Aseguramiento de la Calidad de la Transfusión Sanguinea: Vigilancia Epidemiológica de Hemotransmisibles

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Haemovigilance

A surveillance process dealing with the monitoring of events associated with the blood transfusion chain. It is an essential activity towards the development of a blood strategy in a community and the restoration of confidence in the safety of the blood supply. It is educational about the real risks of transfusion and helps to prioritise safety measures.

HEMOVIGILANCE

Introduced in the beginning of the 1990's as a safety concept.

HV is a quality process and as such aims at continuous improvement of quality and safety of blood transfusion

HV cover the entire blood transfusion chain, including recipients and donors

FROM VEIN TO VEIN

What is hemovigilance?

A system of reporting, collecting and analyzing of transfusion safety data

- **infectious and non-infectious transfusion complications**
- **near misses, errors**
- **process deviations**

In order to achieve the above, a standardized and centralized method of data collection and reporting is needed.

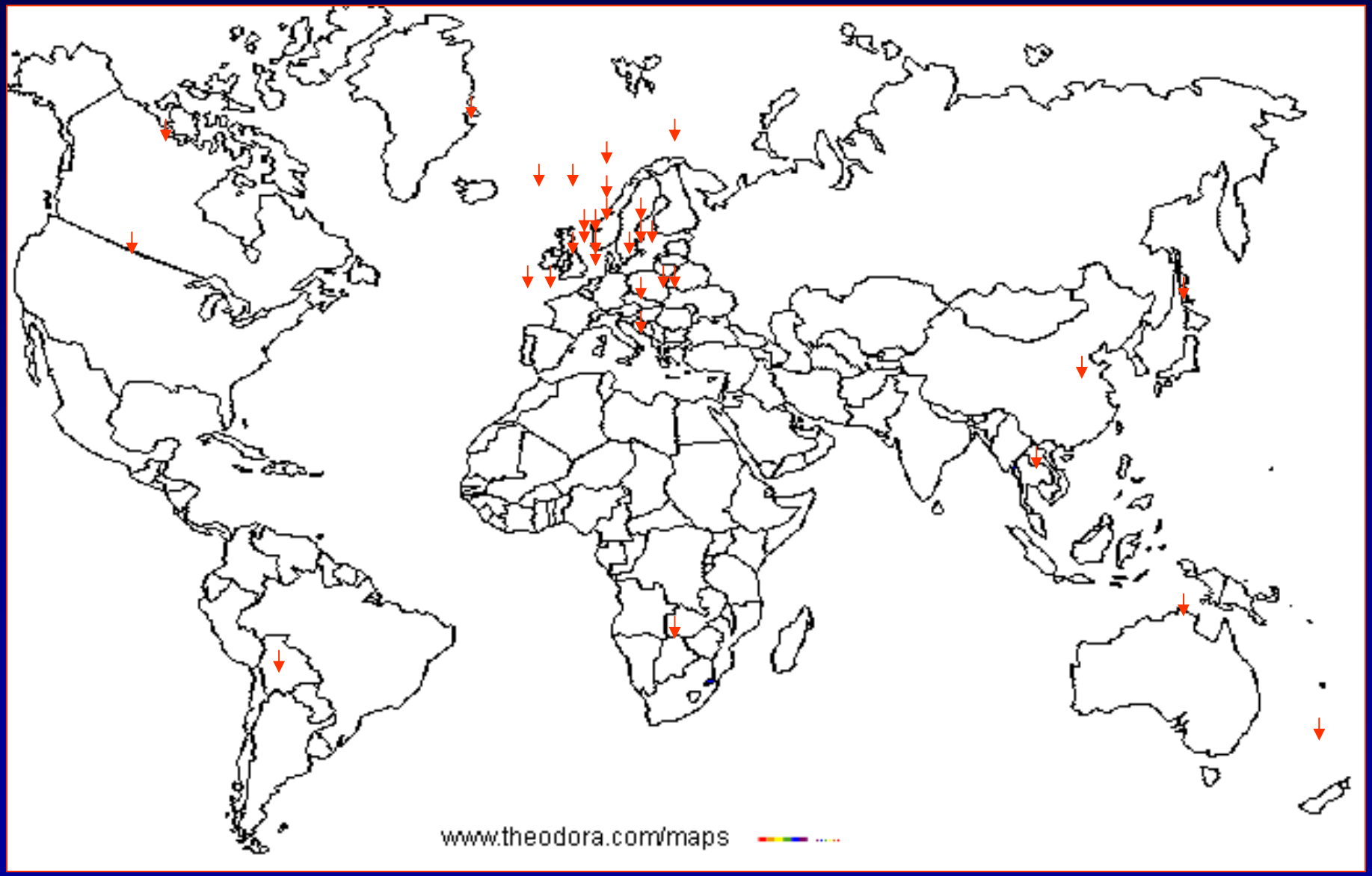
European haemovigilance

- 1994 - mandatory scheme launched in France
  - adverse reactions of all grades but not errors unless harm caused
  - approximately 300 events per 100,000 components transfused
- 1996 - voluntary SHOT scheme launched in UK
  - serious reactions and errors (even if no harm caused)
  - approximately 10 events per 100,000 components transfused
- Systems now established across EU
- Mandated by European Blood Directive
  - does not encompass clinical practice

Main Issues for Hemovigilance Program:

- Legal requirements for establishment
- Level → Local, Regional, National
  - Focused x Comprehensive (severe x all events)
  - Prospective x Retrospective
- Definitions → Standardization
- Categorization
- Adherence :
  - Voluntary x Mandatory
  - Active x Passive
- Resources → Staff, Equipment, Database, Funds
- Reliability and periodic reports
- Not a punitive process
- Keep it simple !

ISBT Working Party on Haemovigilance



DEFINITIONS

- Allergic reaction
- Acute hemolytic transfusion reaction
- Delayed hemolytic transfusion reaction
- Delayed serologic transfusion reaction
- Hypotensive transfusion reaction
- Febrile non-hemolytic transfusion reaction
- Other (hemosiderosis, hyperkaliemia)
- Post transfusion purpura
- Transfusion associated circulatory overload (TACO)
- Transfusion associated dyspnea
- TA- Graft versus host disease
- TRALI
- Unclassifiable complication
- Transfusion associated infection (bacterial, viral, parasitic, other)

PROPOSED STANDARD DEFINITIONS FOR SURVEILLANCE OF NON INFECTIOUS ADVERSE TRANSFUSION REACTIONS
ISBT – WP ON HEMOVIGILANCE
(http://www.terveysportti.fi/kotisivut/docs/f1629861881/isbt_definitions_2006.pdf)

GENERAL DEFINITION - ADVERSE EVENTS

An *adverse event* is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or not result in a reaction in a recipient

GENERAL DEFINITION - ADVERSE EVENTS

An *incident* is a case where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that have lead to mistransfusions. It may or may not lead to an adverse reaction.

GENERAL DEFINITION - ADVERSE EVENTS

A *near miss* is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient

GENERAL DEFINITION - ADVERSE EVENTS

An *adverse reaction* is an undesirable response or effect in a patient temporally associated with the administration of blood or blood component.
It may be the result of an incident or of interaction between a recipient and blood, a biologically active product.

CATEGORIZATION

- Did it meet diagnostic criterion?
  - Definitive, Probable, Possible, NA
- Severity
  - Non-severe, Severe, Life Threatening, Death, Not Determined
- Relationship to Transfusion
  - Definite, Probable, Possible, Doubtful, Excluded, Not Determined
- Outcome
  - Minor or no sequelae, Major or long-term sequelae, Death
  - If patient died, relationship of transfusion to death

Incidents – Several countries

(Koh, Teo & Alcantara - AABB 2007)

Country	Components	N incidents/10^5
Belgium	720,839	300
Denmark	470,000	7
Finland	462,832	31
France	2,373,335	325
Germany	6,006,895	8
Greece	334,882	230
Ireland	163,000	88
UK	3,325,000	8.5

Severity

Grade 1 (Non-Severe):

The recipient may have required medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function.

Grade 2 (Severe):

The recipient required in-patient hospitalization or prolongation of hospitalization directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the adverse event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.

Severity

Grade 3 (Life-threatening):

The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death

Grade 4 (Death):

The recipient died following an adverse transfusion reaction

Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be graded as 1, 2 or 3.

Imputability

Once the investigation of the adverse transfusion reaction is completed, this is the assessment of the strength of the relationship between the transfusion and the adverse reaction.

- **Definite (certain):** Conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.
- **Probable (likely):** Evidence is clearly in favor of attributing the adverse event to the Transfusion.
- **Possible:** Evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.

Imputability

- **Unlikely (doubtful):** Evidence is clearly in favor of attributing the adverse event to causes other than the transfusion
- **Excluded:** Conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion.
- **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

-Adverse reactions for which Imputability is *doubtful* or *ruled out* should not be routinely reported.

Standard for Surveillance of Complications Related to Blood Donation

Working Group on Complications Related to Blood Donation

International Society of Blood Transfusion
Working Party on Haemovigilance

European Haemovigilance Network

2008

(http://www.isbt-web.org/members_only/files/society/StandardSurveillanceDOCO.pdf)

Standard for Surveillance of Complications Related to Blood Donation

A. Complications mainly with local symptoms.

1. Complications mainly characterized by the occurrence of blood outside vessels

- Haematoma
- Arterial puncture
- Delayed bleeding

2. Complications mainly characterized by pain

- Nerve irritation
- Nerve injury
- Tendon injury
- Painful arm

3. Other complications with local symptoms

- Thrombophlebitis
- Allergy (local)

(http://www.isbt-web.org/members_only/files/society/StandardSurveillanceDOCO.pdf)

Standard for Surveillance of Complications Related to Blood Donation

B. Complications mainly with generalized symptoms.

- Immediate Vasovagal reactions
- Immediate Vasovagal reaction with injury
- Delayed Vasovagal reaction
- Delayed Vasovagal reaction with injury

C. Complications related to apheresis

- Citrate reaction
- Haemolysis
- Generalised allergic reaction
- Air embolism

D. Other donation complications

(http://www.isbt-web.org/members_only/files/society/StandardSurveillanceDOCO.pdf)

Standard for Surveillance of Complications Related to Blood Donation

Severe complications

Hospitalization

If it was attributable to the complication.

Intervention

To preclude permanent damage or impairment of a body function

To prevent death (life- threatening)

Symptoms

Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity)

Death

If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

(http://www.isbt-web.org/members_only/files/society/StandardSurveillanceDOCO.pdf)

Standard for Surveillance of Complications Related to Blood Donation

Non-severe complications

The non-severe complications are complications which do not satisfy any of therequirements for being severe.

The non-severe level may be subdivided in *mild* and *moderate* complications as for instance for the following categories:

- **Haematoma**
- **Arterial puncture**
- **Painful arm (subcategory specified or not)**
- **Vasovagal reaction**

(http://www.isbt-web.org/members_only/files/society/StandardSurveillanceDOCO.pdf)

LEVELS

ACTIVE - Trained personnel use standard definitions and a variety of data sources to identify events

PASSIVE - Any adverse reaction thought to be associated with a blood transfusion is reported by patient care staff to transfusion services

CDC, 2008

Systems on Haemovigilance

Two different "poles" of systems exist:

- **In France, where hemovigilance was rendered *mandatory* by law in 1994, the system is centralized and nationwide.**
- **In the UK, hemovigilance is a national *voluntary* scheme between professionals (SHOT, Serious Hazards of Transfusion)1996.**

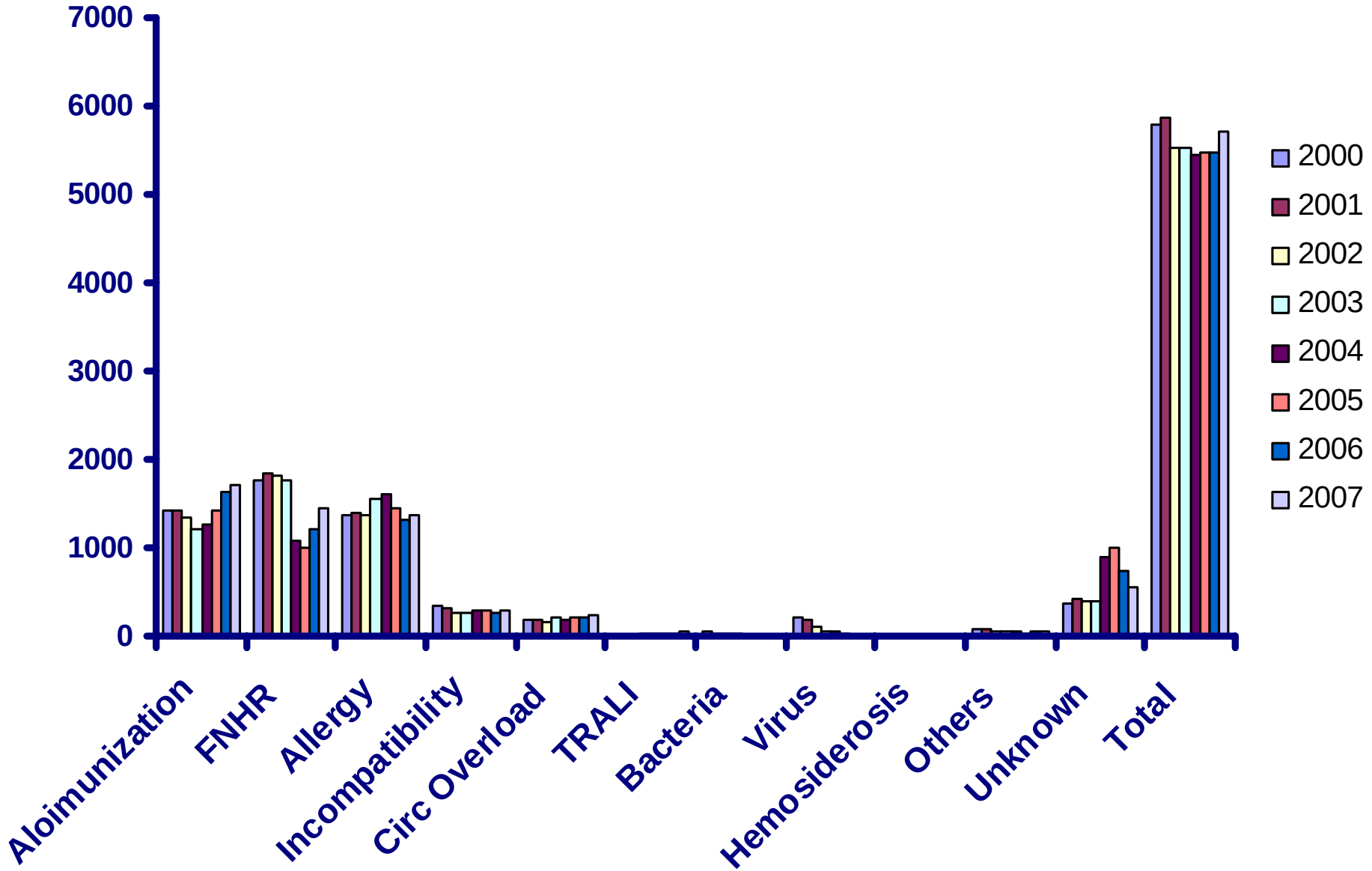
- **the European Haemovigilance Network (EHN) develops into an efficient tool intended to increase safety and quality in European blood transfusion. Recently, it has been changed to International Hemovigilance Network (IHN).**

Hindawi, S – Jeddah, 2009

Haemovigilance by AFS

- Reporting tx. hazards to public health authority: legal requirement
- Correspondents in:
  - 2,000 hospitals performing tx.
  - 137 transfusion centers
  - 51,000 prescribers
  - 507,500 patients
- 24 FT regional co-ordinators
- Traceability essential: hospitals and centres must keep record of ultimate fate of all units

Hemovigilance - France 2000 - 2007



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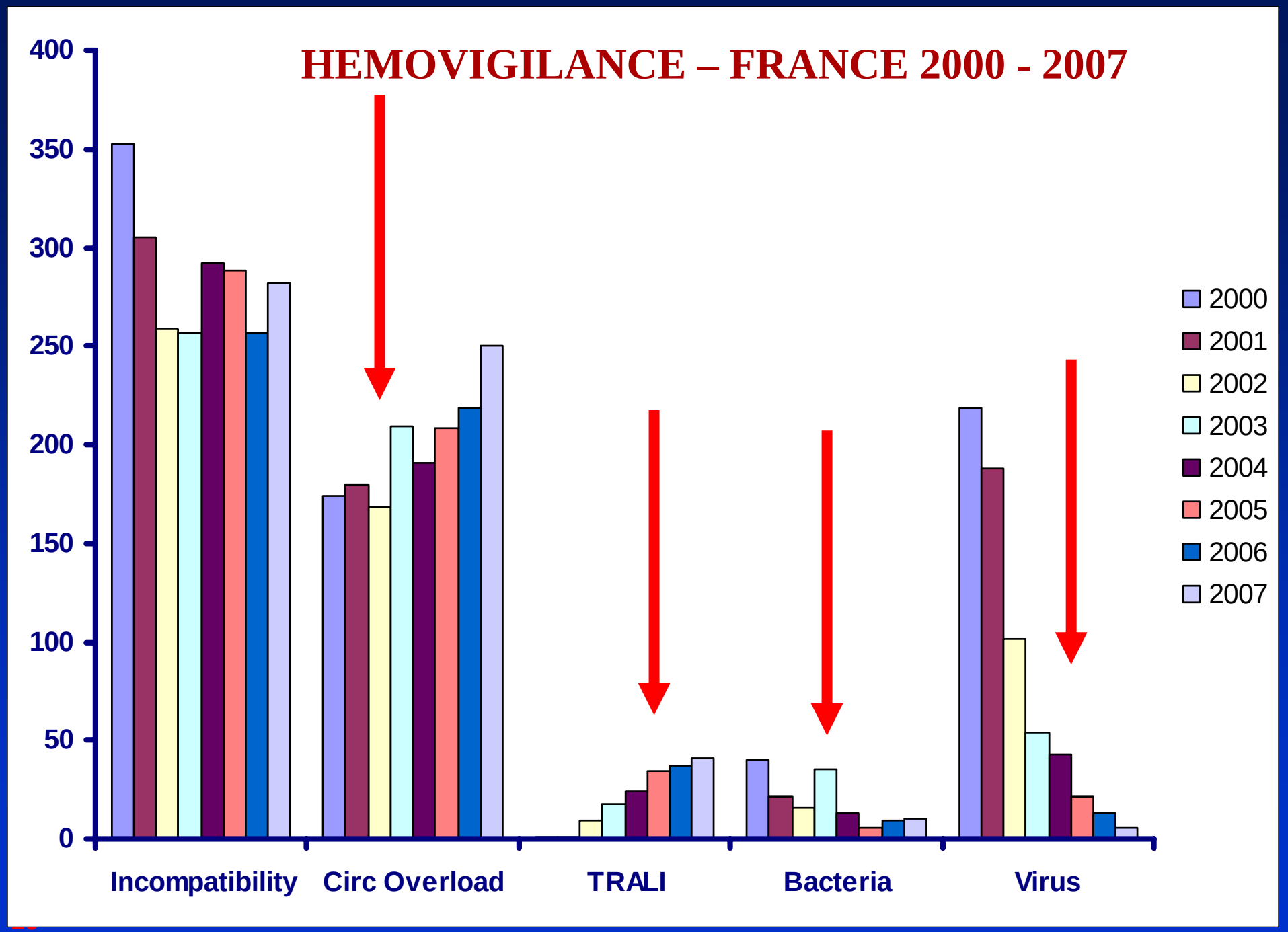
HEMOVIGILANCE – FRANCE 2000 - 2007



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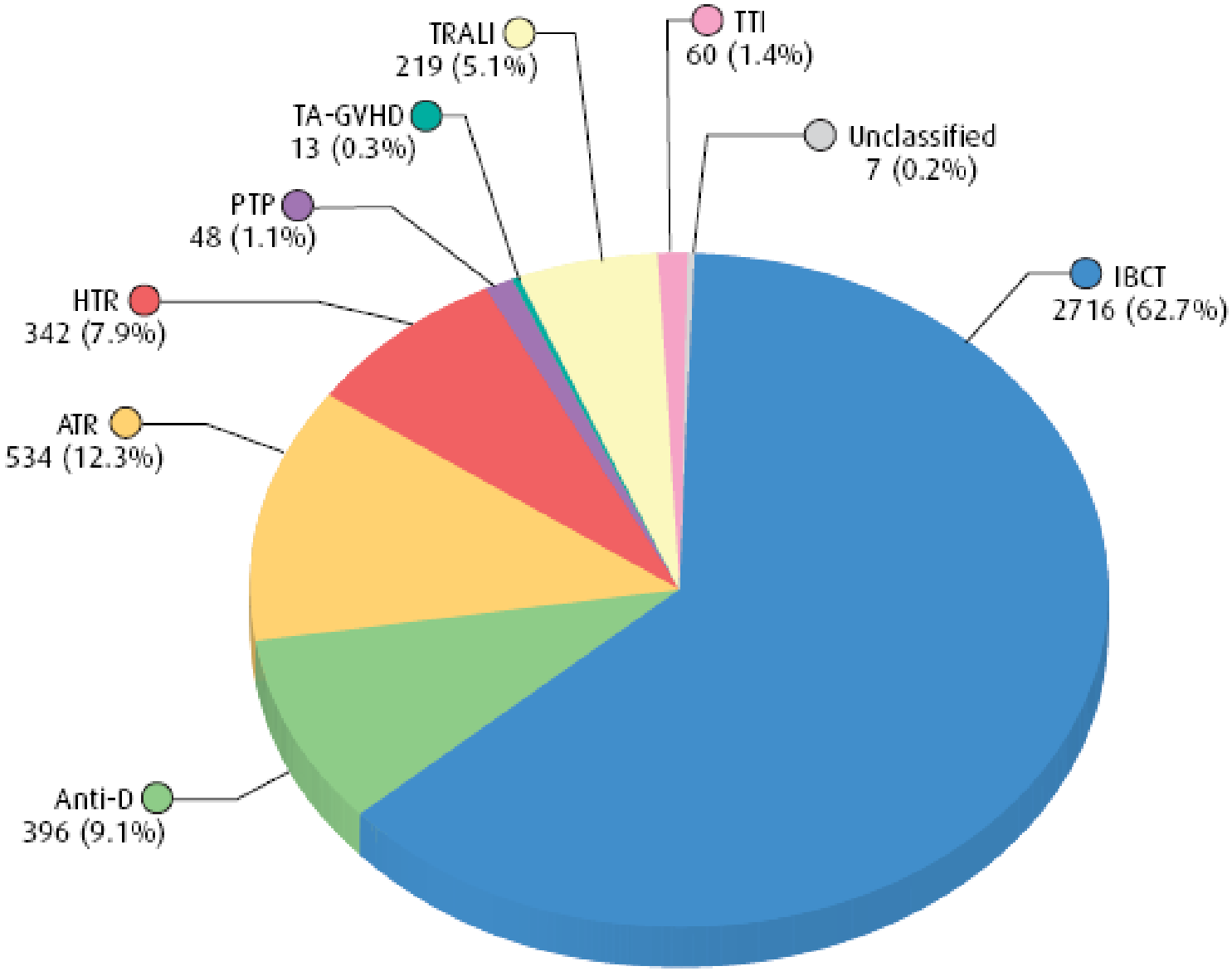
SHOT
(Serious Hazards of Transfusion)

- Launched in 1996
- Professional activity
- UK-wide confidential, anonymised scheme for the reporting of serious hazards of transfusion of blood and blood components

Cumulative numbers of cases reviewed 1996-2007 (n = 4334)

[Before 2006 the HTR category was referred to as delayed transfusion reactions]



http://www.shotuk.org/Summary%202007.pdf

Figure 7
Number of cases of HTR analysed since 1996
[Cases in this section were referred to as delayed transfusion reactions until 2006]

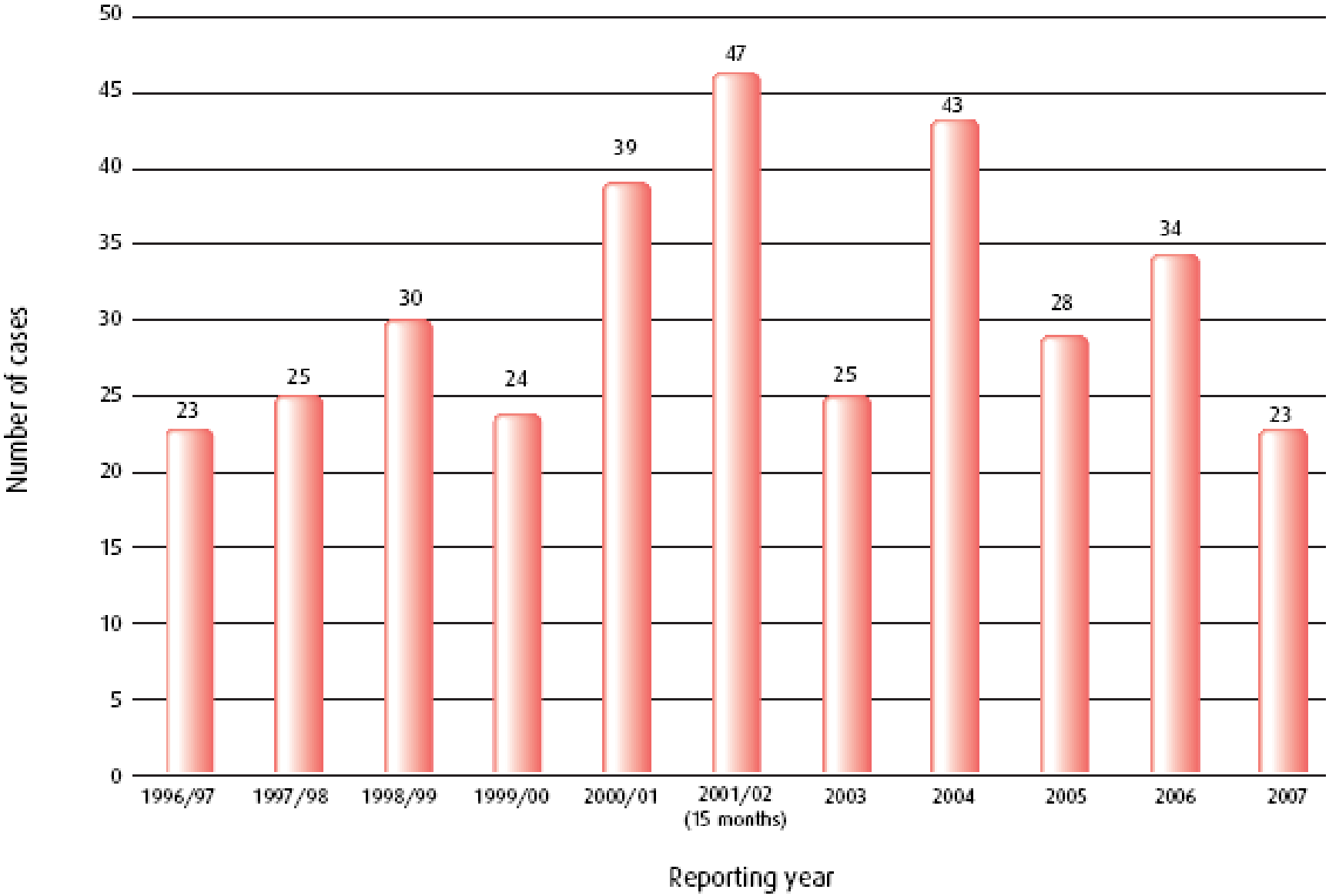
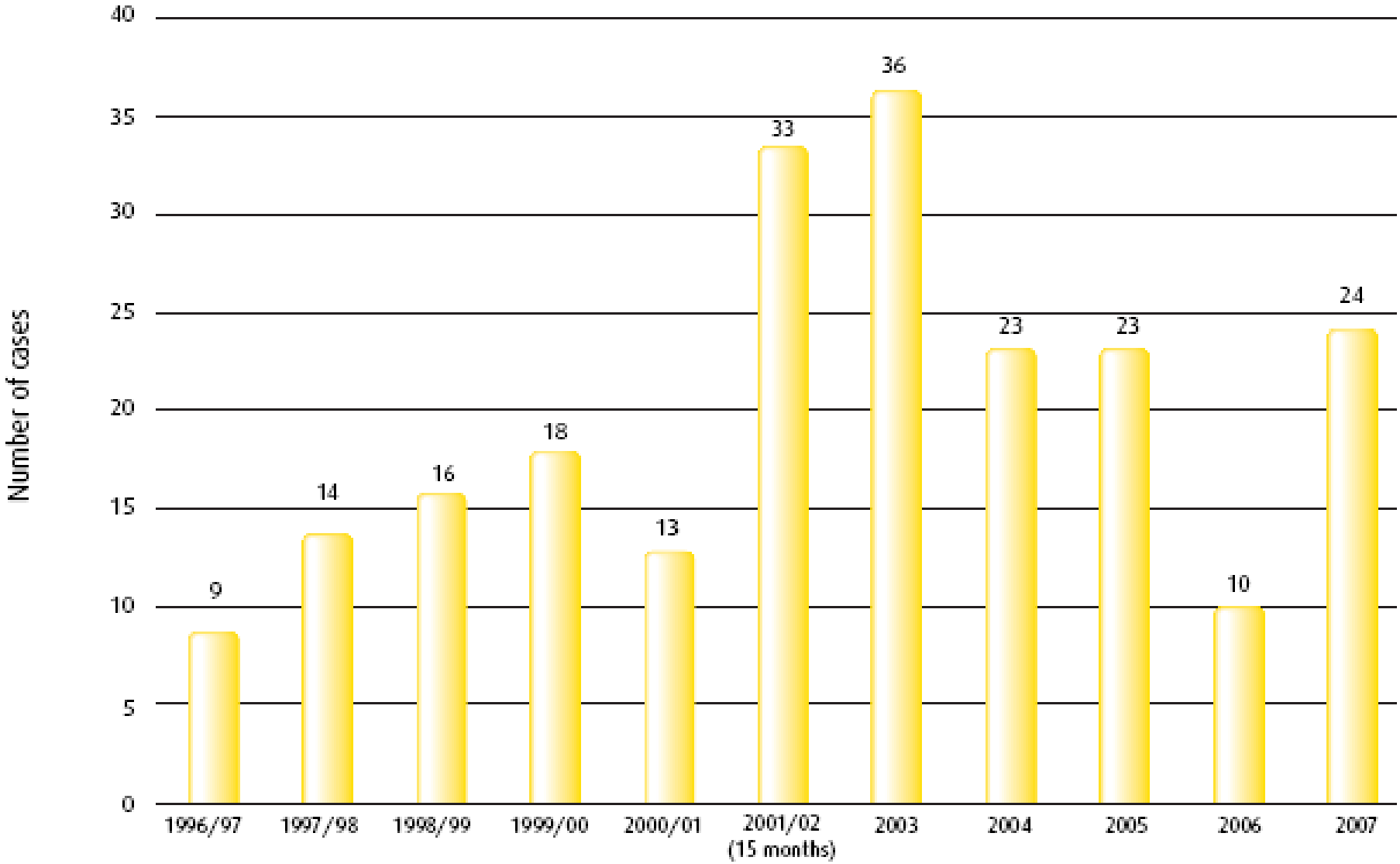


Figure 10
Cumulative cases of TRALI 1996–2007



http://www.shotuk.org/SHOT%20Report%202007.pdf

Figure 16
Confirmed bacterial transfusion-transmitted infections, by year of report and type of unit transfused (Scotland included from 10/1998)*

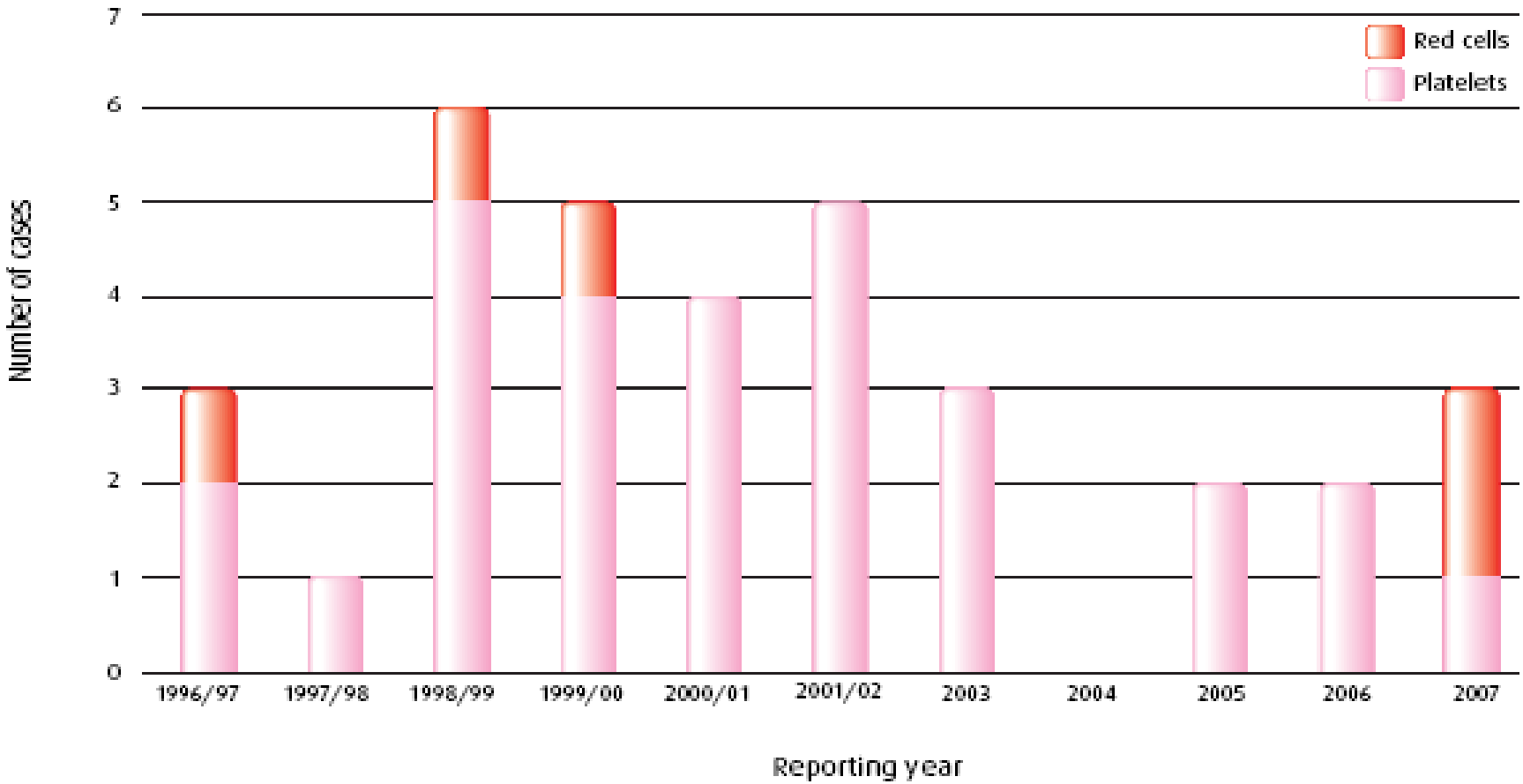


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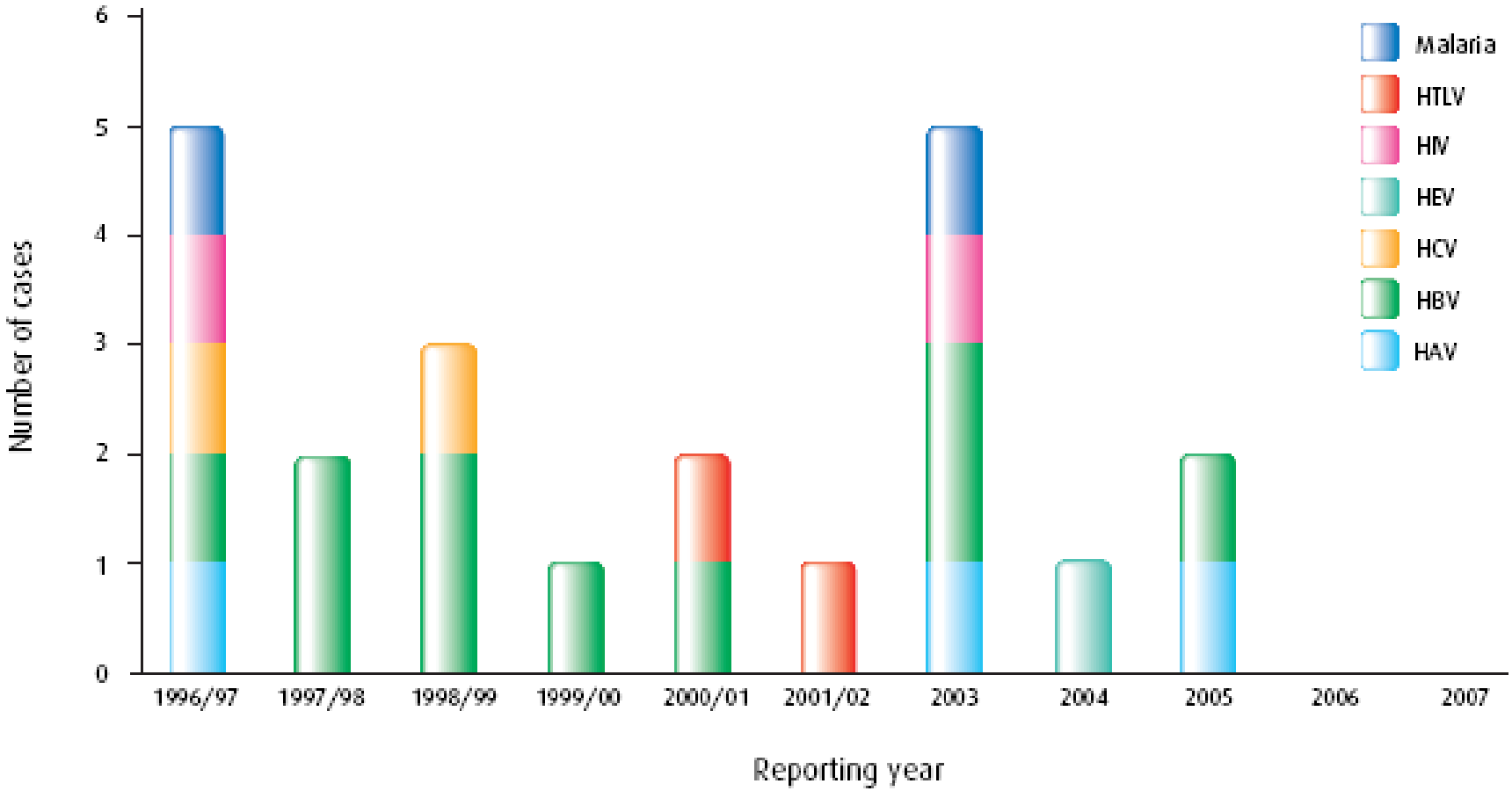
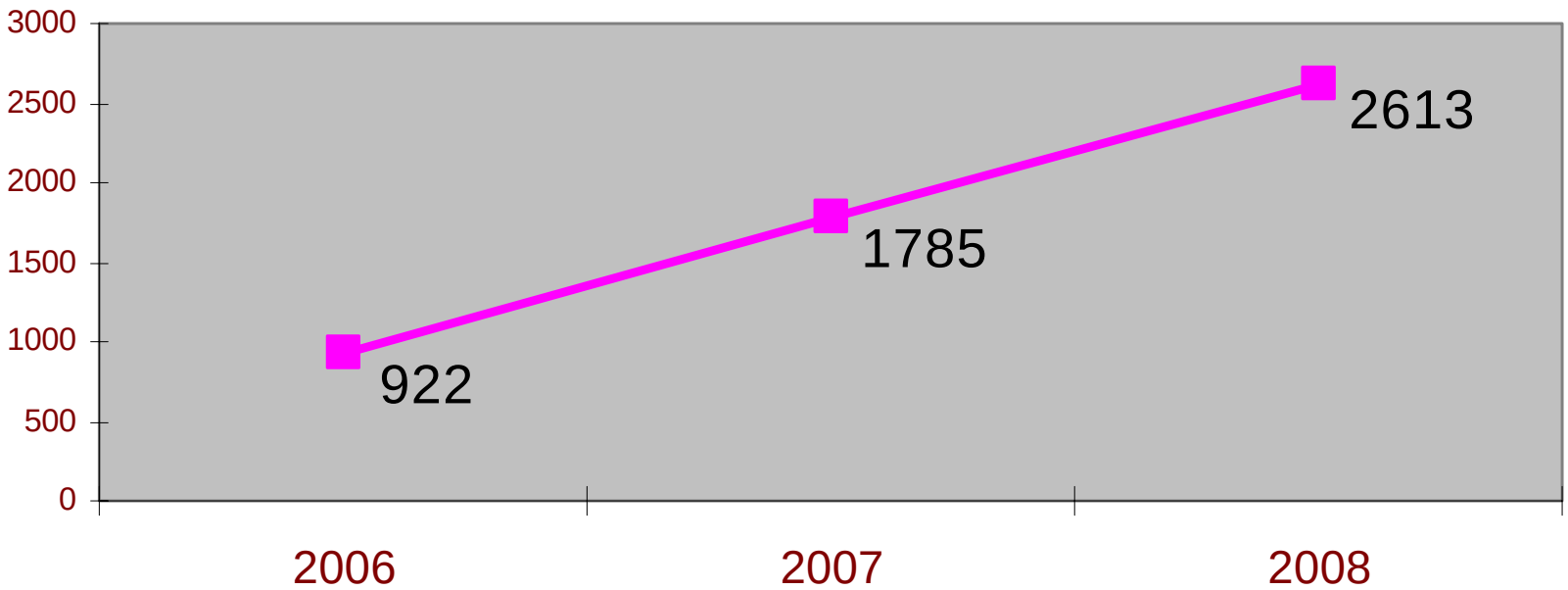
Figure 17
Confirmed transfusion-transmitted viral infections, by year of report and infection (Scotland included from 10/1998)



http://www.shotuk.org/SHOT%20Report%202007.pdf

Notificações de Reações Transfusionais

Incremento das notificações de reações transfusionais entre 2006 e 2008.



EVENTOS-SENTINELAS

Eventos-sentinelas notificados em 2007 e 2008, por ano de ocorrência.

Evento	Ano de ocorrência			
	2005	2006	2007	2008
Óbito	-	3	4	7
Contaminação Bacteriana	-	-	5	5
Doença Transmissível	1	3	1	2
Reação Hemolítica Aguda Imunológica	-	-	15	4

CAUSAS DOS ÓBITOS

Diagnósticos declarados nas notificações de óbitos imputados à transfusão, por ano de ocorrência. Brasil, 2006 a 2008

Óbito	Ano de ocorrência			Total
	2006	2007	2008	
Reação Febril não Hemolítica	0	0	3	3
Reação Hemolítica Aguda Imunológica	0	1	0	1
Reação alérgica	0	0	2	2
TRALI	0	0	1	1
Outras reações imediatas	0	2	1	3
Doença transmissível	3	1	0	4
Total	3	4	7	14

CONCLUSIONS

- Hemovigilance is essential for Blood Safety
- Development varies in different countries
- An ongoing system
- Benefits for society
- Benchmark and sharing data essential
- Reports and confidence are progressive with time
- Dynamic process


MUCHAS GRACIAS
Obrigado