PA/PH/TS (09) 28 2 R Strasbourg, April 2010

EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON BLOOD TRANSFUSION (CD-P-TS)

TS057 - Risk behaviours having an impact on blood donor managment

Final terms of reference proposed for the ad hoc experts group
Project leader: Rut Norda
EDQM Responsible Scientific Officer: M.-E. Behr-Gross

For information :
CD-P-TS European Committee on Blood Transfusion
CD-P-TSobs Observers of the European Committee on Blood Transfusion
TS057 Risk behaviors having an impact on blood donor management

Commission directive 2004/33/EC
Annex III: Eligibility criteria for donors

Permanent deferral, such as for

- Persons whose **sexual** behaviour puts them at **high** risk of acquiring **severe** infectious diseases that can be transmitted by blood

Temporary deferral, such as for

- Persons whose behaviour or activity places them at risk of acquiring infectious disease that may be transmitted by blood. *Defer after cessation of risk behaviour for a period determined by the disease in question and availability of appropriate tests*

A difference of opinion between the two Swedish Competent Authorities - NBHW and the MPA

MPA was recommended by EMA to consult EDQM and CD-P-TS

- Presentation of the Swedish case in November 2009 led to the subordinate ad-hoc working group on

  RISK BEHAVIOURS HAVING AN IMPACT ON BLOOD DONOR MANAGEMENT (TS057)

Meeting agenda

- February 5, 2010, web-meeting 24 Sept 2010, additional data collection July-Nov 2010, 2nd meeting 17 Nov 2010, 3rd meeting 24-25 Feb 2011

External meetings

- DHHS ABSCA 10-11 June 2010, Joint meeting of CA and RC 27-28 Oct 2010, EBA Board 25 March 2011

Participation in the WG TS 057

- European experts nominated by the European Committee on Blood Transfusion of the Council of Europe (CD-P-TS)
- European Commission (EC)
- European Medicines Agency (EMA)
- European Centre for Disease Control (ECDC)
- Unites States Food and Drug Administration (US-FDA)
- World Health Organization (WHO)
- Blood Regulators Network
- European Blood Alliance (EBA)
- Health Canada
- Therapeutic Goods Administration (TGA Australia)
- American Red Cross

Data for 10 MS in TS057

- From the collection, testing and use of blood and blood components in Europe 2006-2008: most recent information used
- from the collection of additional information in TS 057
- from ECDC
- from published and unpublished studies

10 MS in TS057

some 16,5 M WB collections per year

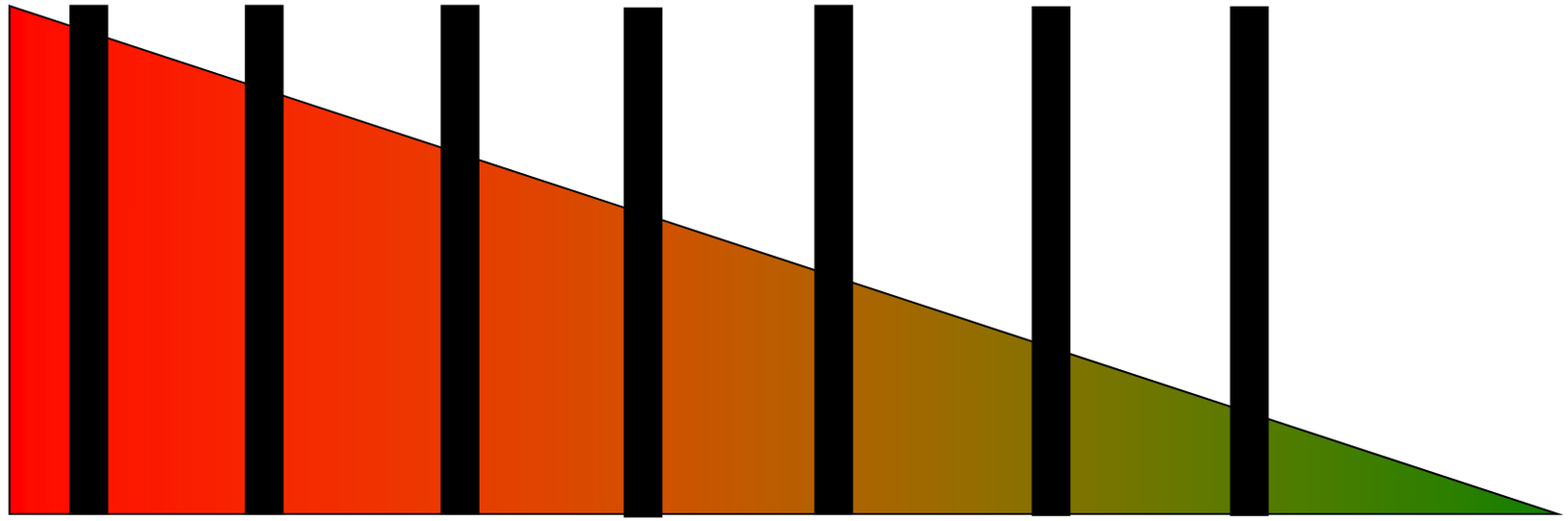
	blood collections per 1000 pop	% first time donors	donors only tested at first visit
Germany	59.4	18.3	17.30%
Turkey	7.1	NA	NA
France	36.7	43.3	none
UK	38.8	15.6	none
Italy	42.1	18.1	40%
Spain	37.6	26.7	none
Netherlands	34.5	7.2	all
Greece	59.5	16.9	none
Sweden	53.7	15.3	all

Some other data from the additional collection

- Data are not applicable for the whole country: 2/10
- National organisation: 3/10
- Donor questionnaires provided in English for the additional data collection: 5/10
- Compliance studies: 4/10 reported studies of various magnitude
- Risk modelling: 7/10 reported yearly assessment of RR or formal studies.

Sexual risk behaviour

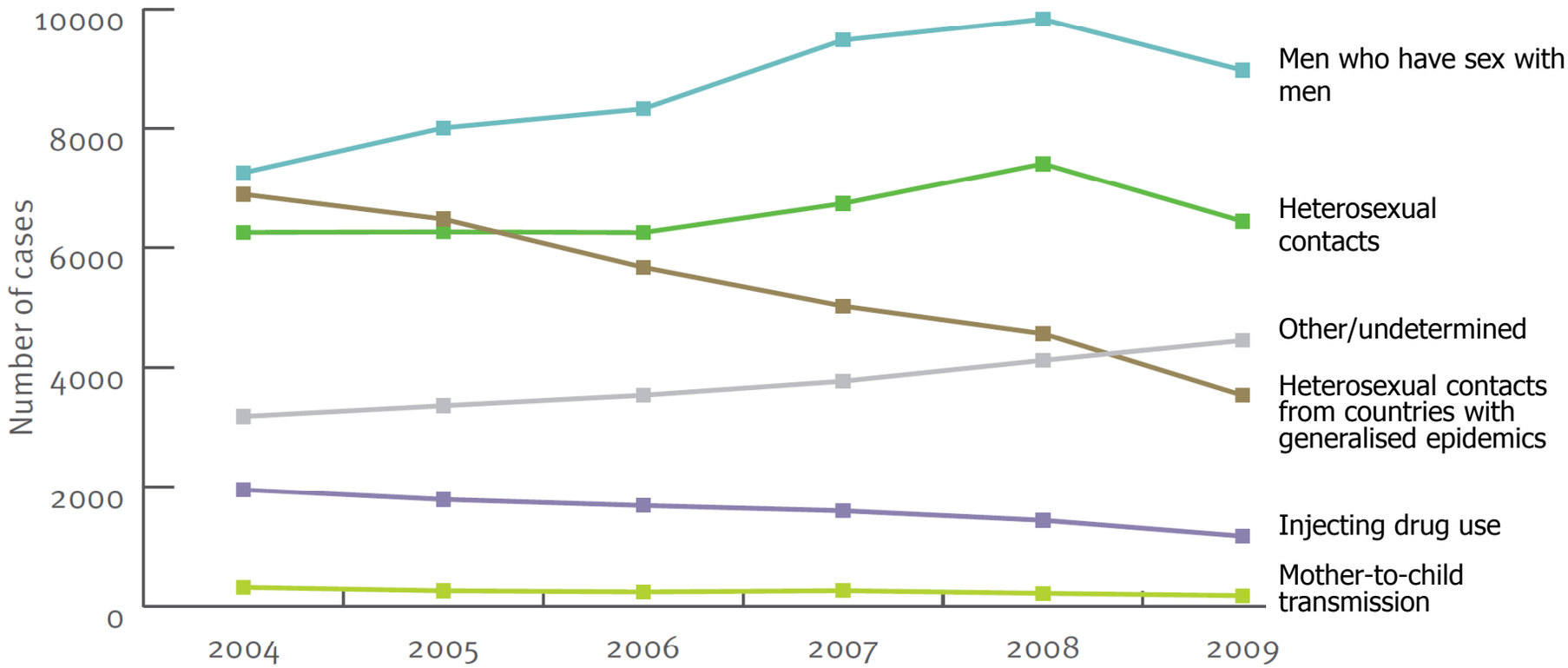
Definition, ranking and deferral for sexual „high risk“ behaviour arbitrary in an international perspective



* high prevalence country

Courtesy R Offergeld 24 Feb 2011

HIV infection by transmission group and origin in EU/EEA countries, 2004 - 2009

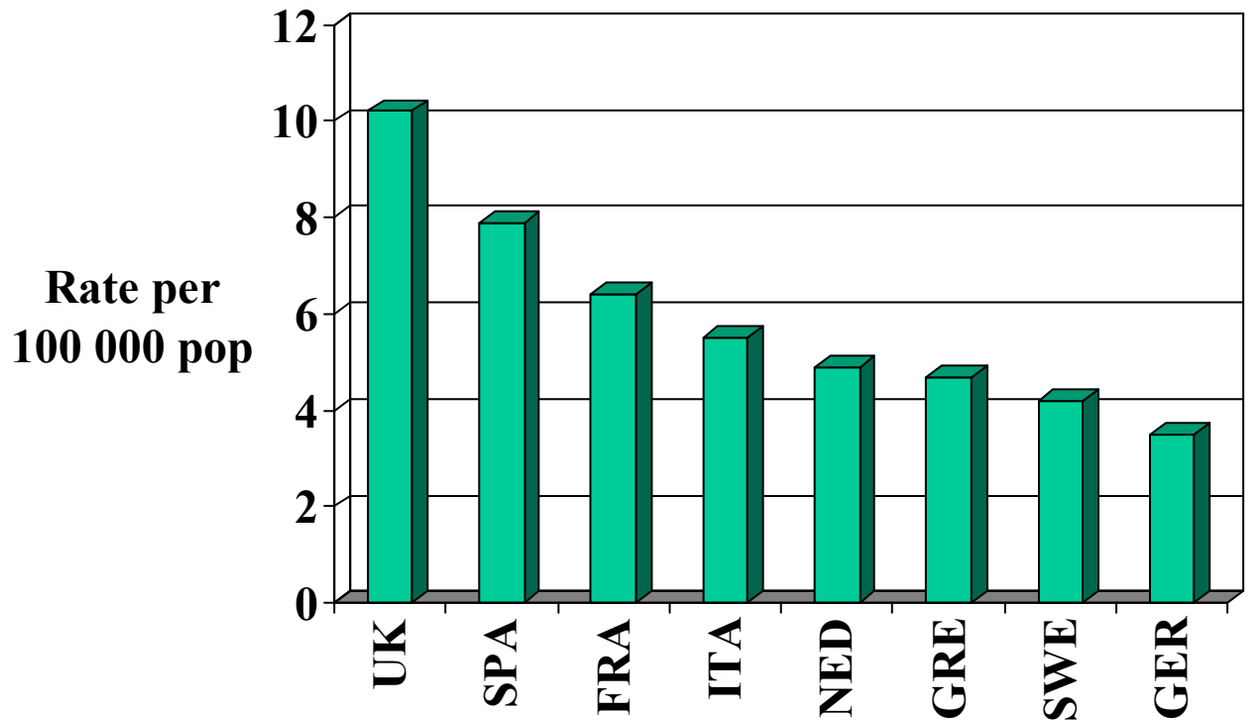


Predominant transmission group: men who have sex with men

Data were not included from: Austria, Estonia and Poland.

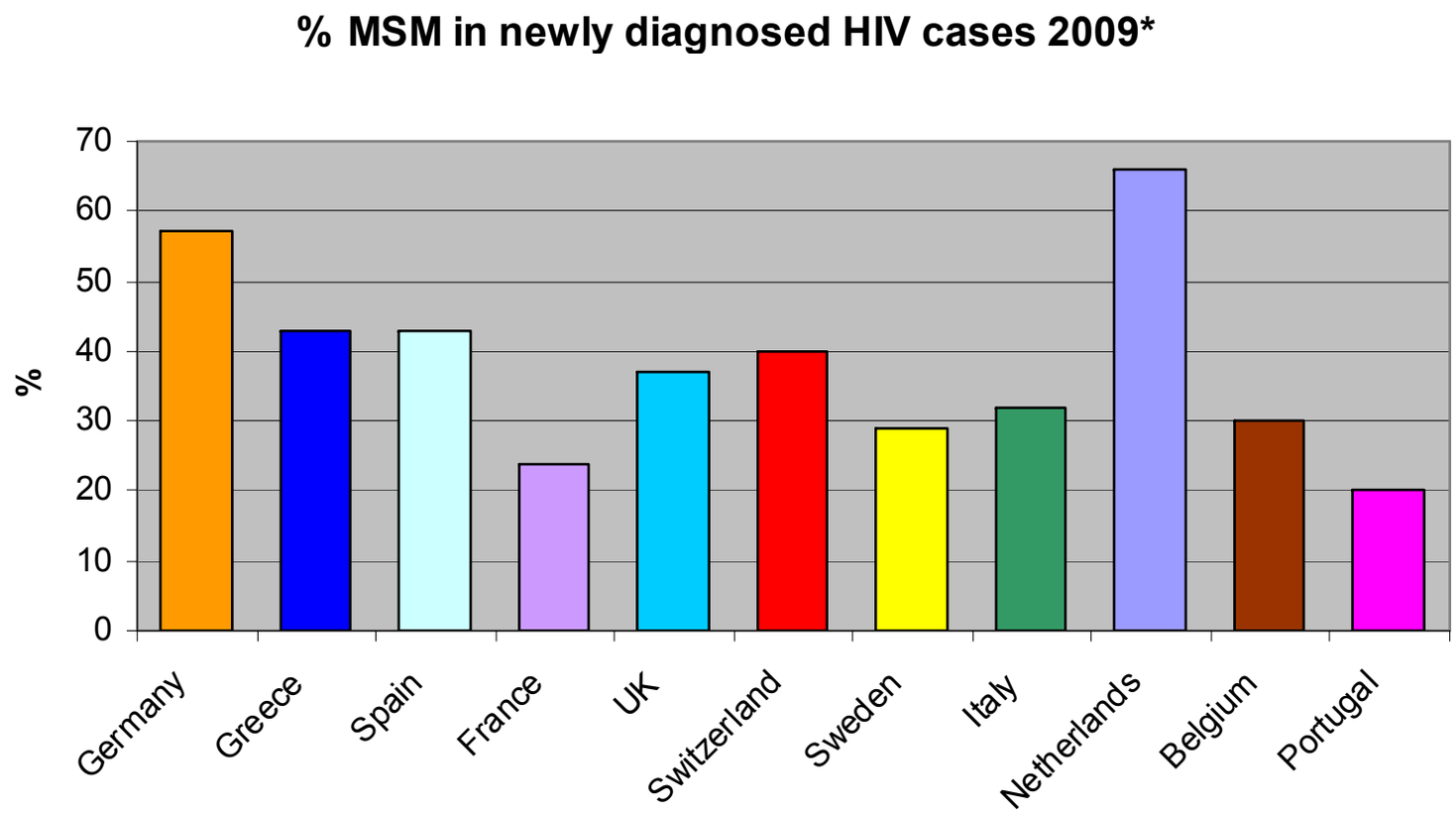
Source: ECDC/WHO. HIV/AIDS Surveillance in Europe, 2009

Notification rate of HIV in 10 MS of TS 057



Notification (of all previously not diagnosed infections) rate of HIV 2008-2009 per 100 000 population : ECDC

MSM and HIV in the general population

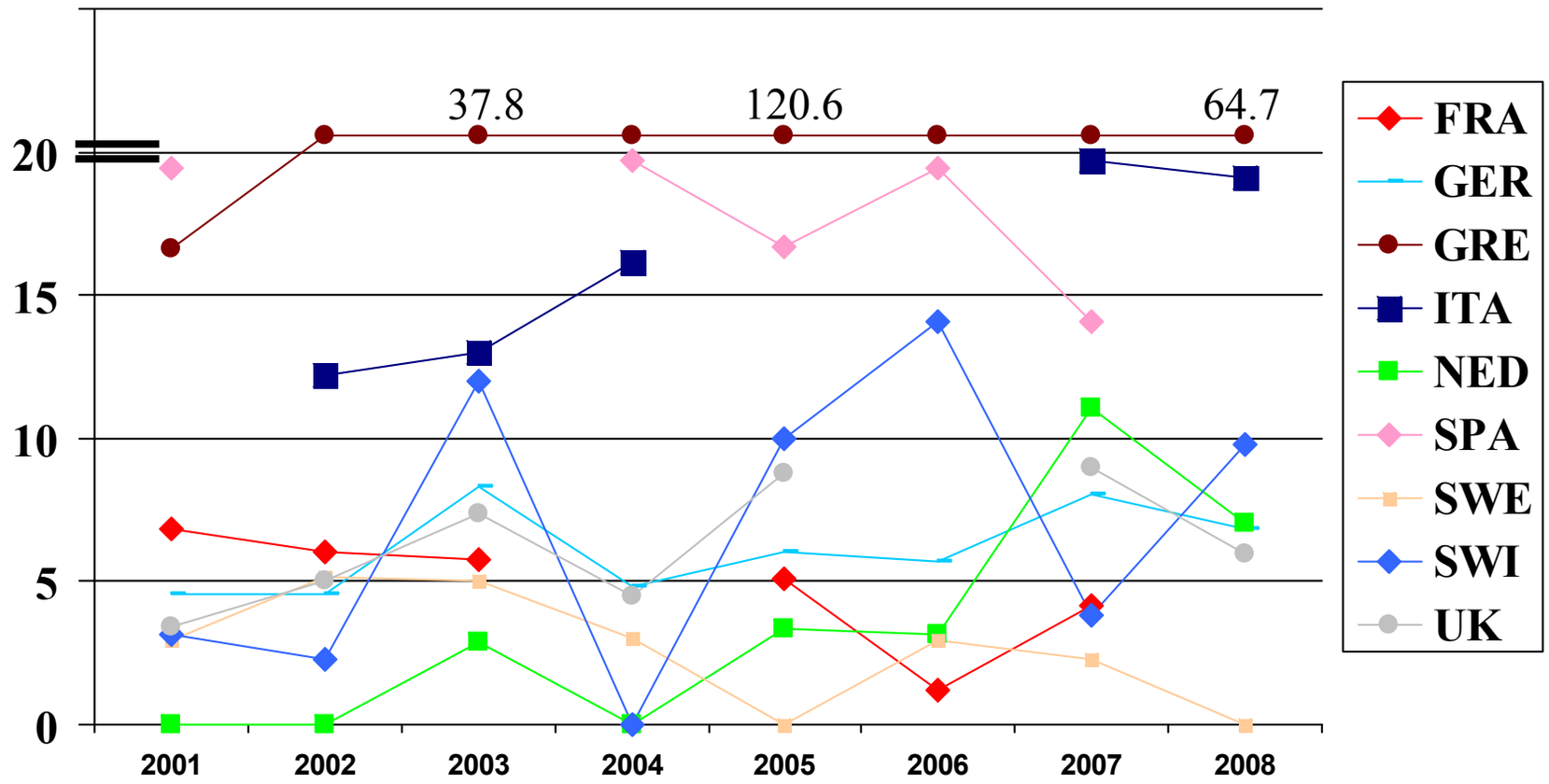


3-10% of MSM are estimated to be HIV+ (UNGASS report)

*ECDC: HIV/AIDS surveillance in Europe 2009

PREVALENCE HIV NEW DONORS (ND)

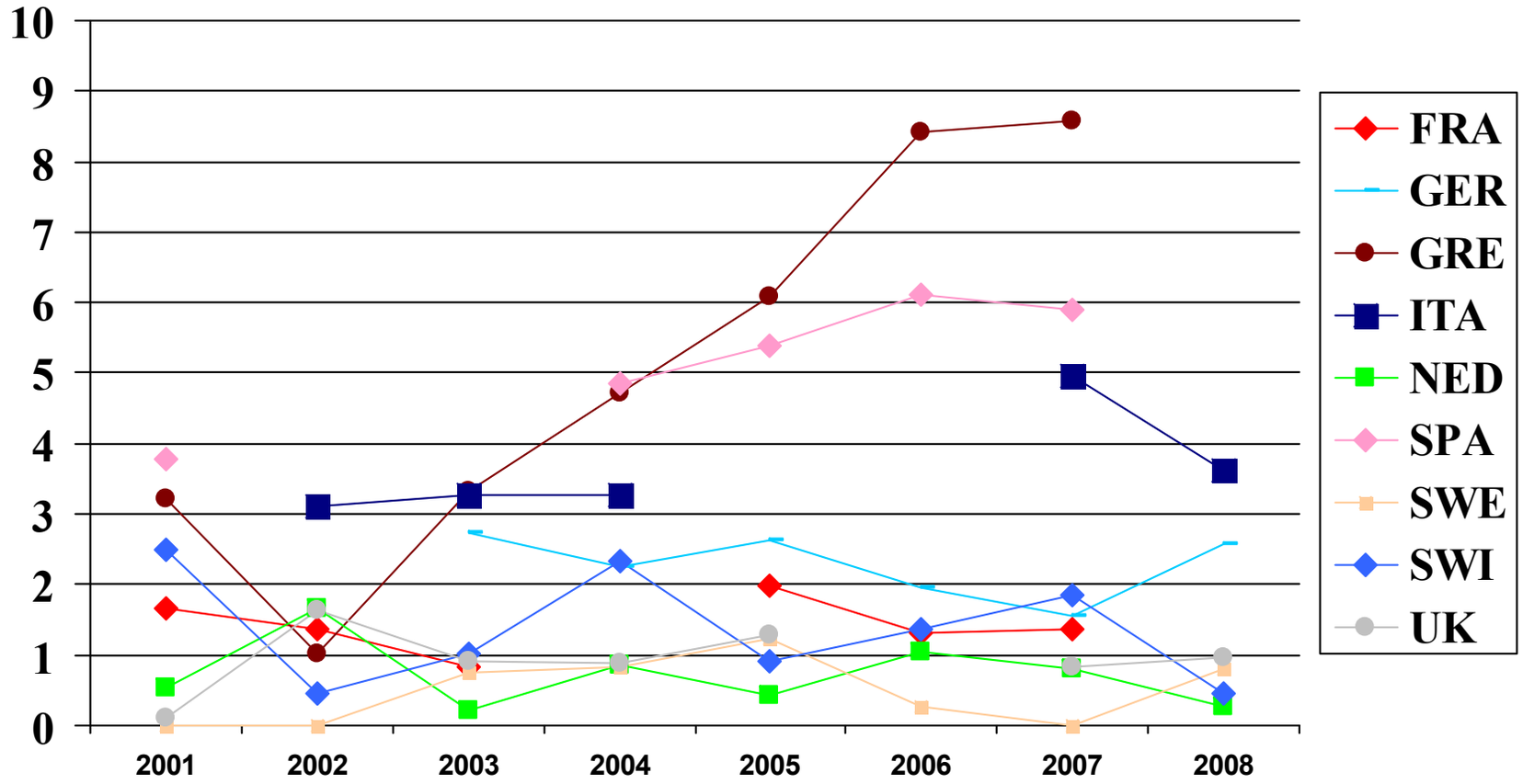
(x 100.000)



Courtesy M Jansen & S Oyonarte 24 feb 2011

INCIDENCE HIV REPEAT DONOR (RD)

(x 100.000)



Courtesy M Jansen & S Oyonarte 24 feb 2011

Trends of testing in Europe 2001-2008

HIV ND (prevalence)

increase: ITA (p=0.05), NED (p=0.034)

decrease: **FRA (p=0.015),** SWE (p=0.034)

HIV RD (incidence)

increase: **GRE (p=0.004)**

SPA (p=0.050)

Courtesy M Jansen & S Oyonarte 24 feb 2011

HIV positive donors: % MSM

MS	Period 1	Period 2
France	50% (2007)	53% (2008)
Germany	51% (2001-2005)	43% (2006-2010)
Greece	53% (2003-2008)	
Netherlands	31% (1995-2003)	45% (2004-2008)
Spain	74% (2008-2009)	
Sweden	29% (1995-2003)	25% (2004-2009)
UK	29% (1996-2008)	19% (2009)

Courtesy R Offergeld 24 Feb 2011

Modelling studies to interpret risks of

changes in donor deferral

- incidence and prevalence of markers in donor populations; testing and handling performance: risk factors for fast spread of new sexually transmitted infections (STI)

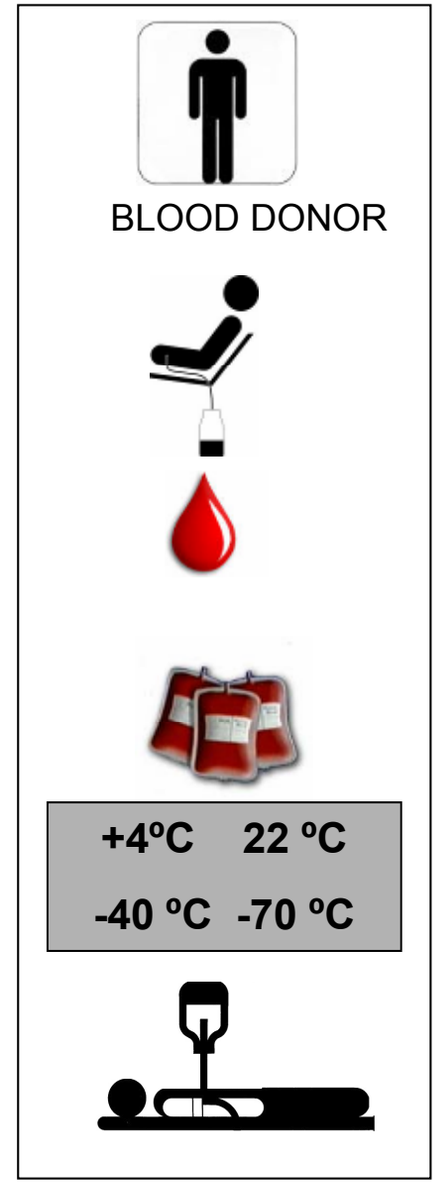
emerging STI

- risk factors: many sexual partners per interval; concurrency of partnerships; clustering and assortativity (= the sexual network); long asymptomatic phase of emergent infections,

Courtesy of Christel Kamp, Feb 2011

Safety and quality of blood components

- Recruitment and selection
- Blood collection
- Testing
- Preparation of components
- Release and distribution to
- Medicinal products or Transfusion



Better informed communities, present and future blood donors

Improved compliance by a number of tools:

- improved quality of information material
- ”state of the art” media techniques
- improved, standardised questionnaires for donors
- improved delivery of questionnaires
- evaluation of compliance

Improved data collection for regular assessment

- standardised post-donation interviews for verified positive donors

Courtesy M Heiden 24 Feb 2011

Sources of Data to Assess the Efficacy of Donor Deferrals (1)

Donor-derived data

- Prevalence and incidence
- Rates of deferral, post-donation information, other operational measures
- Collection of same information by a different mode
  - Post-donation risk interview (marker positive donors)
  - Post-donation risk survey (all donors)

Courtesy A Williams 24 Feb 2011

Sources of Data to Assess the Efficacy of Donor Deferrals (2)

General population data

- Marker prevalence
- Limited general population behavioral risk surveys
- FT donors after one instance of donor qualification vs. untested general population

Courtesy A Williams 24 Feb 2011

Channels for legislatory impact of the work by CD-P-TS

- Proposal of a resolution to be adopted by the Committee of Ministers
- Utilisation of the Guide to the collection, preparation and utilisation of blood components (Rec 1995/15)

Burning questions

- Are data strong enough to support a change in deferral criteria?
- Will we be able to uphold the common legislation?

Current synthesis from TS 057

- TS 057 has conducted its tasks
- and will present the proposed resoultion and the report to the CD-P-TS in Nov 2011