European requirements for blood donor selection and testing

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WORKSHOP QUALIFICATION OF NEW BLOOD DONORS BEFORE DONATION

Rome, 3 February 2014

Agenda

- EU legislation: product centred
- Transposition and implementation assessment

- Donor selection and testing req.: recent issues and evolutions
  - Deferral criteria in case of pandemic flu
  - Sexual risk behaviour
  - WNV NAT
  - IVD regulation
  - HIV risk mitigation

- How requirements could evolve?
- Conclusions

EU Directives for Blood and BCs: product centered

- **Directive 2002/98/EC**: standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
- **Directive 2004/33/EC**: information & eligibility of donors, storage, transport and distribution for blood & BC, QC
- **Directive 2005/61/CE:** traceability requirements and notification of serious adverse reactions and events
- **Directive 2005/62/CE:** Community standards and specifications relating to a quality system for blood establishments
- **Directive 2009/135/CE:** temporary derogations to certain eligibility criteria for WB & BC donors in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic

Requirements for donor selection (2002/98/EC) - 1

Art 16.Provision of information to prospective donors

Member States shall ensure that all prospective donors of blood or blood components in the Community are provided with information referred to in Article 29(b).

Art 17. Information required from donors

Member States shall take all necessary measures to ensure that, upon agreement of a willingness to commence the donation of blood or blood components, all donors in the Community provide the information referred to in Article 29(c) to the blood establishment.

Requirements for donor selection (2002/98/EC) - 2

Art 18 Eligibility of donors

1. BEs shall ensure that there are evaluation procedures in place for all donors of blood and BCs and that the criteria for donation referred to in Art 29(d) are met.

2. The results of the donor evaluation and testing procedures shall be documented and any relevant abnormal findings shall be reported to the donor.

Art 19. Examination of donors

An examination of the donor, including an interview, shall be carried out before any donation of blood or BCs. A qualified health professional shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.

Requirements for donor selection (2002/98/EC) - 3

- **Whereas (20).** Modern blood-transfusion practice has been founded on the principles of voluntary donor services, anonymity of both donor and recipient, benevolence of the donor, and absence of profit on the part of the establishments involved in blood transfusion services.
- ***Art. 20 Voluntary and unpaid blood donation***

1. Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.

2. Member States shall submit reports to the Commission on these measures two years after the entry into force of this Directive, and thereafter every three years.

Requirements for blood donor selection (DIRECTIVE 2004/33/EC)

ANNEX II. INFORMATION REQUIREMENTS

A. Information to be provided to prospective donors of WB or BC

B. Information to be obtained from donors by BEs at every donation

ANNEX III. ELIGIBILITY CRITERIA FOR DONORS OF WB AND BCS

1. ACCEPTANCE CRITERIA FOR DONORS OF WB and BCs
2. DEFERRAL CRITERIA FOR DONORS OF WB & BCs
    1. **Permanent deferral criteria for donors of allogeneic donations**
    2. **Temporary deferral criteria for donors of allogeneic donations**
    3. **Deferral for particular epidemiological situations**
    4. **Deferral criteria for donors of autologous donations**

BASIC TESTING REQUIREMENTS FOR WHOLE BLOOD AND PLASMA DONATIONS (Art 21 & Annex IV 2002/98/EC)

BEs shall ensure that each donation of blood and blood components is tested in conformity with requirements in Annex IV.

The following tests must be performed for whole blood and apheresis donations, including autologous predeposit donations:

— ***ABO Group*** *(not required for plasma intended only for fractionation)*

— ***Rh D Group*** *(not required for plasma intended only for fractionation)*

— *testing for the following infections in the donors: Hepatitis B (**HBs-Ag**), Hepatitis C (**Anti-HCV**), HIV 1/2 (**Anti-HIV 1/2**)*

Additional tests may be required for specific components or donors or epidemiological situations.

- *2004/33/EC ANNEX V, 2.2.* **Appropriate bacteriological control of the collection** and manufacturing process **must be performed**.

Technical requirements and their adaptation to technical and scientific progress (Art 29, 2002/98/EC)

The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2).

The following technical requirements and their adaptation to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2):

(d) requirements concerning the ***suitability of blood and plasma donors*** *and the* ***screening*** *of donated blood including*

— permanent deferral criteria and possible exemption thereto

— temporary deferral criteria;

Procedures for the exercise of implementing powers conferred on the Commission (Decision 1999/468/EC)

Art 5. Regulatory procedure

1. *The Commission shall be assisted by a **regulatory committee** composed of the representatives of the Member States and chaired by the representative of the Commission.*

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft…

3 – 6 …

Art 7. Rules of procedure, conditions on public access to documents, information of European Parliament…

Transposition check of EU blood directives (DG SANCO, 2012)

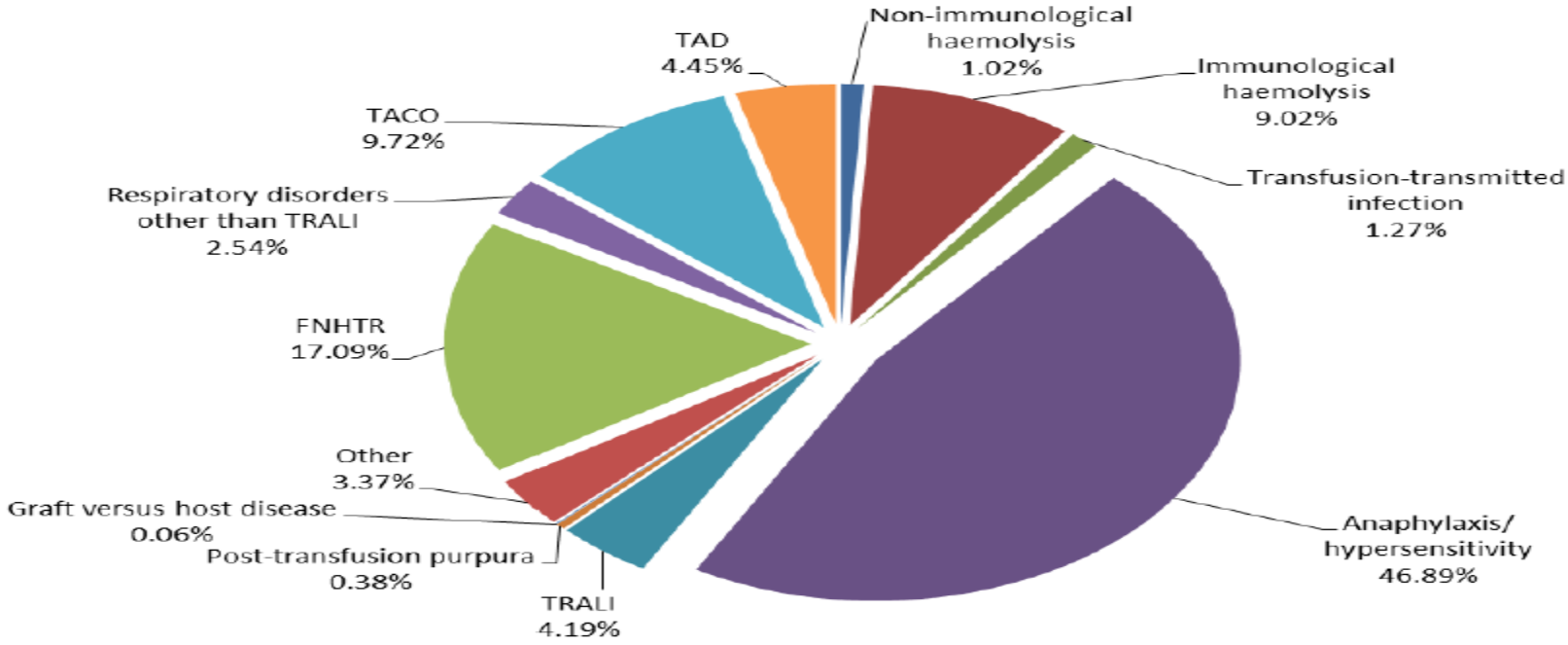
- 22 MS implemented EC directives.
- 2 MS were not compliant with lists of deferral criteria for donors
  - autologous donations ,
  - age of "17 to 18 years, unless classified as a minor by law, or written consent of parent or legal guardian in accordance with law"
  - "active bacterial infection" as a deferral criteria.
- 2 MS had less stringent age requirements.
- 1 MS has translational problems from English to other language.

Conclusion (EC): **directives have been properly transposed by the majority of the MS and no infringement procedures were initiated.**

EC ANNUAL REPORTING OF SERIOUS ADVERSE EVENTS AND REACTIONS FOR WB AND BCs for 2011

Transmitted infections: 20 cases (1.27% of reported SARs)

- 18 cases of bacterial infections (1.14%),
- 1 case of viral infection (not specified) (0.06%)
- 1 case of parasitical infection (malaria) (0.06%)



Deferral criteria in case of pandemic flu: a new EU Directive in short time

- **Sept 2009-** 2 EBA consultations on H1N1 Flu (May – Sept) shared with DG SANCO and EU MS.
- **Oct 2009-** Blood regulatory committee meeting

« unanimously supported the proposal for a Directive relaxing exceptionally and temporarily 2 blood donors selection criteria in case of risk of blood shortage due to the pandemic ».

- **NOV 3 2009:** COMMISSION DIRECTIVE 2009/135/EC allowing temporary derogations to certain eligibility criteria
  - minimum haemoglobin levels: 120 g/L (F), 130 g/L (M)
  - deferral period of no less than 7 d after cessation of symptoms of flu-like illness

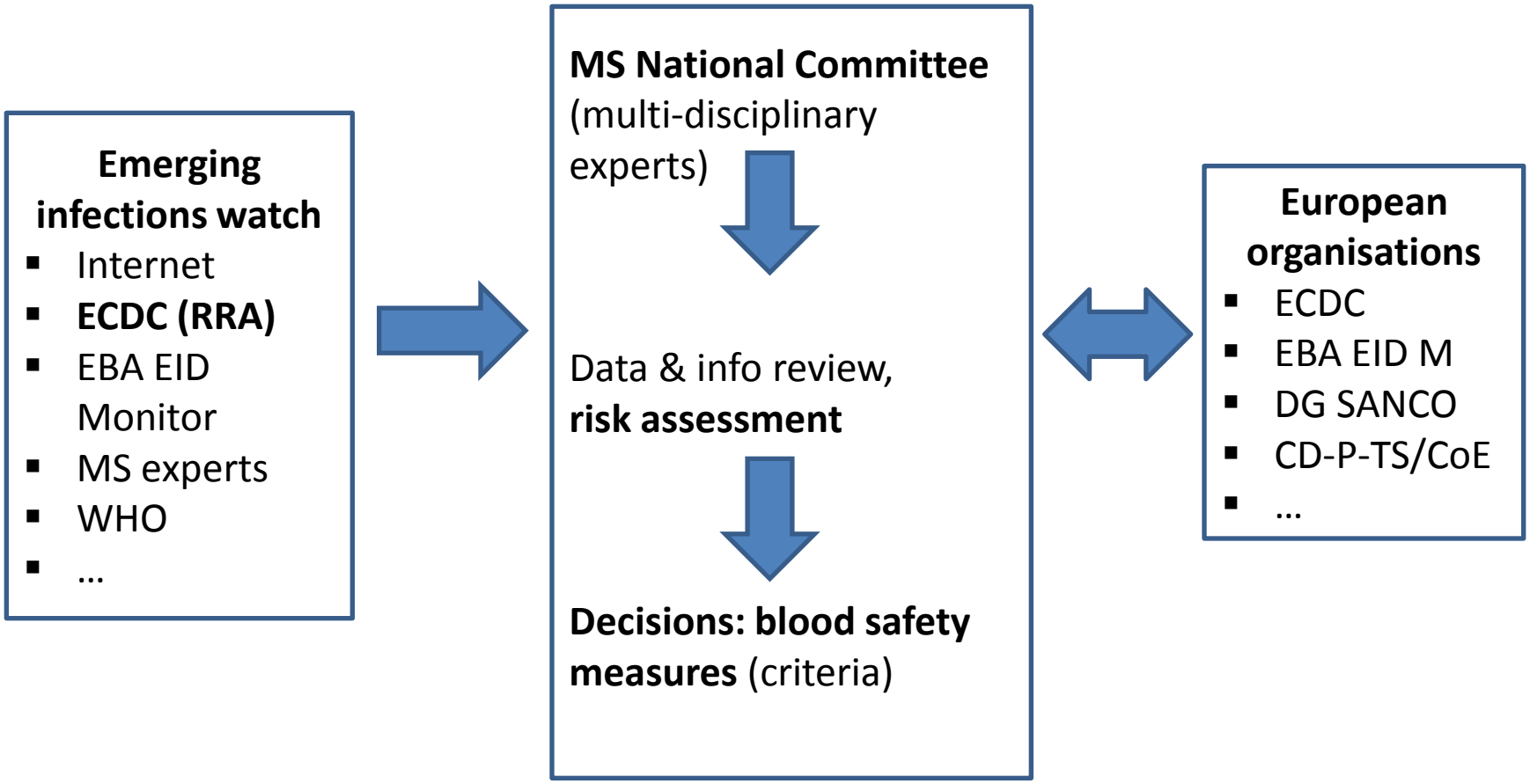
Selection of donors with sexual risk behaviour: a longer process, not completed yet

- Discrepant interpretation of “risk” and “high risk” of acquiring severe infectious diseases that can be transmitted by blood
- Work by international experts (CD-P-TS 2010-12)
- CoE Com Ministers Resolution (2013)
  - Collect, evaluate **epidemiological data** to facilitating **risk analysis**
  - Temporary deferral for a given risky sexual behaviour when **demonstrated** that this sexual behaviour does not put the donors at high risk of acquiring severe infect. diseases transfusion-transmissible
  - Improving **donor adherence** to all donor-selection criteria in force
  - Standardised collection of data on risky sexual behaviour having an impact on blood donor management and transfusion safety for an internationally **harmonised interpretation of related deferral criteria**
- Still need for more in EU Directive?

WNV Risk: converging and effective approach

- **Preparedness plan 2011**
  - Developed from work/studies by international experts
  - Risk assessment
  - Blood safety measures for affected and non affected areas: **algorithm** depending on risk level
- **Preparedness plan 2012**
  - **NAT screening for donors** when lot of travellers come back from affected areas in order to ensure the **blood supply**
  - No need for a revision of Directive 2004/33/EC
- Improved but to be further developed:
  - Collaboration **Regulators – BEs**
  - **Information sharing** (epidemiological data, safety measures)

Adapting requirements to evolving infectious risks: converging decision making systems



IVD regulation: unexpected threat for patients

- EC proposal for Regulation on IVD: removal of "in-house manufacturing" for class D (detection of transmissible agents, blood grouping)
- Suppression of "niche" IVDs manufactured by BEs: **major risk for patient safety**, through infection of recipients or immunological incompatibility
- Lobbying resulted in modifications avoiding these risks in amendments voted by MEPs (OCT 2013).
- But, change in definition of **Health institution** could impede implementing modifications in BEs
- Ongoing lobbying at **EU Council** to solve this in final Reg.

Mitigating HIV transmission in EU: ongoing since last notification (2013)

- **Notification** (FEB)
- **DG SANCO – NCA meeting** (APR)
  - Non detection (window period), risk behaviour not indicated at pre-don interview
  - Discussion: treshold / sensitivity for HIV NAT (pool 96), **pre-don. qualification of new donors?**
- **DG SANCO – NCA meeting** (OCT)
  - Draft objectives of a WG on pre-don. qualification of new donors presented (ECDC-EBA EID M - Regulators)
    - Assessment of measure (retro- and prospectively)
    - If interest confirmed, develop guidelines (regulation?)
- To be explored and discussed further (Rome, Feb 3- 2014)

How donor selection requirements could evolve?

- De Kort et al 2013. “DHQ is not a cost-effective tool for further reducing TTIs. The high costs per case prevented and the small number of QALYs gained argue against maintaining deferral policy through the DHQ at the current level.”
- O’Brien et al 2013. “Tattoos and piercing are not predictive of TT disease in our donors and the safety benefit of these deferral criteria in Canada is, therefore, questionable.”
- **Deferral criteria should be more evidence based**
  - Nature and size of the risk?
  - Prevalence/incidence of the risk?
  - Validity of the test?
  - (If there is no test:) Validity of the question?
- **Cost-effectiveness of deferral criteria should be reviewed**

Conclusions, proposed ways forward

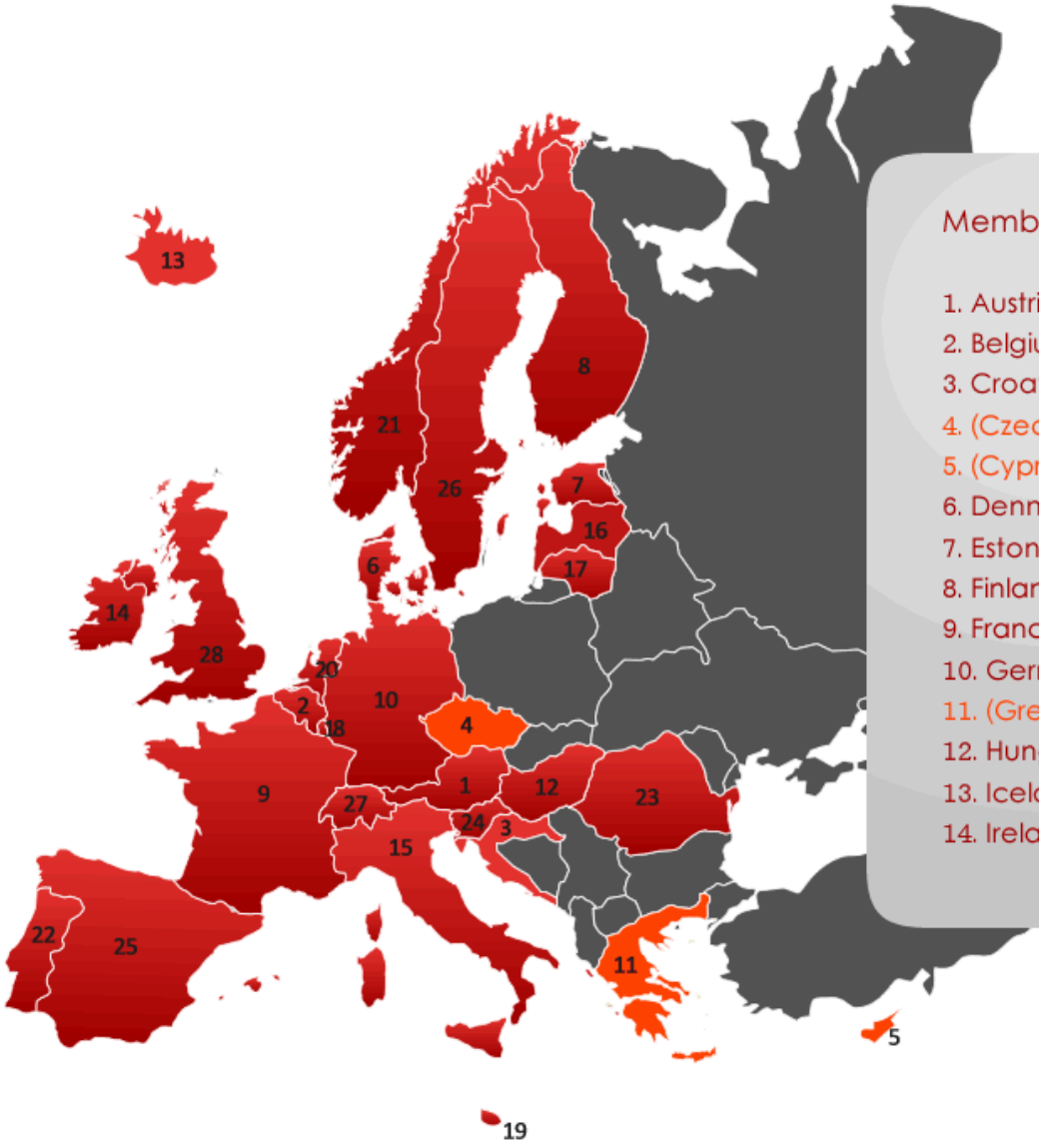
- Current regulation: well transposed and implemented

- In the perspective of a revision of blood directives, need to study evolutions of donor selection (and testing) requirements
  - Review criteria with available evidence
  - Review cost effectiveness of criteria
  - Improve haemovigilance: data and analysis completed to allow for **benchmarking practices and resulting safety**
  - Blood directive more patient centred?

- Develop collaboration between Regulators and BEs, where needed

Thanks for your attention!

EBA European Blood Alliance



Member (Dormant)

1. Austria
2. Belgium – 2
3. Croatia
4. (Czech Republic)
5. (Cyprus)
6. Denmark
7. Estonia
8. Finland
9. France
10. Germany – 2
11. (Greece)
12. Hungary
13. Iceland
14. Ireland
15. Italy
16. Latvia
17. Lithuania
18. Luxembourg
19. Malta
20. The Netherlands
21. Norway
22. Portugal
23. Romania
24. Slovenia
25. Spain
26. Sweden
27. Switzerland
28. United Kingdom – 4

Population: 450 M
Blood donations: 18 M