Benchmarking blood donor safety practices: a first experience

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Background and objectives

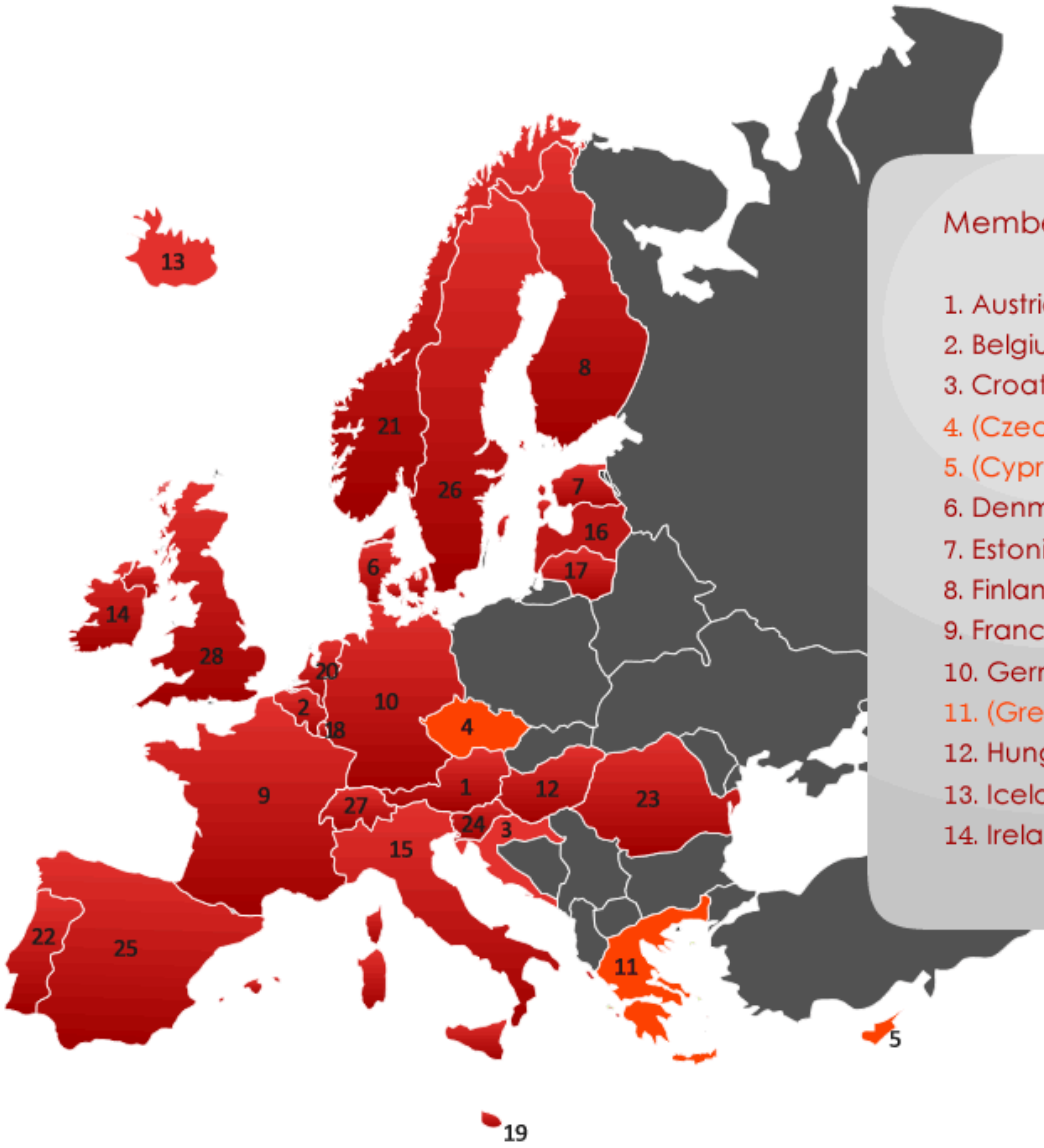
Background: blood donor safety

- Major importance
- Assessment in scientific studies: recent
- Important variations in practices still persist.

Objectives

- To **benchmark donor safety practices** implemented at EFS, with help from international experts
- To **identify ways of improvement**
  - for EFS
  - and other blood establishments of EBA.

EBA European Blood Alliance



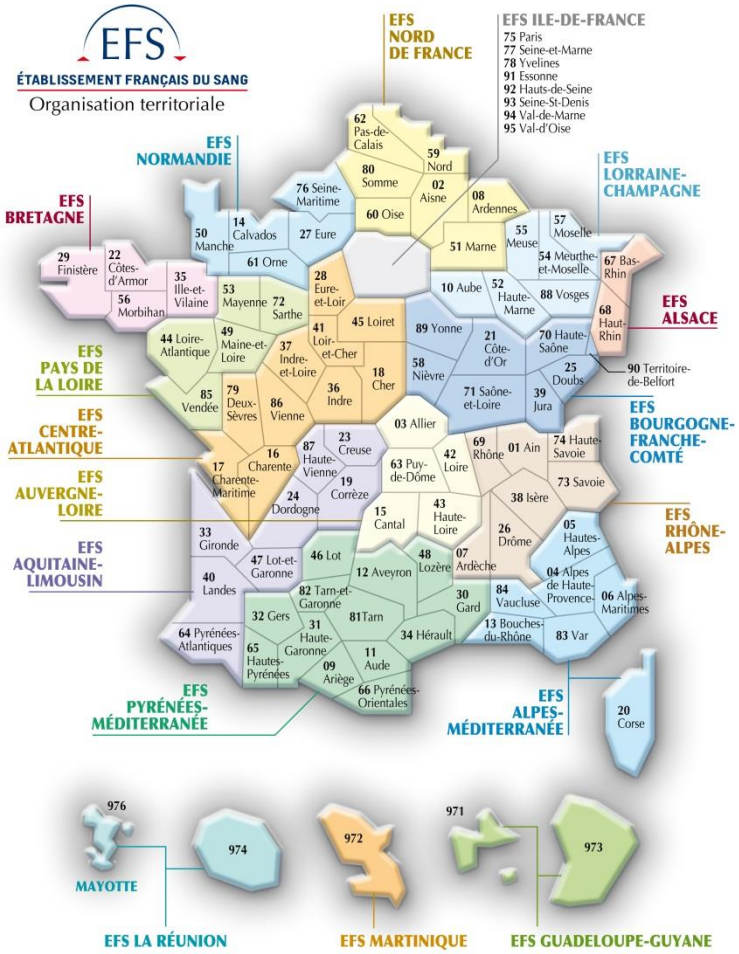
Member (Dormant)

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

Etablissement Français du Sang

LE LIEN ENTRE LA GÉNÉROSITÉ DES DONNEURS DE SANG ET LES BESOINS DES MALADES



2012:

- 3,1 million blood donations
- 1.7 million blood donors of which 360,000 first-time donors
- 153 blood centers, 40,000 mobile blood collection operations
- 9,800 employees
- A budget of €846 million

L'EFS: the only transfusion establishment in France:

- Risk for emulation, constructive criticism and innovation
- Professional expertise seldomly present outside of the EFS
- Expert transfusion « regulators »: most often trained at the EFS
- Insufficient outreach towards «non-french » transfusion experts by our regulators and health authorities

Maybe are we not that good!?

Emulation (Webster) : ambition or endeavor to equal or excel others

Benchmarking: definition and process (N. Heddle, 2013)

Definition

*"A structured, continuous, collaborative process in which comparisons for selected indicators are used to **identify factors** which when **implemented** will **improve** transfusion practices".*

Benchmarking process components

1. **Comparisons** between institutions to identify practice variation;
2. Communication and/or evaluation process to **identify** factors associated with **best practices**;
3. **Introduce** best practice factors into one's own setting;
4. **Re-evaluate** performance.

Methodology and Main Outcomes

Material and Methods

- **Voluntary basis**: request from EFS to EBA
- **Joint EFS – EBA Meeting / Paris, 20 – 21 June 2013**
- **EFS presentation to 4 experts** (DE, FI, NL, UK):
  - D1: Visit of blood collection site
  - D2: Workshop with presentation by EFS of all available data as to means and results with regard:
    - to **preventing** adverse donor reactions
    - **curing / managing** donors with adverse reactions
    - donor **vigilance**

- Discussion with EFS managers involved in donor safety.
- EBA - facilitated identification of best practices and ways for improvement of donor safety.
- Identification of strengths, weaknesses and actions review approved by all participants.

Specifics

Whole blood donation volumes

Practice variation

- **EU Regulation:** 450 +/- 50mL
- **FR, UK:** donors deferred if planned collected volume exceeds 15 % of blood volume (BV)
- This limitation is apparently not always implemented elsewhere.

Good Practice (GP) recommended

- Blood establishments (BE) not doing so yet should implement CoE Guide recommendations: "*Because of risk of adverse reactions, no more than 15 % of estimated BV should be collected. In case of* ***women weighing < 65 kg*** *and donating a total > 485 mL (****450*** *+ 35 mL for testing), the blood volume should be calculated.*"

Calculated minimum blood volume of a female donor donating 485, 510, or 535 mL

(CoE Guide, 17th edition, 2013)

Volume of blood to be collected	Maximum percentage of blood volume collected	Minimum acceptable blood volume
450 mL + 35 mL	15%	3,233 mL
475 mL + 35 mL	15%	3,400 mL
500 mL + 35 mL	15%	3,567 mL

- Men weighing ≥ 50 kg have a sufficiently large BV to donate a total 535 mL (500 + 35)
- Women weighing ≥ 50 kg have a sufficiently large BV to donate a total 485 mL (450 + 35)

Hemoglobin measurement and levels

Practice variation

- **EU Reg:** Hb in donor's blood ≥ 125 g/L (F); ≥ 135 g/L (M)
- **France** (based on Lotfi 2005 and Ziemann 2006 studies)
  - Pre-donation Hb screening: new & returning donors, donors with <125 g/L (F);< 135 g/L (M) at previous donation blood count
  - Blood count performed at each donation
  - No Hb screening if ≥ 125 g/L (F); ≥ 135 g/L (M) at previous donation
- **Other countries**: pre-donation Hb screening in all donors .

Conclusion/action

EFS encouraged to submit its experience for publication in a peer reviewed journal, with regard to donor safety (and in the perspective of a possible EU blood directive revision).

Prevention of Vasovagal reactions

EFS Data, 2012
3,1 million blood donations

Incidence per 100 000 donations

Immediate vasovagal reactions	99,9

Whole Blood	101,2
Apheresis	93,0

Donor 18<=30 years old	191,0
Donor > 30 years old	28,4

Male donors	85,1
Female donors	117,4

New	288,4
Repeat	68,2

Delayed vasovagal reactions	12,1

Whole Blood	12,0
Apheresis	12,8

Donor 18<=30 years old	13,9
Donor > 30 years old	7,5

Male donors	3,6
Female donors	22,2

New	18,8
Repeat	11,0

Prevention of Vasovagal reactions

Practice variation

- **EU Regulation:** no requirement
- **FR:** donor hydration is set up; muscle tension not encouraged
- **Other countries:** donor hydration set up and muscle tension encouraged.

GP recommendation

- Donor hydration and muscle tension to be considered as GP
- EFS encouraged to reorganize the post-donation resting areas to insure facial contact between donors and staff
- EFS encouraged not to wait too long to perform its study on effectiveness of isotonic hydration and muscle tension.

"Evasion" study: randomized clinical trial evaluating the impact of isotonic hydration and/ or muscle tension on the frequency and severity of vasogal reactions in 4500 whole blood donors

Prevention of cardiovascular decompensation

Practice variation

- **EU Regulation:**
  - Prospective donors with active or past serious CV disease: permanent deferral
  - Blood pressure (BP), pulse rate (PR): no requirement
- **FR, DE, NL:** BP and PR measured before each donation
- **FI, UK:** BP and PR not measured in blood donors

Conclusion/action

- Studies needed to assess potential value of BP and PR for donor safety
- FR requested to make its SOP available for all other criteria implemented for preventing this type of risk.

Qualification required for pre-donation interview

Practice variation

- **EU Regulation:** interview by a **qualified healthcare professional**
- **FR, DE:** interview must be carried out by a **MD**
- **FI and UK:** interviews carried out by **non-MDs (**MD on call).
- **NL:** MD for new and returning donors, non-MDs for regular donors, MD on site.

Conclusion/action

– Impossible to objectively identify GP for pre-donation interviewer qualification (MD or not).

– EFS to pursue its project to introduce qualified nurses for pre-donation interviews and publish its experience.

Staff training and qualification

EFS practice

- Training procedure
- Staff qualification
- Staff assessment after re-training: maintain, upgrade or downgrade qualification.

Conclusion/action

- EFS practice appreciated by the international experts
- EFS requested to make available to other BEs its staff training and qualification procedures (available in english).

Self-assessment system to reduce risks

EFS practice

Internal accreditation / Enabling

Self-assessment system to reduce risks

EFS practice

1- Internal standard established on the basis of essential security feature identified

2- Self-assessment guide established on:

-> what is expected regarding the internal standard

-> a scoring system

3- A technical committee in charge of:

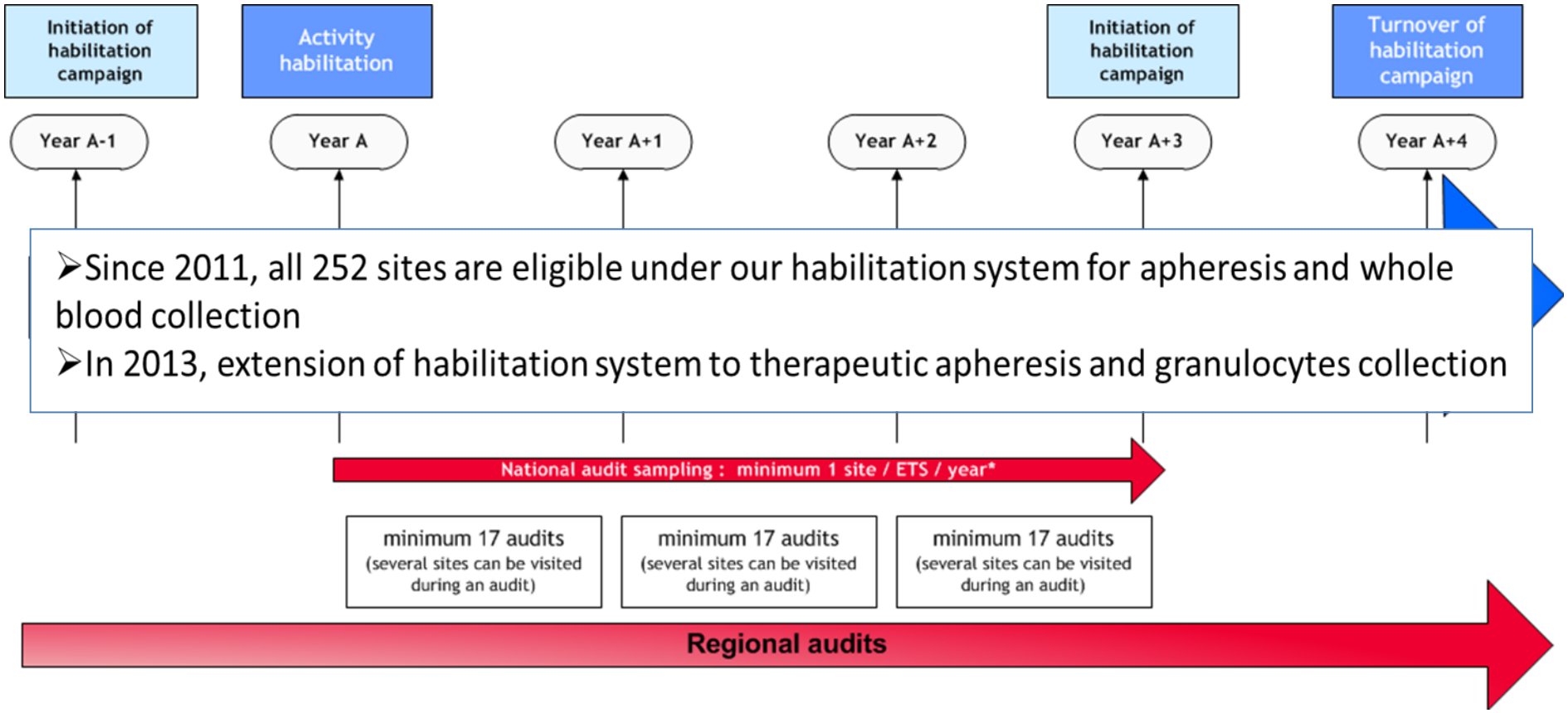
-> analyzing and evaluating all results and actions plan regarding safety aspect

-> recommending actions

-> concluding about eligibility

-> appointing audits on specific sites

Self-assessment system to reduce risks



Conclusion/action

- EFS practice appreciated by the international experts
- EFS encouraged to publish its experience and to further assess and validate the method in a second country.

Donor vigilance to monitor/assess donor adverse events ("near misses") and reactions

Practices: globally equivalent in all 5 countries

- Rates of severe adverse reactions in donors roughly comparable
- All significant SARD and SAE quickly reported to BE board staff and discussed at national level
- Difficulties for benchmarking practices and deducing donor safety measures from current vigilance data.

GP recommendations

- Regular discussion on donor safety issues at national level should be encouraged as GP
- Need to improve capacity to deduce donor safety measures from vigilance data

Post-workshop follow up: current status

Whole blood donation volumes

Practice variation

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Post-donation rest areas will be adapted when needed current 2014 Evasion study underway, 2000 donors included as of february 2014

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SOP in english being prepared

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Practice variation

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Large scale experimentation to evaluate feasibility and safety of pre-donation interviews by nurses scheduled to be initiated in 2014

Staff training and qualification

EFS practice

- Training procedure
- Staff qualification
- Staff assessment afte… …grade or downgrade qua…

Staff training and qualification procedures to be made available

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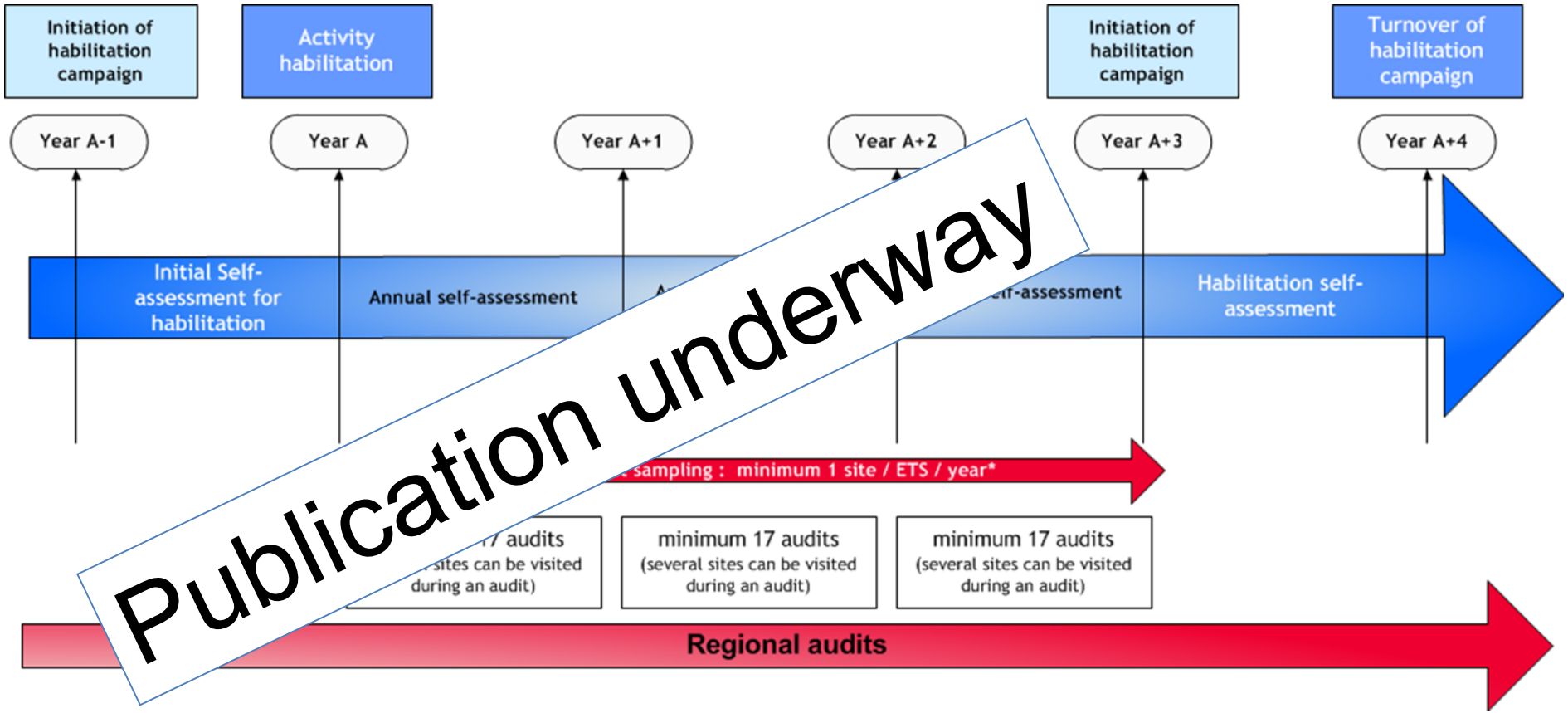

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– Need to improve capacity to deduce donor safety measures from vigilance data

For all of us!

Conclusions

- The international experts appreciated the efforts of EFS and the method used for this meeting.
- The benchmarking method set up for this meeting on donor safety proved to be effective in identifying practice variation and for a number of items good (best) practice
- They expressed confidence in the system and measures implemented by EFS for donor safety
- A follow up of the meeting outcomes will be organized to assess if this benchmarking exercise succeeded in inducing changes in practices, and beyond in improving donor safety.

Benchmarking donor safety practices: lessons drawn

- **Added value, helped identifying:**
  - GPs for medical points (blood donation volumes, muscle tension) and organisational points (staff training and qualification);
  - Domains for which GPs cannot be identified, needing (further) studies (Hb screening, qualification for pre-donation interview).
  - Potentially helpful for regulation revisions
- **Feasibility, acceptability**
  - Based on a careful preparation (neither inspection, nor audit)
  - All participants positively involved
- **Ways for improvement**
  - Completing the benchmarking cycle

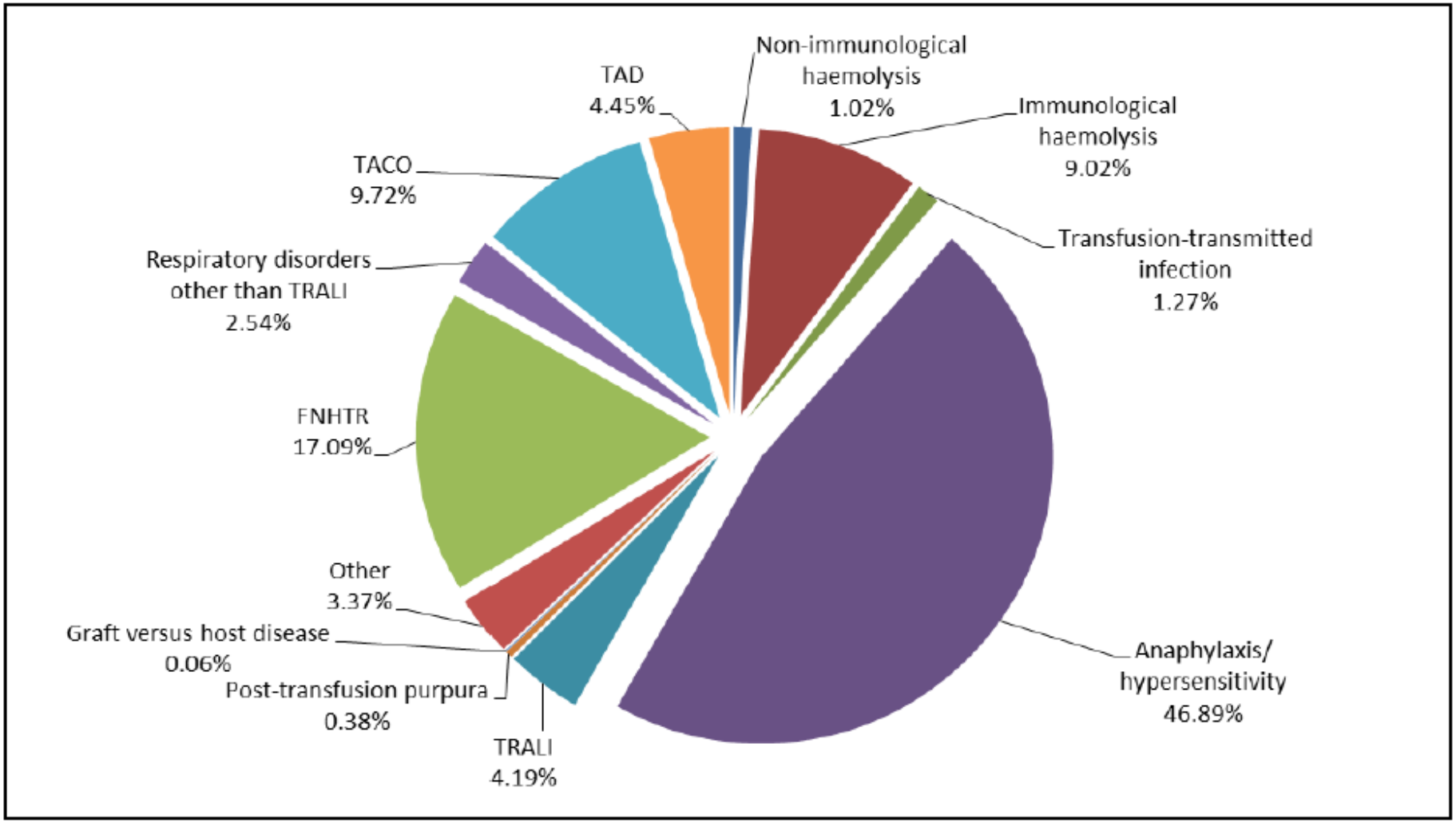
Current limitations of donor vigilance

- **Definitions**
  - Universally accepted definitions still missing despite huge efforts
- **Denominators**
  - Sometimes questionable or even missing (eg units distributed vs transfused)
- **Distance between vigilance data and safety practices**

→ **Capacity of haemovigilance to bring measures to improve donor (and patient) safety?**

→ **Benchmarking safety practices: a desirable complement to haemovigilance?**

Annual EU reporting of serious adverse reactions for blood & BCs (2011): haemovigilance limitations



Conclusions, ways forward

- **Benchmarking donor safety practice**
  - An effective method to identify good practices and also domains needing further studies to do so.
  - Subject to careful review of practices, collaboration with international experts, and completion of benchmarking cycle.
- **Towards a more effective role of donor vigilance to continuously improve donor safety?**
  - Prioritising practices to benchmark
  - Re-assessing impact after implementation
- **Applicability to patient haemovigilance?** To be evaluated.

Acknowledgements

European experts

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- Rachid Djoudi

Thank you for your attention!

Questions, comments?