OVERVIEW OF PRINCIPAL MODELS IN HAEMOVIGILANCE

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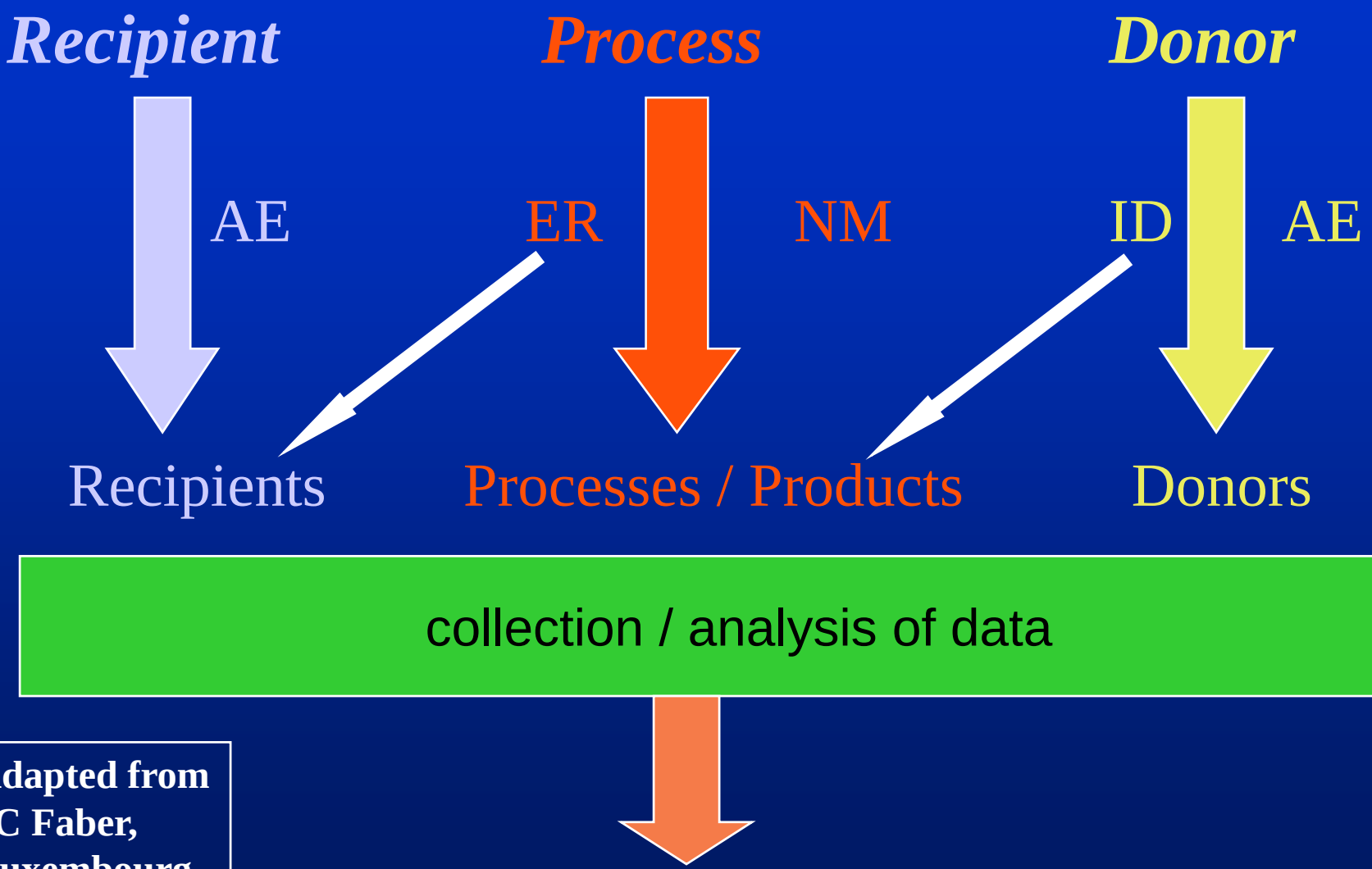
Modern Hemovigilance



Adapted from JC Faber, Luxembourg Red Cross

continuous improvement of transfusion safety

TYPES OF GOVERNANCE FOR HAEMOVIGILANCE SYSTEMS

- **Blood regulator**
  - **France, Switzerland, Germany**
- **Blood manufacturer**
  - **Singapore, Japan, South Africa**
- **Professional organisations**
  - **Netherlands (TRIP), UK (SHOT)**
- **Public Health**
  - **Canada (TTISS)**
- **Public-private partnership**
  - **USA Biovigilance Network**

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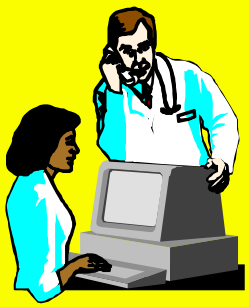
BLOOD REGULATOR

FRANCE

Medical & nursing team



EFS

AFSSaPS

Medical & nursing team

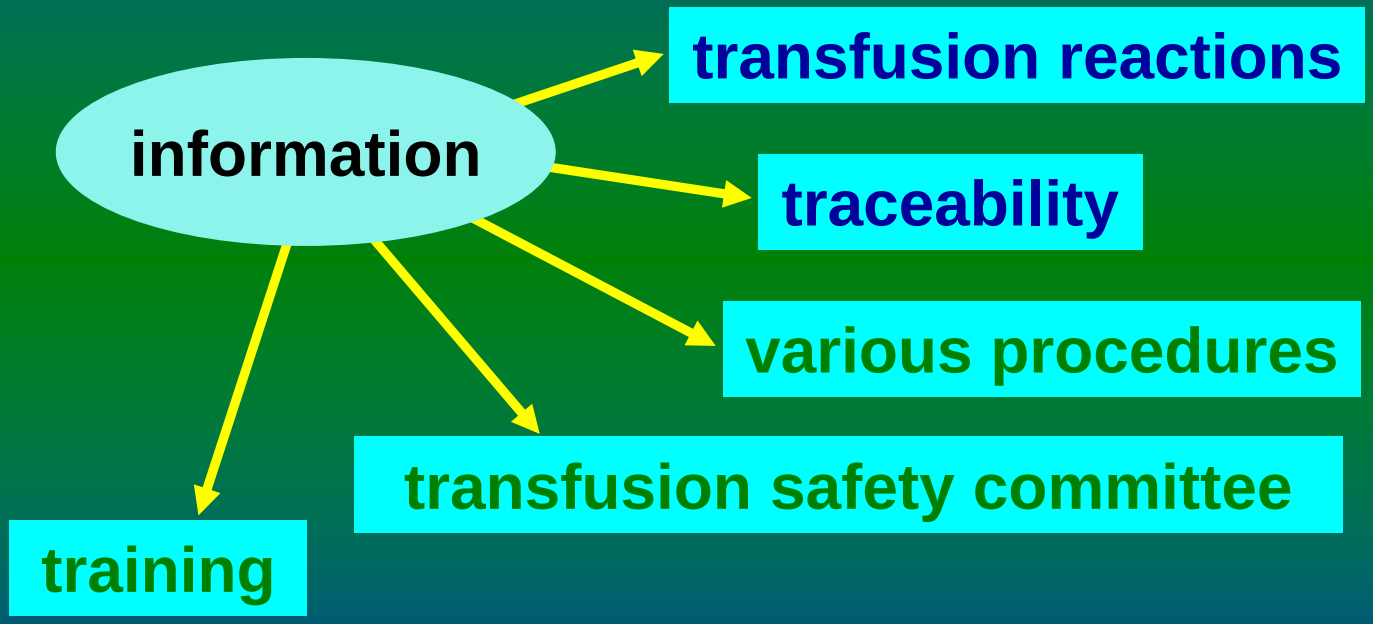
TSHC

Haemovigilance officers (HO)

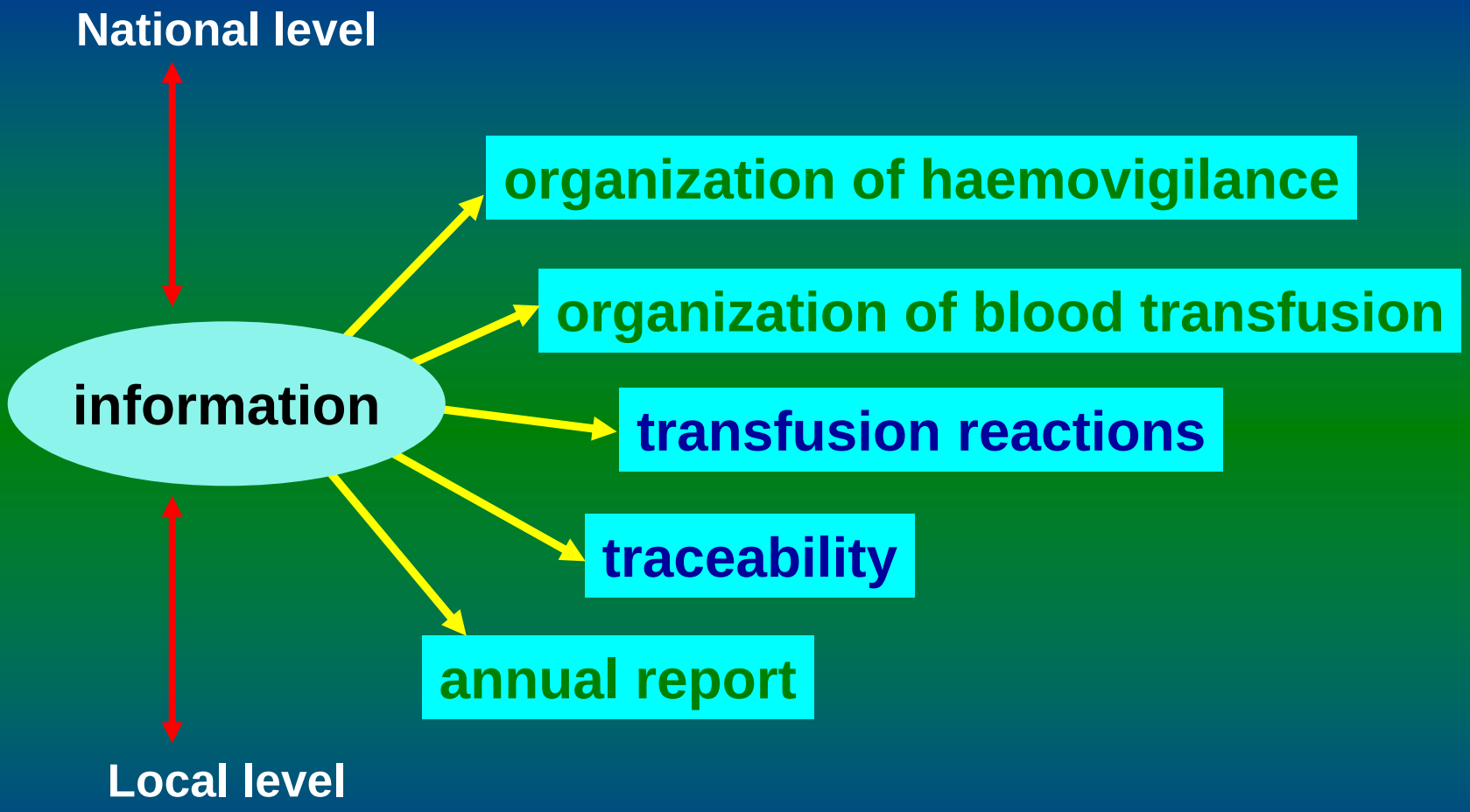
Regional coordinator

The local level

Healthcare facility HO + EFS HO



The regional level



The national level

- Hemovigilance unit – Afssaps
- Hemovigilance unit – EFS
- Hemovigilance unit - LFB
- National Health Surveillance Institute - InVS
- Regional coordinators' national conference
- National committee for the computerization of traceability
- National commission for hemovigilance
- French Society of Vigilance and Transfusion Therapeutics

Advantages

- The **centralization** :
  - Definition and implementation of national policies
  - Development and use of standardized tools
  - Uniform standardized practice in adverse event reporting and traceability
  - Hemovigilance part of global healthcare risk management
  - Easier detection of rare events
- The **manpower** :
  - Essential for good results
- The **multidisciplinary approach**

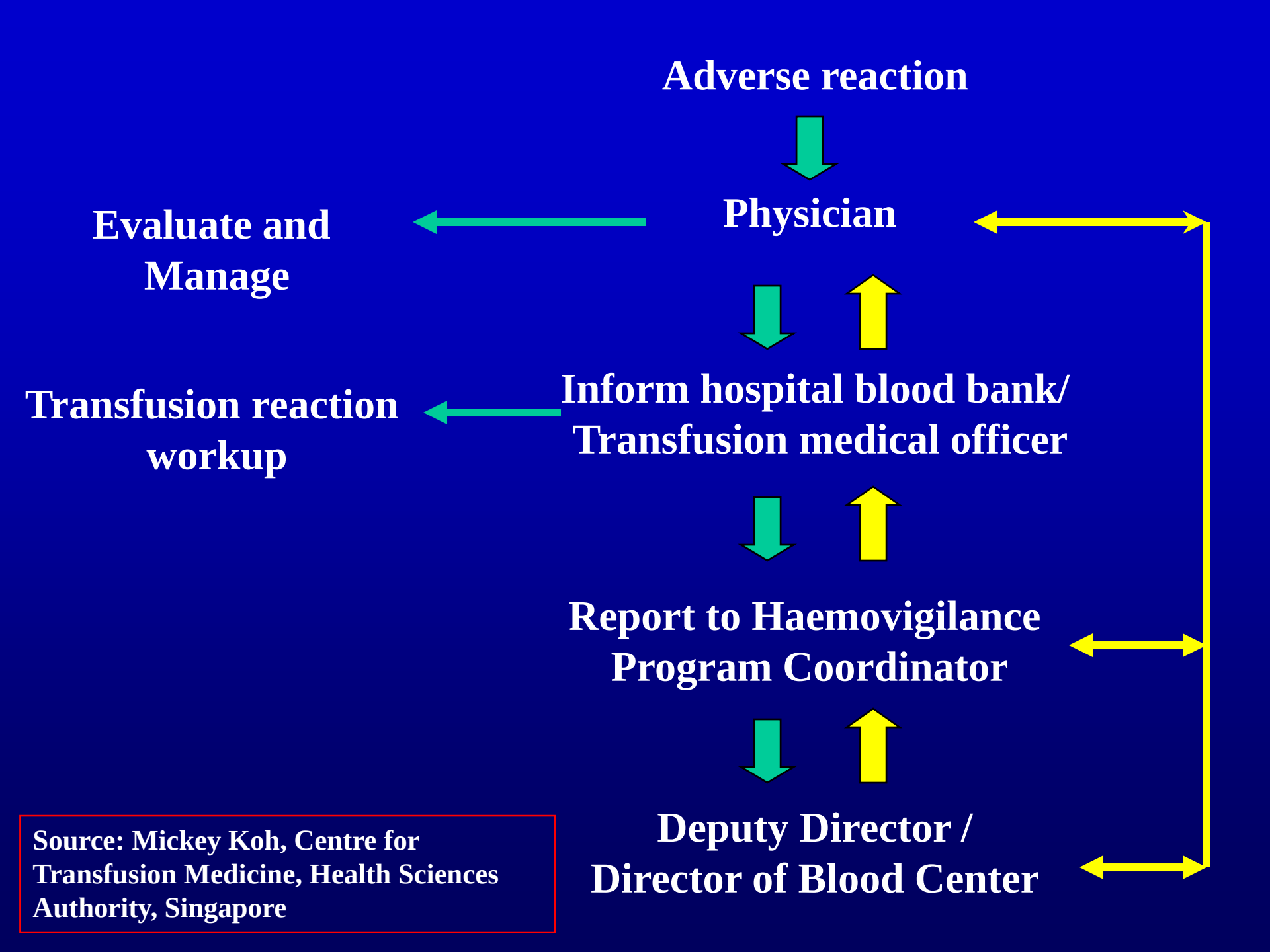
Disadvantages

- The centralization :
  - A top heavy organization, very dependent on political whim and public opinion
  - A vigilance system mostly concerned with blood components – what about transfusion practice ?
- The manpower :
  - The cost : is the system cost-effective ?
  - What is the real place of clinical medical staff in the system ?

Reporting to the regulator might prevent some institutions to report errors

BLOOD MANUFACTURER

SINGAPORE



Source: Mickey Koh, Centre for Transfusion Medicine, Health Sciences Authority, Singapore

Reporting Numbers

Period of Study	Total number of Reported Cases	Number of Participating Healthcare Institutions	Total number of Component Units Transfused
1 Jan 2003 – 30 June 2003	61	5 (41.7%)	59, 197
1 July 2003 – 31 Dec 2003	235	11 (91.7%)	65, 077
1 Jan 2004 – 30 June 2004	353	12 (100%)	69, 337
1 July 2004 – 31 Dec 2004	407	12 (100%)	77,846
1 Jan 2005 – 30 June 2005	371	12 (100%)	78, 477
1 July 2005 – 31 Dec 2005	397	12 (100%)	84,129
1 Jan 2006 – 30 June 2006	325	12 (100%)	77,868
1 July 2006 – 31 Dec 2006	**363**	**12 (100%)**	**86,865**

Source: Mickey Koh, Centre for Transfusion Medicine, Health Sciences Authority, Singapore

Advantages: Supplier

1. Tighter feedback loop: Intimate knowledge of the transfusion process
2. “better qualified” to develop the system and to intepret and analyse the data
3. Regulators often come from a different perspective and mindset
4. Impetus for change stronger and quicker
5. Less fear of reprisals from hospitals due to accumulation of long term records of possible defects in care

Source: Mickey Koh, Centre for Transfusion Medicine, Health Sciences Authority, Singapore

Diasdvantages: Supplier

1. One of the major participants in the transfusion process. What if analysis of data casts a spotlight on blood centre/provider's deficiencies?
2. Pressure to highlight the achievements of the blood centre; disregarding the shortfalls.
3. Public perception on accuracy of data
4. Higher stakes: if something does emerge and doubts emerge from public on preservation of self interest from the supplier
5. Protection of data a more complex issue.

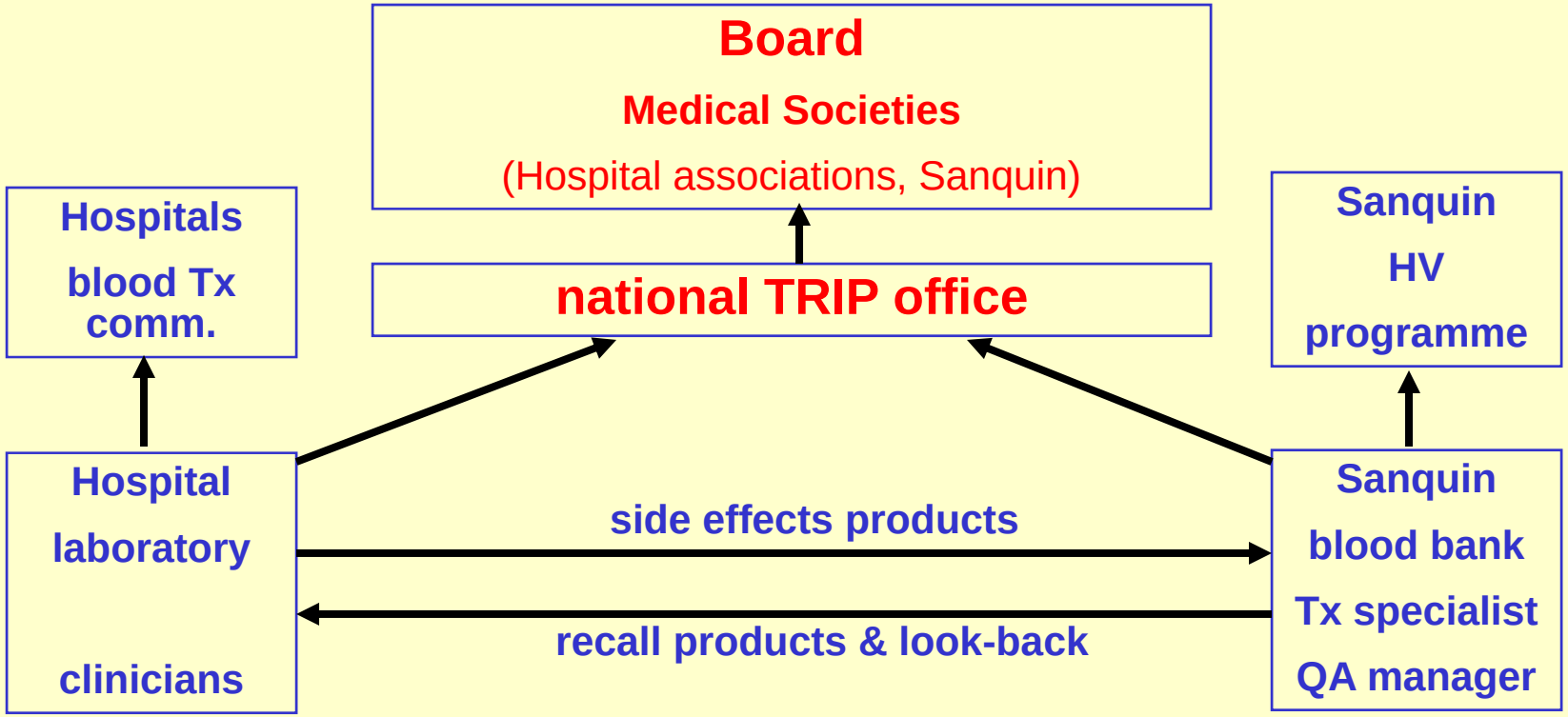
Source: Mickey Koh, Centre for Transfusion Medicine, Health Sciences Authority, Singapore

PROFESSIONAL ORGANISATIONS

NETHERLANDS

Development of hemovigilance

TRIP foundation created in 2001



Source: M. Schipperus, TRIP, Netherlands

TRIP (Transfusion Reactions In Patients)

Hitherto ‘voluntary’ participation,

- regarded as the norm by Inspectorate
- professional standard in consensus guideline

Reporting system

what types, definitions, recommended further investigation

how to report: paper / online

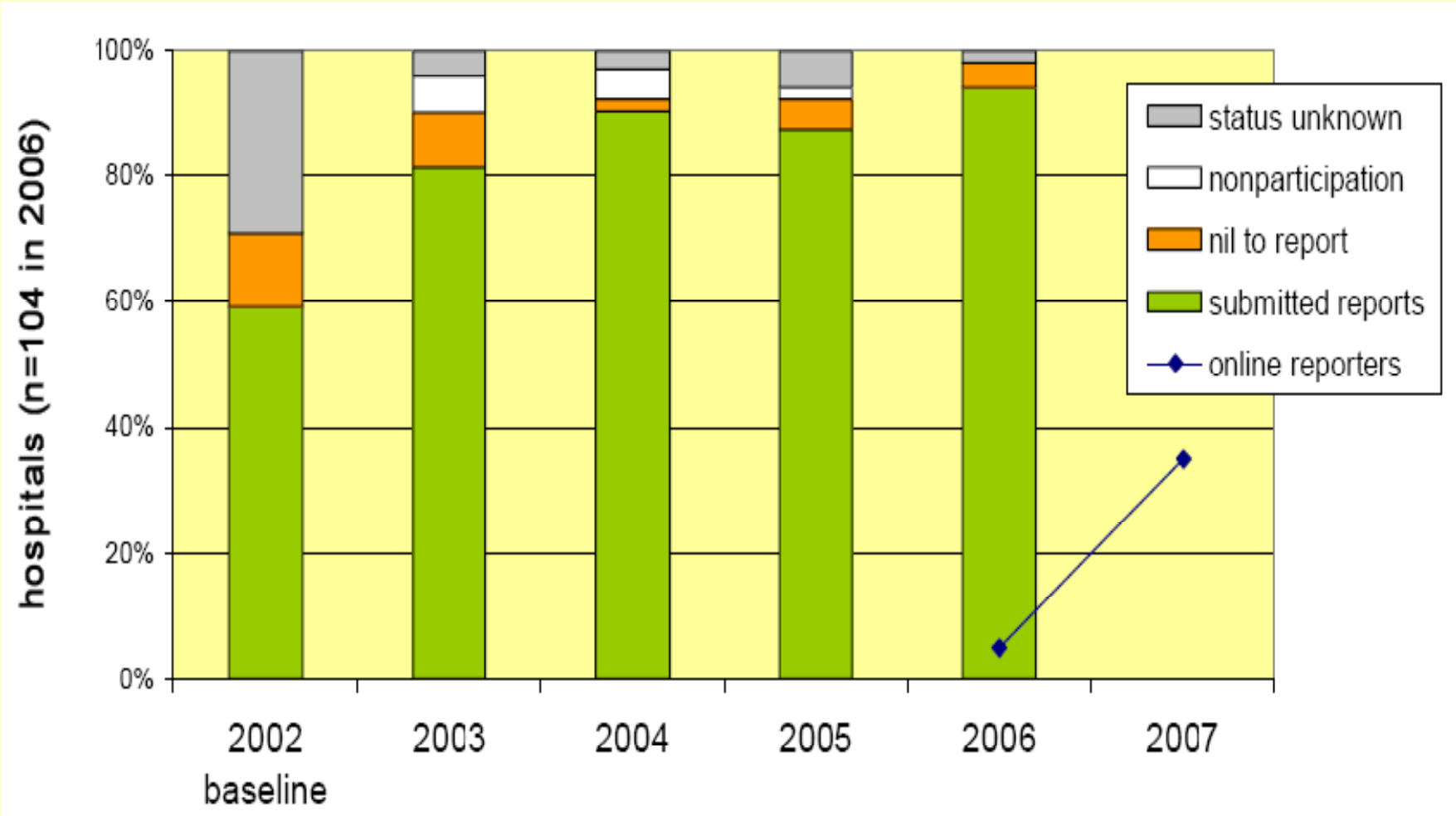
Verification (expert review)

Denominator data, statistical analysis

Publication (transparency)

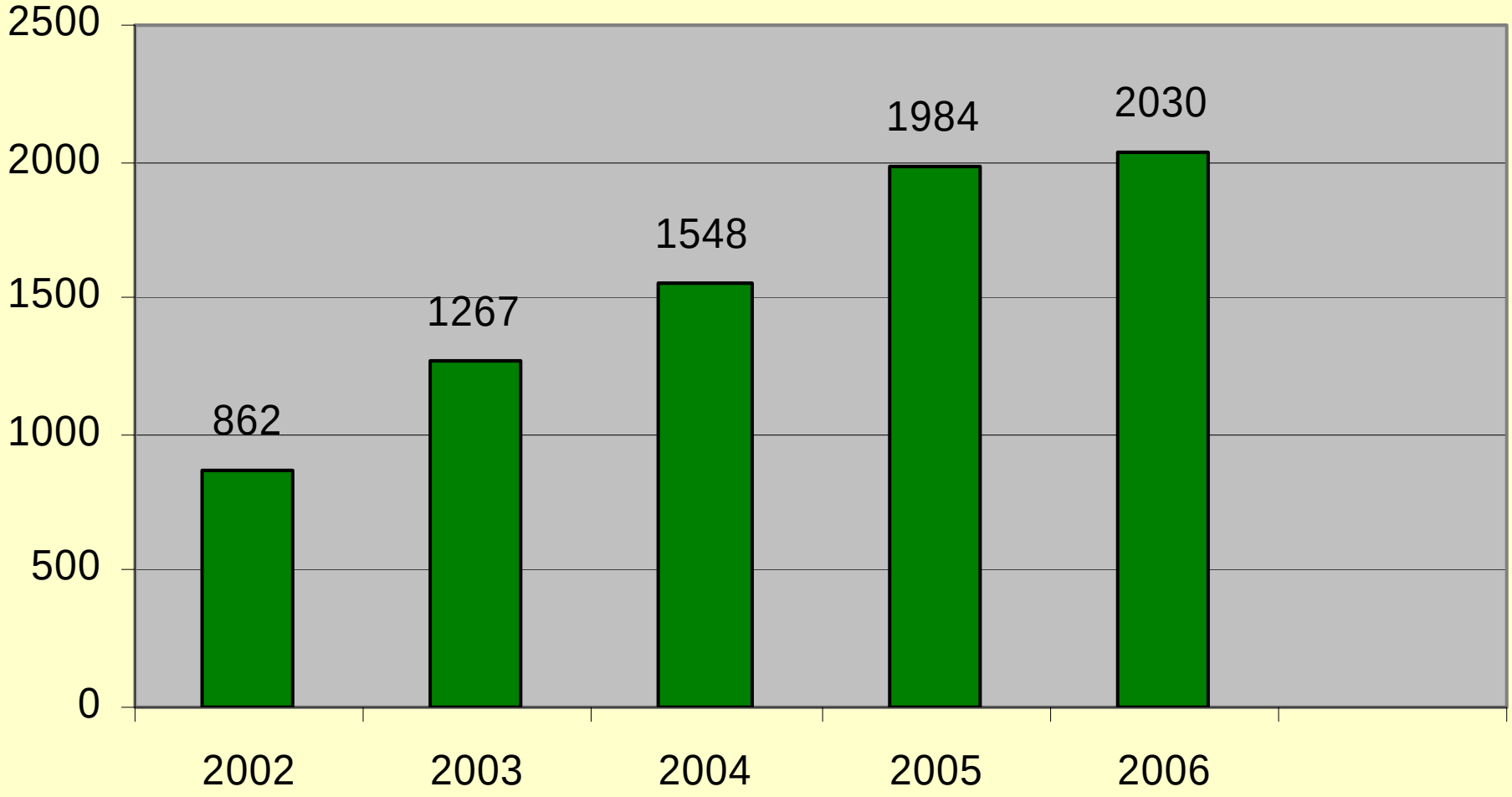
Source: M. Schipperus, TRIP, Netherlands

Participation by hospitals



Source: TRIP, English Newsletter 2008/1

Reports per year



Source: M. Schipperus, TRIP, Netherlands

Advantages of the TRIP system

- scientifically validated data using agreed definitions
- user-friendly system
- stimulus for research
- 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

Source: M. Schipperus, TRIP, Netherlands

Weaknesses of TRIP system

- **Dependent on willingness of professionals to report**
- **Late reporting (cold hemovigilance)**
- **Difficult to fund staff in the hospitals**
- **Simultaneous initiatives on the same subject possible (no official central steering)**
- **“Polder model”: many people decide. Democratic, effective but slow !**

Source: M. Schipperus, TRIP, Netherlands

PUBLIC HEALTH

CANADA

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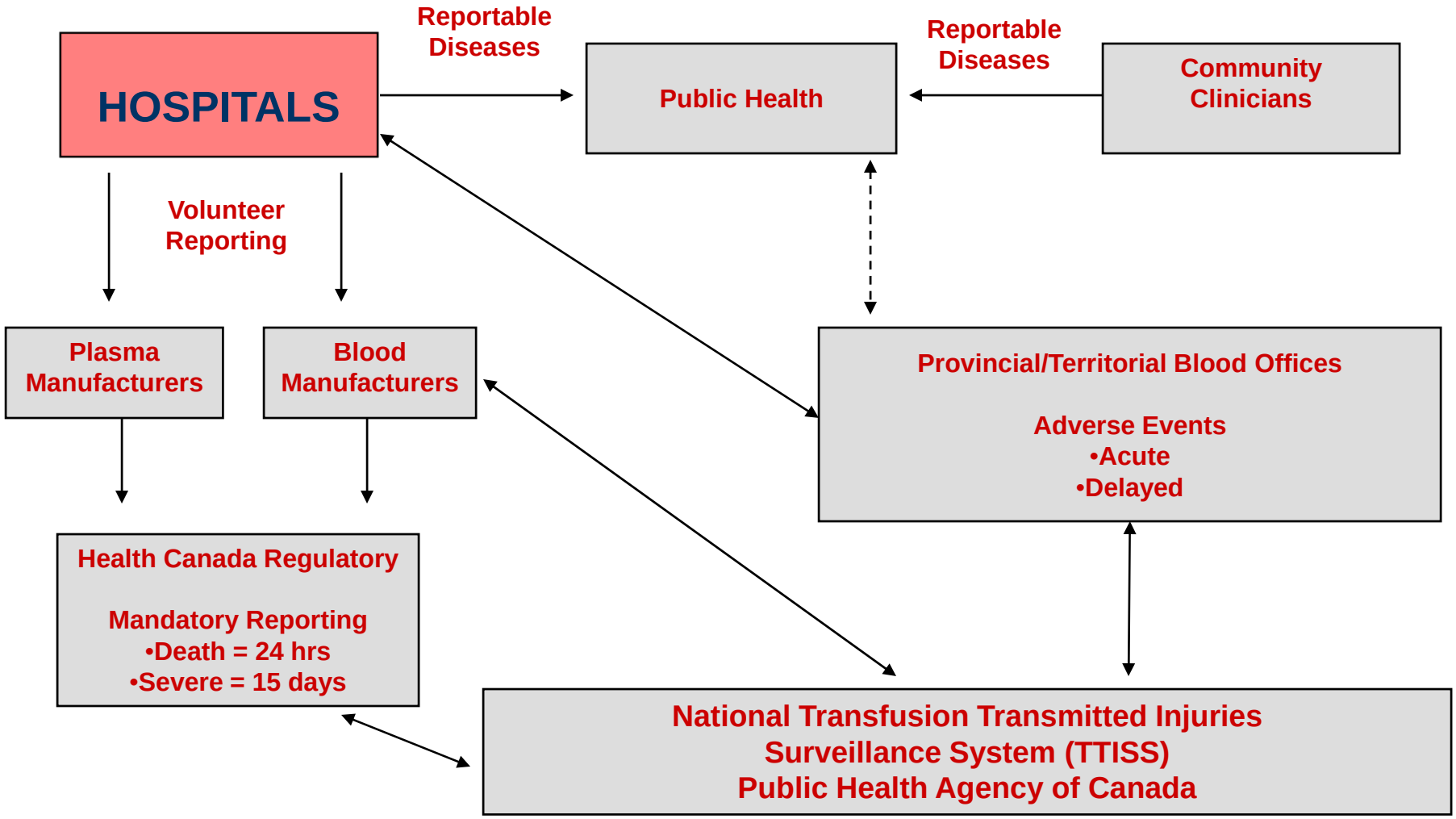
Background

- In collaboration with Canadian Provinces/Territories, Health Canada Regulatory and Canadian Blood Manufacturers, the Public Health Agency of Canada (PHAC) implemented a voluntary Transfusion Transmitted Injuries Surveillance System (TTISS) to monitor adverse transfusion events (ATEs)

Infrastructure for National TTISS Reporting



National TTISS Working Group

- **Membership**
  - All provinces/territories represented
  - Blood manufacturers
  - Health Canada regulators
- **Terms of Reference**
  - Identify and address issues related to a national surveillance program to determine the risk of transmission of infections and injuries by blood transfusions
  - Recommend future directions, quality, efficacy and effectiveness of the TTISS as a national surveillance program

National Data Review Group

- **Membership**
  - Members are selected for their individual medical/scientific expertise in the fields of:
    - public health
    - infectious diseases
    - epidemiology
    - transfusion medicine
  - Ex-officio representatives are from PHAC, Health Canada, Canadian Blood Services and Héma-Québec

- **Terms of Reference**
  - Reviewing and evaluating surveillance based epidemiological data concerning the risk of transmission of infections and injuries through blood, blood components and plasma derivatives
  - Develop research questions and hypotheses for investigation purposes
  - Identify signals or unusual events that should be further investigated

Methods

- Data on Adverse Events is collected at the hospitals/sites
  - Most sites voluntarily report the data to a provincial/territorial office
  - Few sites report directly to the Public Health Agency of Canada
- Non-nominal data are transferred as per the provincial/federal TTISS agreement to the Public Health Agency of Canada

Disadvantages of Public Health Governance

- No prior knowledge of transfusion medicine in public health
- Lack of trust and credibility by the transfusion community at the outset
- No established network between public health and transfusion community
- Not perceived as a major public health issue within public health

How to handle disadvantages

1. LISTEN TO THOSE WHO HAVE EXPERTISE IN TRANSFUSION MEDICINE
2. START WITH A PILOT PROJECT TO ESTABLISH TRUST AND CREDIBILITY
3. PROVIDE REGULAR FEEDBACK TO DATA PROVIDERS
4. HIRE PEOPLE WITH EXPERTISE TO HELP BUILD THE SYSTEM

Advantages of Public Health Governance

- Extensive knowledge in surveillance methodology
- Extensive experience in managing surveillance databases
- Extensive knowledge in analysing and interpreting surveillance data
- Some guarantee of sustainability once endorsed by public health

PUBLIC-PRIVATE PARTNERSHIP

USA

The US Biovigilance Network

Biovigilance Network Task Force

"Moral support"
Encouragement for participation
Routes to ongoing funding
Support for implementing changes

US:CDC
c US:CMS
iance US:FDA
US:HRSA
US:NHLBI
sst. Sec., OPHS

Biovigilance Network Steering Committee

Direction
Review
More encouragement for participation

Biovigilance Network Working Group
PHASE I: Transfusion Service Operations

Make it happen!

James AuBuch cCombie
Neil Blumberg, Rabin-Fastman
Jeannie Callum, MD — Pierre Robillard, MD
Rodeina Davis — Kent Sepkowitz, MD
Anne Eder, MD, PhD — Beth Shaz, MD
Mark Fung, MD — Tait Stevens, MD
Linda Hahn — Leon Su, MD
Barbee Whitaker, PhD, staff

Biovigilance Network International Correspondents

Critiques from experience

Geo
Sim)
Emer Lawlor, MD (Irl) — Paul Strengers, MD (ISBT)

The Public-Private Partnership

CDC is providing:

- **Support for initial programming effort**
- **Access to NHSN programmers and structure**
- **Program managers**
- **Support for AABB staff**
- **Confidentiality and legal protections**

Blood Banking (through Task Force) is providing:

- **Technical expertise for system design**
- **“Marketing”**
- **Fundraising for ongoing operation**
- ***Data analysis through expert groups***

USBVN Timeline

Phase I: Transfusion Service Hemovigilance

- Terminology and definitions: Completed
- Design specifications: Completed (almost)
- Programming initiation: *Winter 2008*
- Pilot trials: Spring, 2008
- Opening of system: Fall, 2008

Phase II: Collection Center Hemovigilance

- Terminology and definitions: Underway
- Design specifications: Early 2008
- Programming initiation: Contracted

Phase III: Tissue Transplantation Biovigilance

- TTSN: Development underway (CDC/UNOS/AATB)

Types of haemovigilance systems

France	Singapore	Netherlands	Canada	*Québec/ Canada*
Hemovigilance	Hemovigilance	TRIP	TTISS	*QHS*
1994	2002	2002	2002	*2000*
Confidential	Confidential	Confidential	Anonymous	*Confidential*
Mandatory	Voluntary	Voluntary	Voluntary	*Voluntary*
Non-punitive	Non-punitive	Non-punitive	Non-punitive	*Non-punitive*
All reactions	All reactions	All reactions	Only serious reactions	*All reactions*

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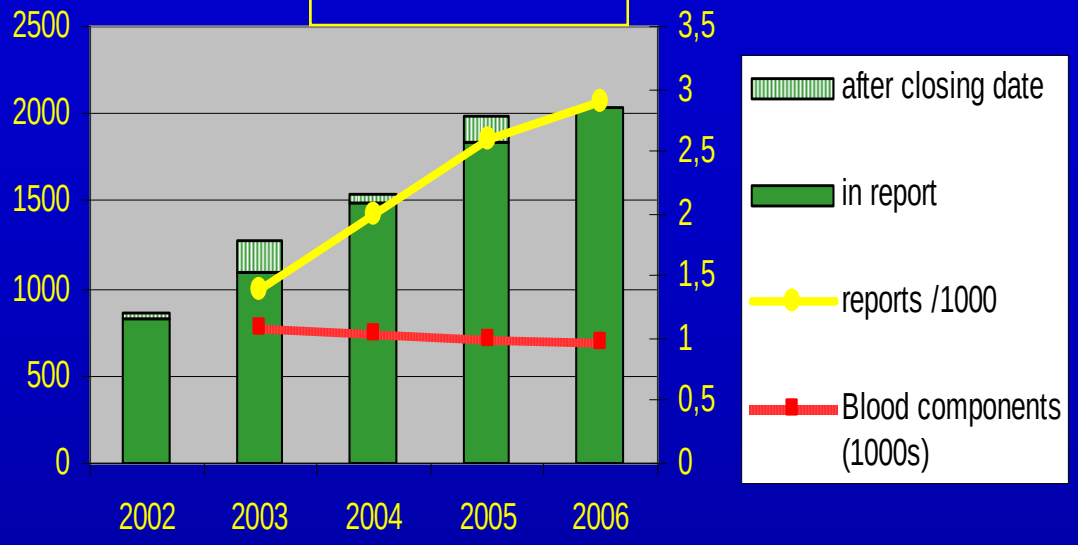
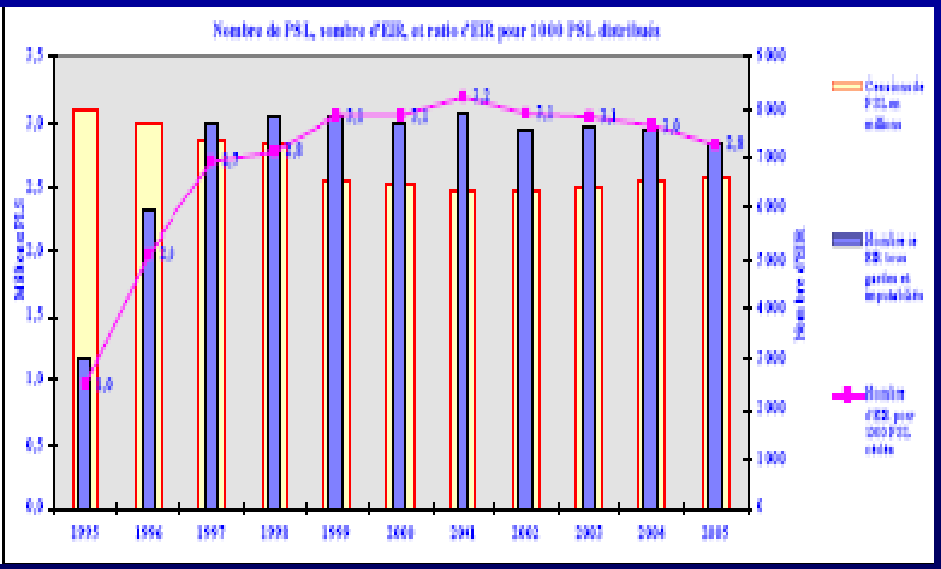
Reporting in haemovigilance systems

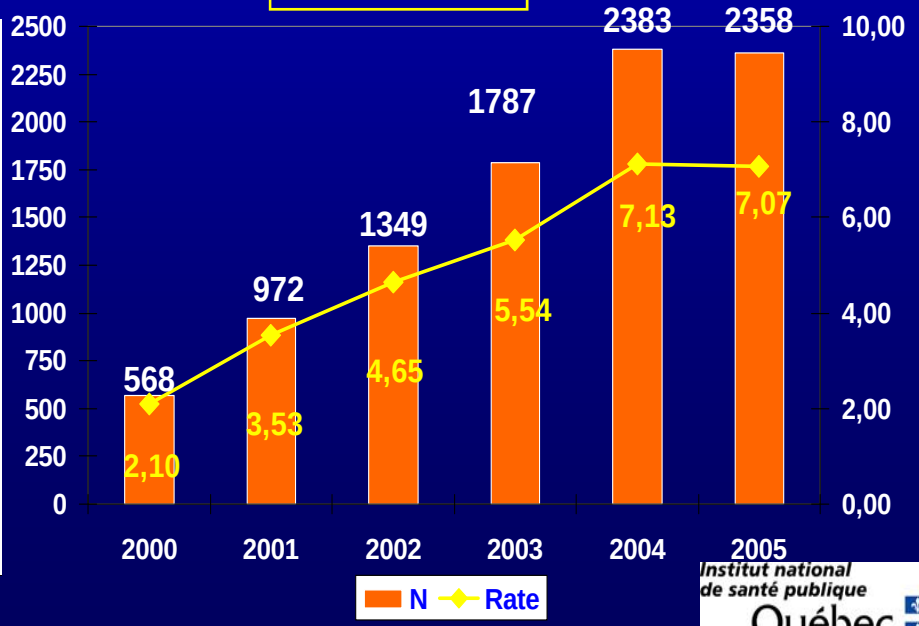
TRIP



FRANCE



QHS



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Reporting in haemovigilance systems

Country/ region	*Reports/ 1000 units	What is reportable	Type of system
UK	0.20	Serious reactions + IBCT	Voluntary
Canada	0.31	Serious reactions not IBCT	Voluntary
Ireland	1.22	Serious reactions + IBCT	Voluntary
France	2.83	All reactions	Mandatory
Netherlands	2.90	All reactions	Voluntary
Québec	7.07	All reactions	Voluntary

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CONCLUSION

- Haemovigilance has become an integral part of a quality system in transfusion
  - it covers the whole transfusion chain
    - donors, processes and recipients

- Irrespective of the structure of the system
  - Haemovigilance works and provide quality data for priority settings and evaluation of preventive strategies