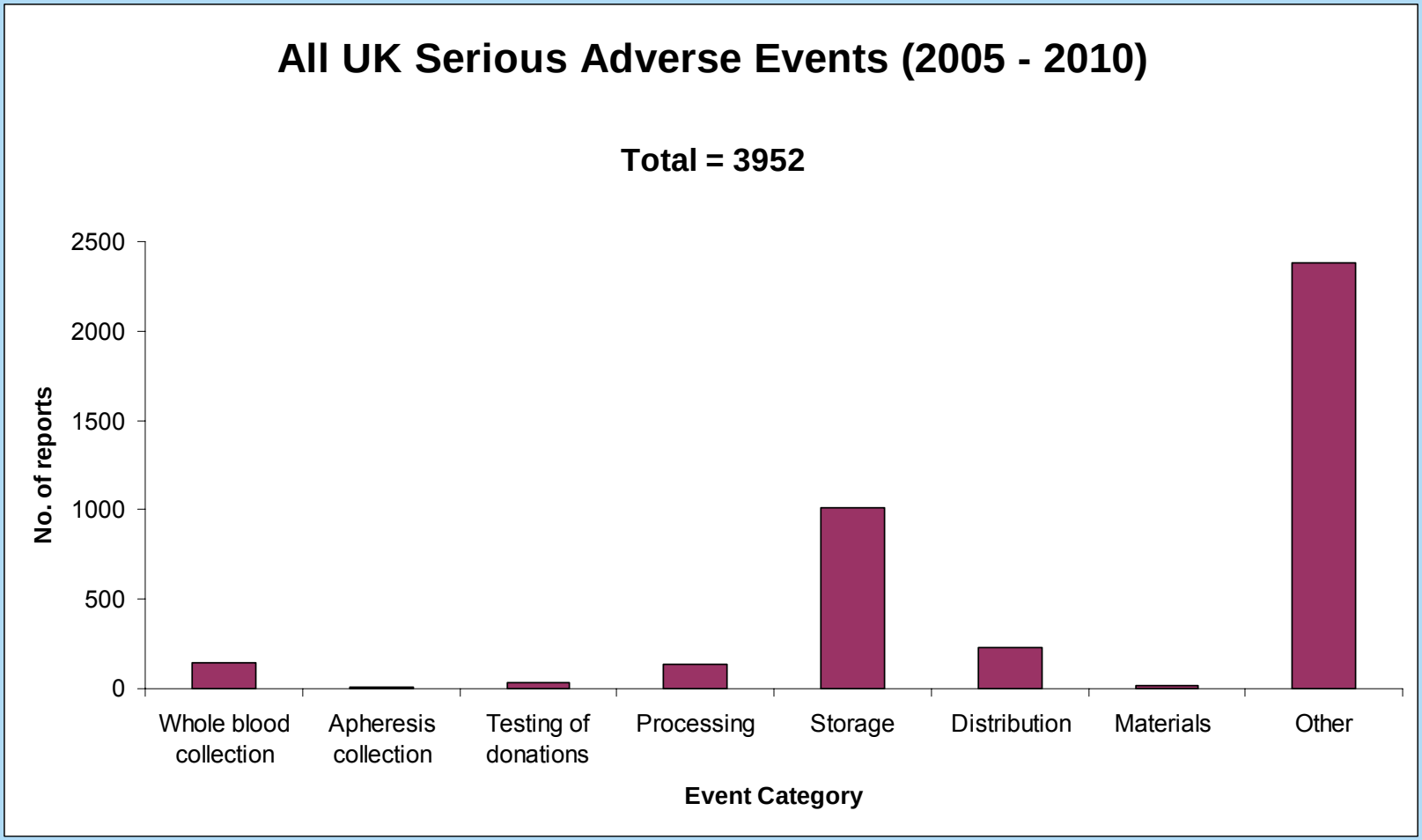
# All UK SABRE reports (2005 – 2010) by RTC region



# South East RTC region SABRE reports

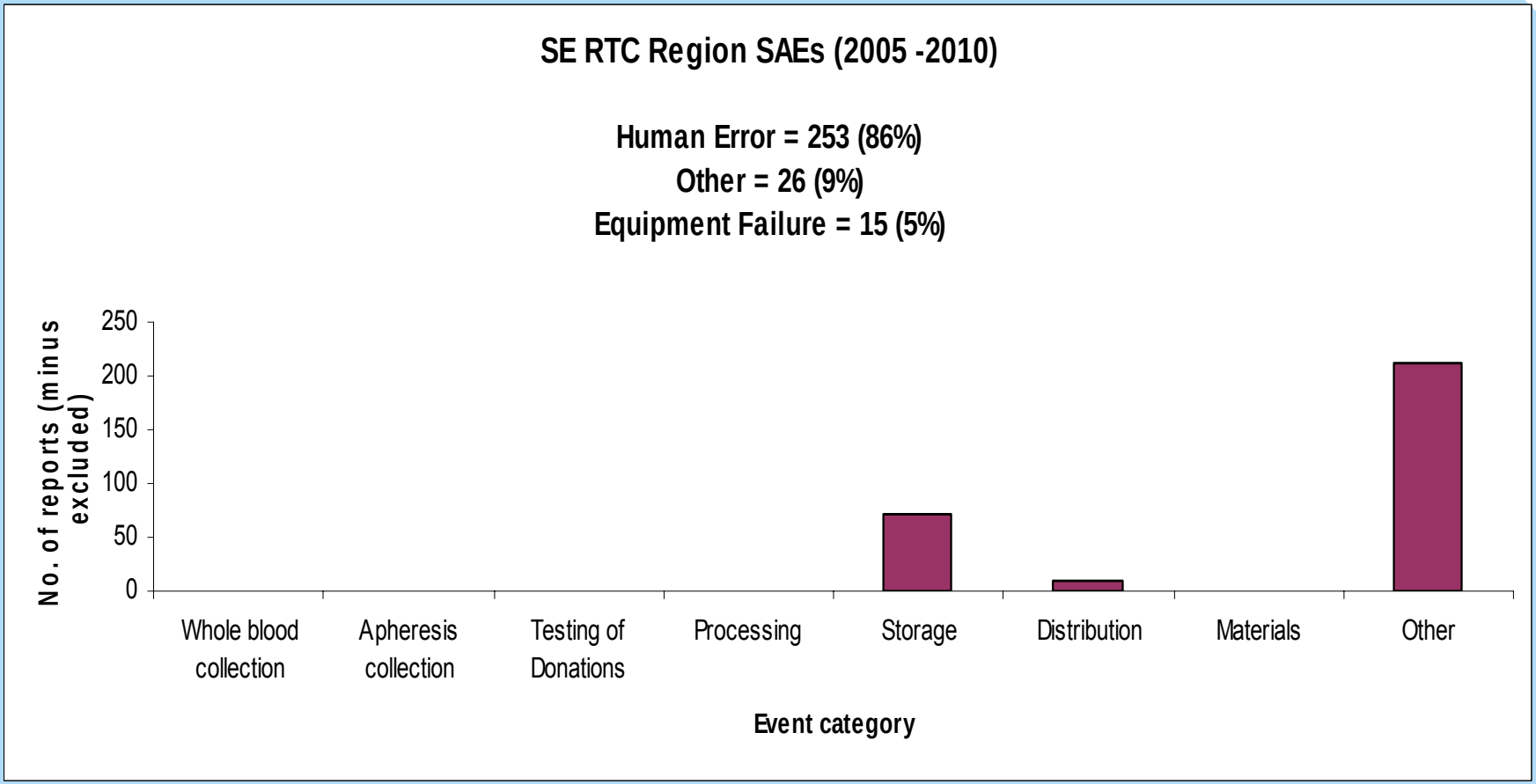


# Serious Adverse Events



# SE RTC Serious Adverse Event reports

## (cumulative 2005 -2010, n= 294 minus excluded reports)



# Serious Adverse Events:

## Storage Errors

- Out of temperature control
  - Fridge alarm failures
  - Incomplete cold chain documentation
  - Components left in transport boxes
- Expired components available for transfusion
- Components available for transfusion after dereservation date

# Serious Adverse Events:

- Other/Human Error Top Five

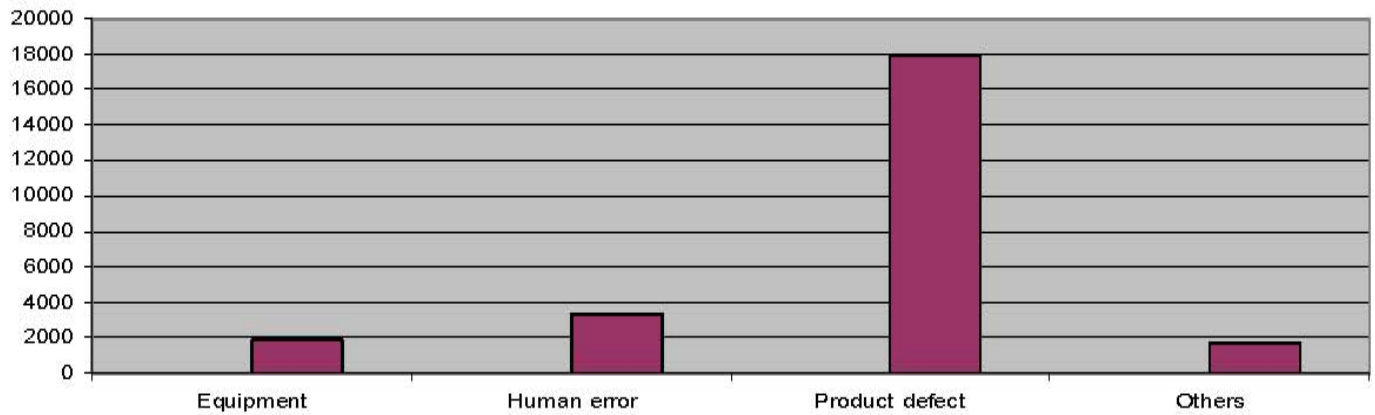
  - Incorrect blood component issued (missing special requirements)
  - Component labelling errors
  - Pre-transfusion testing errors
  - Sample processing errors
  - Data entry errors

# EU Commission data

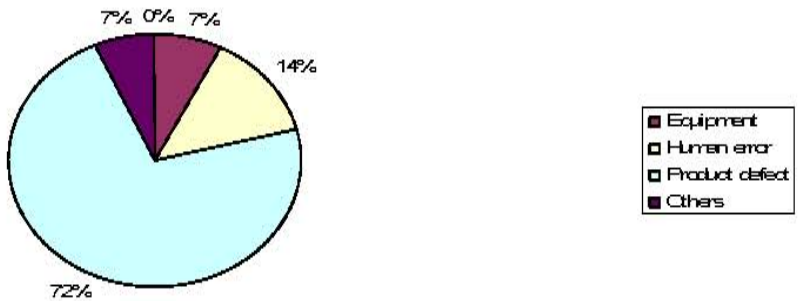
Directorate-General for Health & Consumers

## The outcome

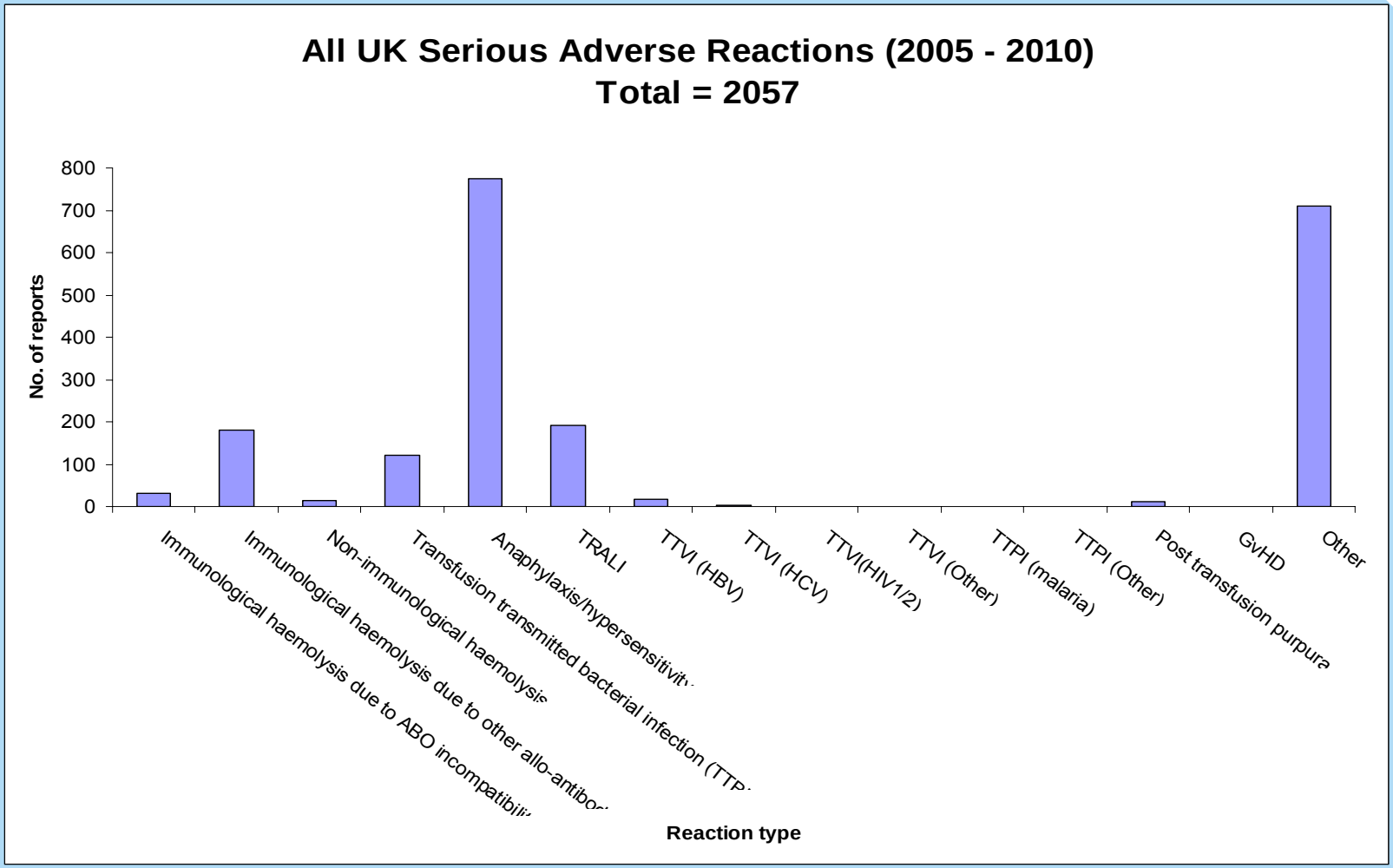
**Number of SAE by specification**




- Important variations between MS esp. For product defect
- Better reporting of 'human error'

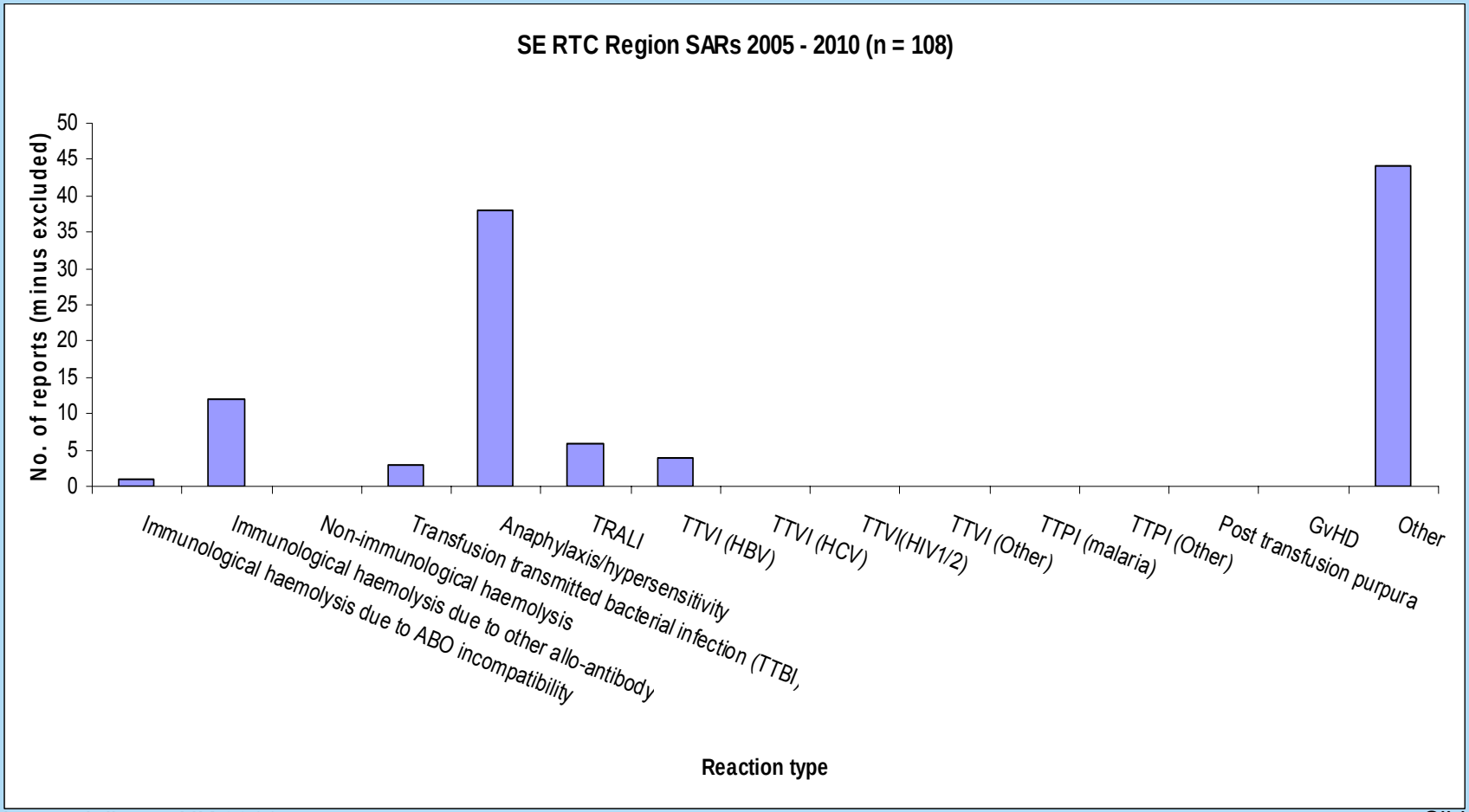


# Serious Adverse Reactions



# SE RTC REGION SARs (2005 – 2010)

- Other = 40 x FNHTR, 4 x TACO



# EU Commission data

Directorate-General for Health & Consumers

## SARE – TOP 10 CATEGORIES

Total sum of all products for all MS

| | | Non death | Death |
|---|---|---|---|
| 1. | Anaphylactic hypersensitivity | 1344 | 8 |
| 2. | Haemolysis - Non-immunological | 330 | 1 |
| 3. | Pyrogenic reaction | 256 | 0 |
| 4. | Tf related lung injury | 223 | 15 |
| 5. | Tf transmitted bacterial infection | 189 | 6 |
| 6. | TACO | 164 | 7 |
| 7. | Febrile non-heamolytic tf reaction | 120 | 0 |
| 8. | Haemolysis - Immunological, ABO | 119 | 4 |
| 9. | Haemolysis - Immunological, other allo-AB | 108 | 5 |
| 10. | Tf transmitted HBV +HCV | 46+60 | 1+1 |

Except for 1. anaphylactic hypersentivity no similarity in order between MS

Some numbers are completely compiled within one/a few MS

# The SABRE Reporting Cycle :

- Registration
- Notification
- SAE/SAR
- Investigation and CAPA
- Confirmation report
- Review, follow-up and closure on HITS
- Referral
- Annual summary reports

# Root Cause Analysis of Human Error

- Many definitions
- Simplest is

  - "Mistakes by people leading to accidents and incidents"

- But it's just human error
- They made a mistake, they're normally very good
- They've been trained, so what can you do?
- There is nothing you can do about human error

# What is human error?

- Human error is influenced by a number of factors :
  - ORGANISATIONAL FACTORS
    - Quality culture
    - Capacity planning
    - Effective recruitment
  - JOB FACTORS
    - Workload
    - Environment
    - Equipment
    - Training
  - PERSONAL FACTORS
    - Tiredness/illness
    - Attitude
    - Frustration
    - Capability

# Five basic types of human error :

- Attention lapses
  - distraction/interruptions/noise – environmental
- Genuine errors
  - Believing you are doing the right thing – training
- Misperceptions
  - Over-familiarity with a task leading to oversight
- Misplaced priorities
  - Cutting corners in emergency situations
- Deliberate disobedience
  - Wilful disregard for policies and procedures

# Root Cause Analysis of Human Error:

- Was the procedure up to date or recently changed?
- Is the process flow of the job logical?
- Was the person trained?
- Was the training effective?
- Was the person distracted?
    - Noise
    - Interruptions
    - Personal issues
    - Tiredness
    - Workload/ rushing
- Deliberately cutting corners

# Effective Root Cause Analysis:

- Find out all the errors (5 why)
- Decide the root cause for each
- Don't just find out how something went wrong, find out why

## EXAMPLE – 'Fridge broke down'

HOW– fan stopped working
WHY– build up of ice over time
WHY- there was no procedure to defrost the fridge
WHY- the engineer missed the 6 monthly service and was not rescheduled

- Address each root cause
- Don't always rely on extra checks
- Target CAPA more effectively

# FUTURE PLANS:

- Annual Report
  - Feedback to reporters and incident trend analysis
  - Input from Inspectors – Good Practice guidelines and common inspection findings
- Educational workshops
  - Informal Haemovigilance site visits – local trend analysis
  - Sessions at Regional Transfusion Meetings – regional trend analysis
- Enhanced collaboration with MHRA Inspectors
  - Development of risk based signalling from SABRE to Inspectors (to assist with BSQR compliance monitoring)
- Input into European Commission working party
  - Obtaining comparative data from Europe
  - Influencing future guidance and policy decisions