Total Traceability
How is this mandatory instruction being in Europe?

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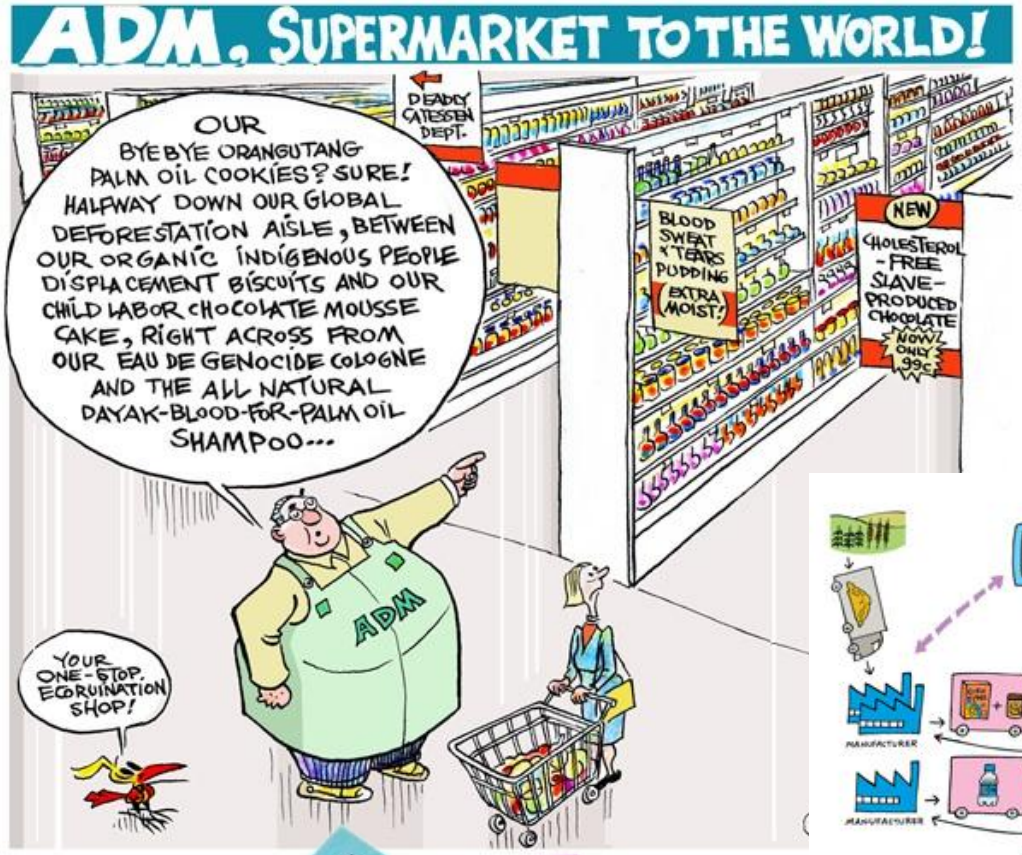
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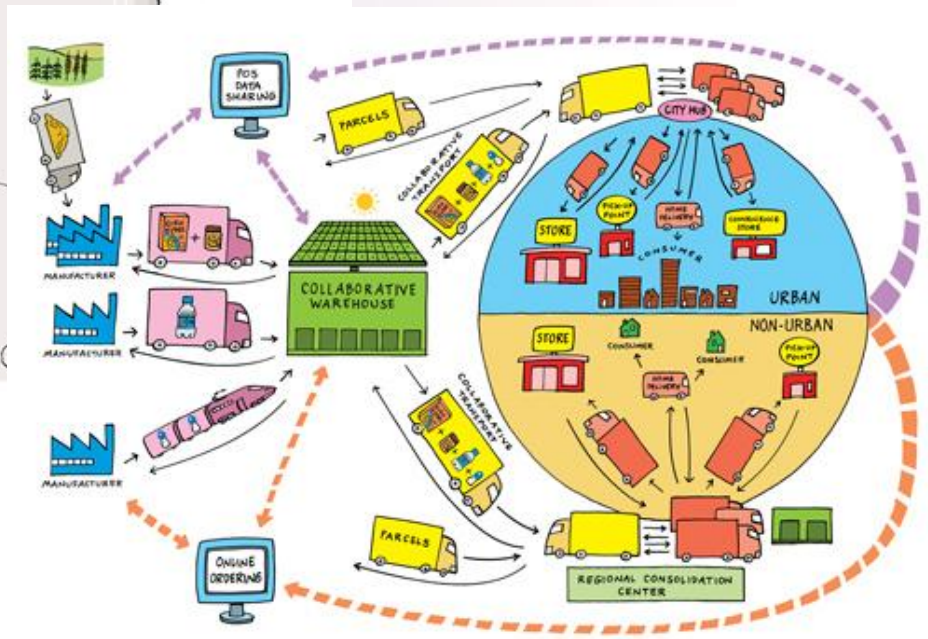
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Aim

- To assess the implementation of blood components traceability status at European and global level, collect information about current practices and evaluate the compliance for confirming the final destination of blood components.

Haemovigilance Requirements

- Traceability
- Notifications of serious adverse events and reactions

Traceability
Directive 2002/98/EC

- Blood and blood components must be traceable from donor to recipient and vice versa.
- MS must implement unmistakeable identification procedures, record and maintenance.
- MS must implement an appropriate labeling system.
- Traceability information should be kept at least 30 years.

CHAPTER V

HAEMOVIGILANCE

Article 14

Traceability

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.

To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a).

With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2. Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3. Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

Traceability
Directive 2005/61/EC

- The regulations require not only "unambiguous traceability" of all blood and blood components but also the evidence of final destiny of all blood components.

- The regulations require the compliance with the Directives identification system, data record and labeling requirements.

Article 2

Traceability

1. Member States shall ensure the traceability of blood and blood components through accurate identification procedures, record maintenance and an appropriate labelling system.

2. Member States shall ensure that the traceability system in place in the blood establishment enables the tracing of blood components to their location and processing stage.

3. Member States shall ensure that every blood establishment has a system in place to uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given blood component has been delivered.

4. Member States shall ensure that all facilities have a system in place to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded or returned to the distributing blood establishment.

5. Member States shall ensure that every blood establishment has a unique identifier that enables it to be precisely linked to each unit of blood that it has collected and to each blood component that it has prepared.

Article 3

Verification procedure for issuing blood or blood components

Member States shall ensure that the blood establishment, when it issues units of blood or blood components for transfusion, or the hospital blood bank has in place a procedure to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

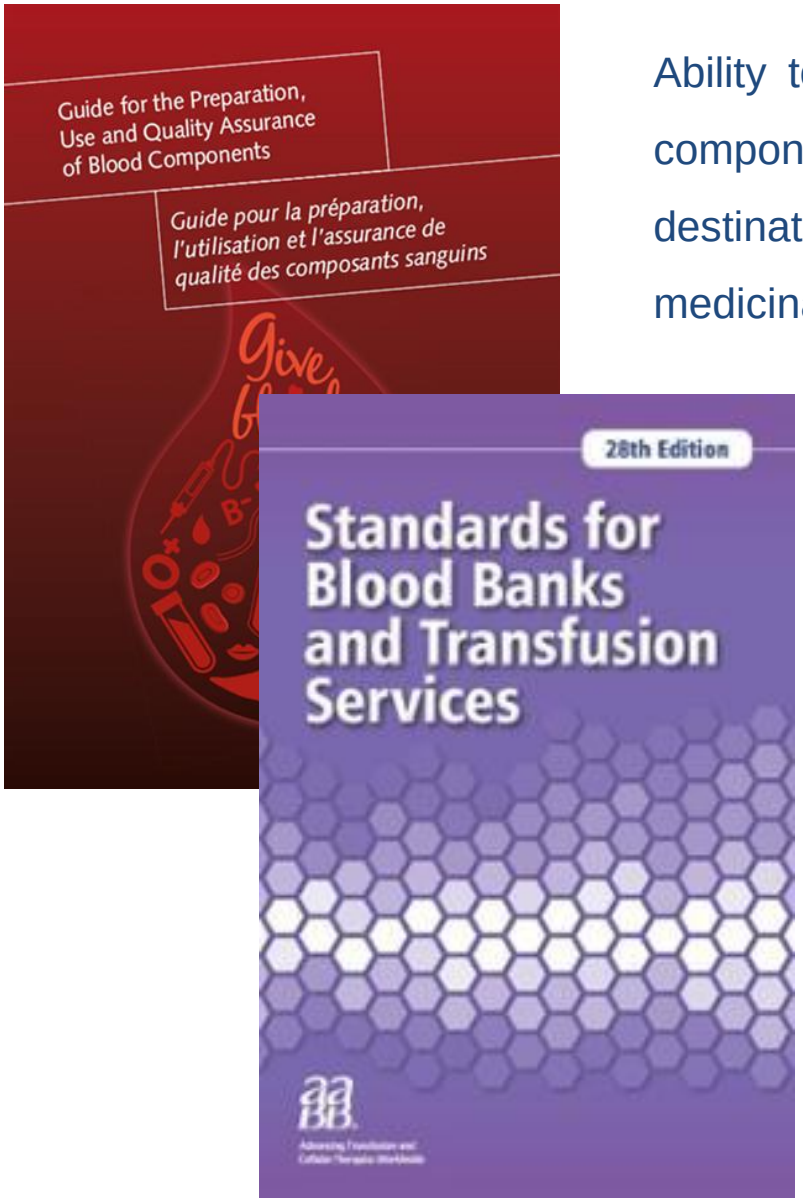
Article 4

Record of data on traceability

Member States shall ensure that blood establishments, hospital blood banks, or facilities retain the data set out in Annex I for at least 30 years in an appropriate and readable storage medium in order to ensure traceability.

Traceability definition
Directive 2005/61/EC

- Traceability means the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa.



Ability to trace each individual unit of blood or blood components derived from it from the donor to its final destination, whether this is a patient, a manufacturer of medicinal products or disposal, and vice versa.

5.1.6.2. Traceability

The blood bank or transfusion service shall ensure that all blood, blood components, tissue, derivatives, and critical materials used in their processing, as well as laboratory samples and donor and patient records, are identified and traceable.

The ability to follow the history of a product or service by means of recorded identification.

The Survey

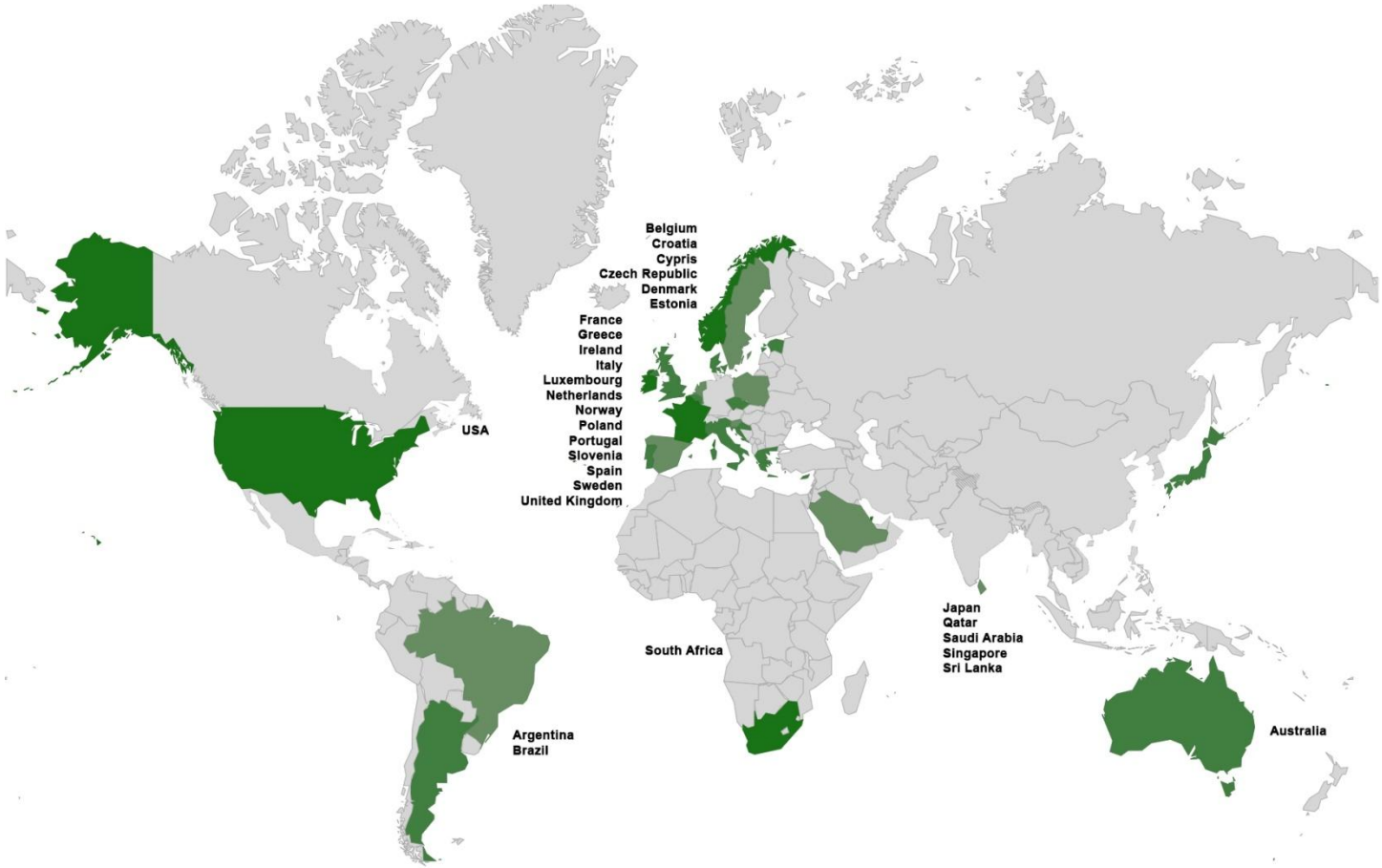
- 28 EU MS Competent Authorities as well as Norway
- 29 ISBT Haemovigilance Working party members, from different countries outside Europe.

The Questionnaire

- ✓ Respondents 'characteristics
- ✓ Blood Supplier
- ✓ Haemovigilance System
- ✓ Full traceability
- ✓ Identification procedures and records
- ✓ Labelling System requirements
- ✓ Record of data
- ✓ Goods traceability procedures

The survey was available online from 2 December 2013 to 7 February 2014.

The Survey – Respondent countries



30 answers were received from 29 countries
European countries – 19 answers – 65.5%
Non European countries – 11 answers – 37.9%

The Survey – Profile of Respondents

	European	Non European	Total	%
Regulatory Agency /Competent Authority	14	2	16	53.3
National Haemovigilance Office	2		2	6.6
Professional society		1	1	3.3
Blood Establishment	7	8	15	50
HBB selection and compatibility testing	4	6	10	33.3
Clinical use of components	1	5	6	20

* More than one answer was allowed

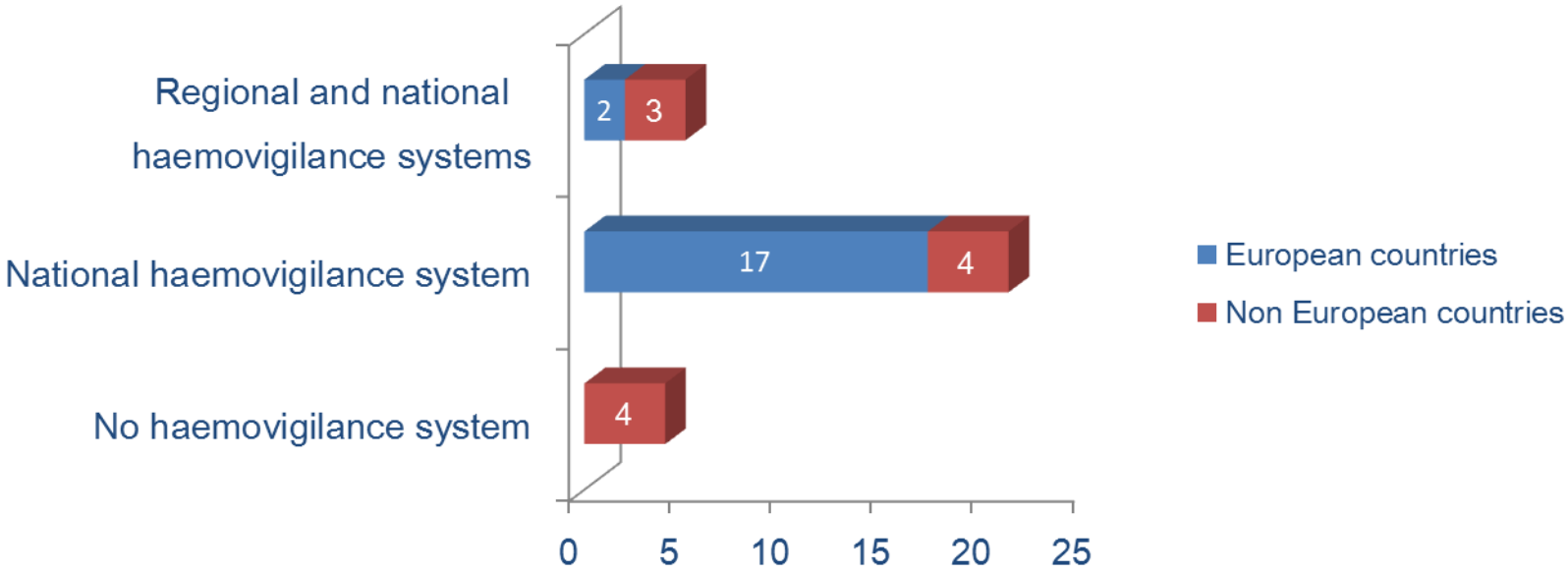
73.3% of the respondents were senior staff e.g. head, director, chief, national coordinator or senior consultant in their organizations.

73.7% of European respondents were from Regulatory agency/ Competent Authority and 10.5% from national haemovigilance offices.

36.4% of Non European respondents were involved with Blood Establishment responsibility area, Hospital blood bank and clinical use of components.

Blood supplier Haemovigilance System

	European countries	Non European countries	Total	%
One blood supplier	2	5	7	23.3
More than one blood supplier	17	6	23	76.7
Total	19	11	30	100



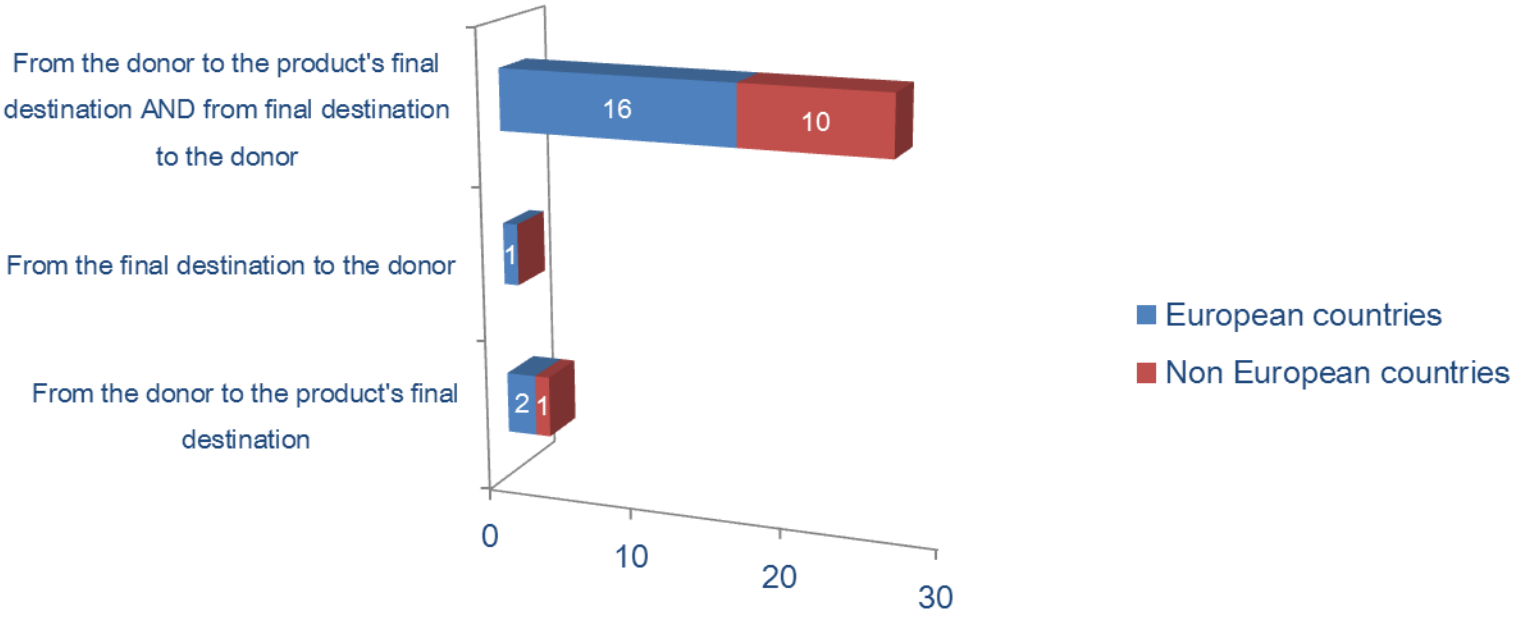
86.7% of the countries, 100% of European countries, have a Haemovigilance System in place .

Traceability Regulations/ National Law Directives

- All the respondent countries but two, Sri Lanka and Singapore, have regulations or national law on traceability.

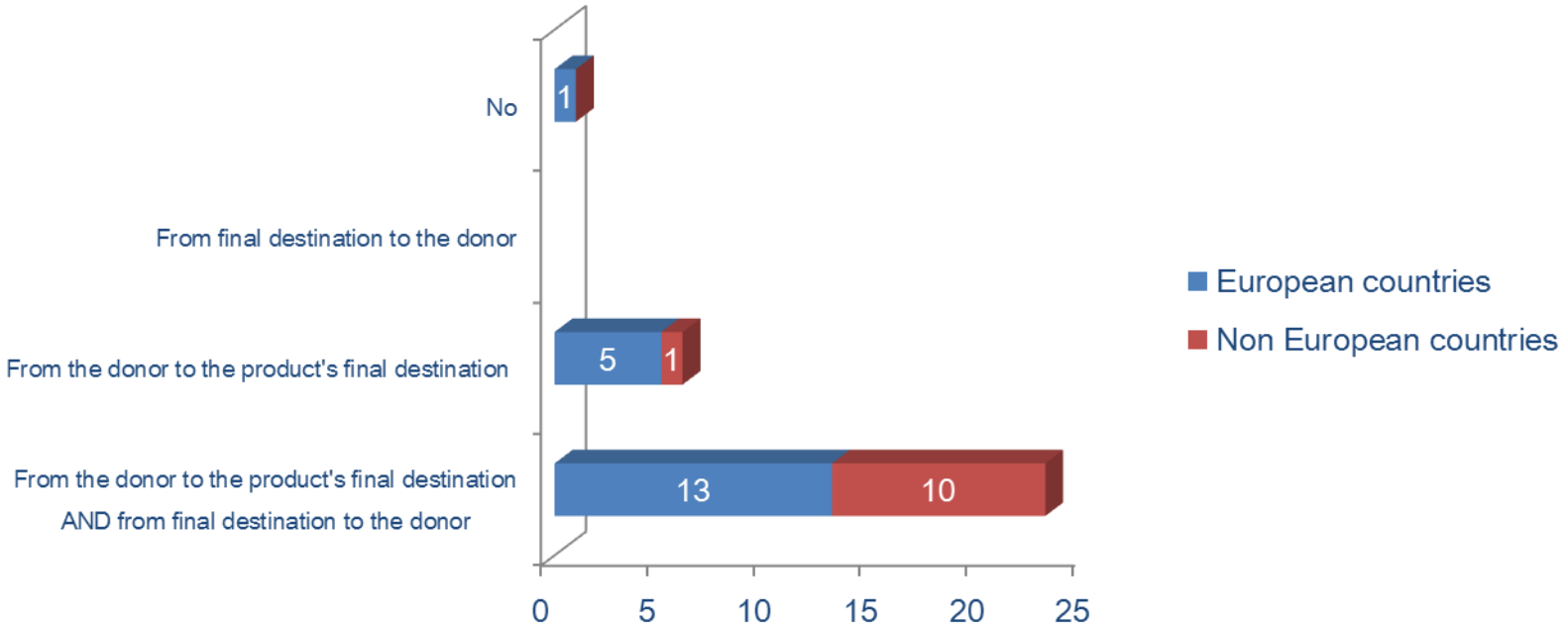
- In all EU MS the European Directives were transposed into national law between 2005 and 2007.
  - 2005 – Belgium, Denmark, Estonia, Greece, Ireland, Norway, UK.
  - 2006 – Croatia, Luxembourg, France, Poland, Sweden.
  - 2007 - Cyprus, Czech Republic, Italy, Netherlands, Portugal, Slovenia, Spain.

Procedures to trace each blood donation and its components



86.7% of the respondents (84.2% of the European respondents) have procedures in place to trace each blood donation and its components from the donor to their final destination and vice versa.

Procedures to trace each blood donation and its components in emergency situations



76.6% of the responding countries (68.4% of the European respondents) have procedures in place to trace each blood donation and its components from the donor to its final destination and vice versa in emergency situation*.

**Situations where patients may not have been identified at the time of transfusion or in mass disaster.*

Full component traceability

Component Traceability	European countries	Non European Countries	Total	%
100%	12	3	15	52
90%	3	5	8	27.5
80%	3	2	5	17.2
70%	1	0	1	3.4
60%	0	1	1	3.4

As a % of full component Traceabilty

This classification is based in:

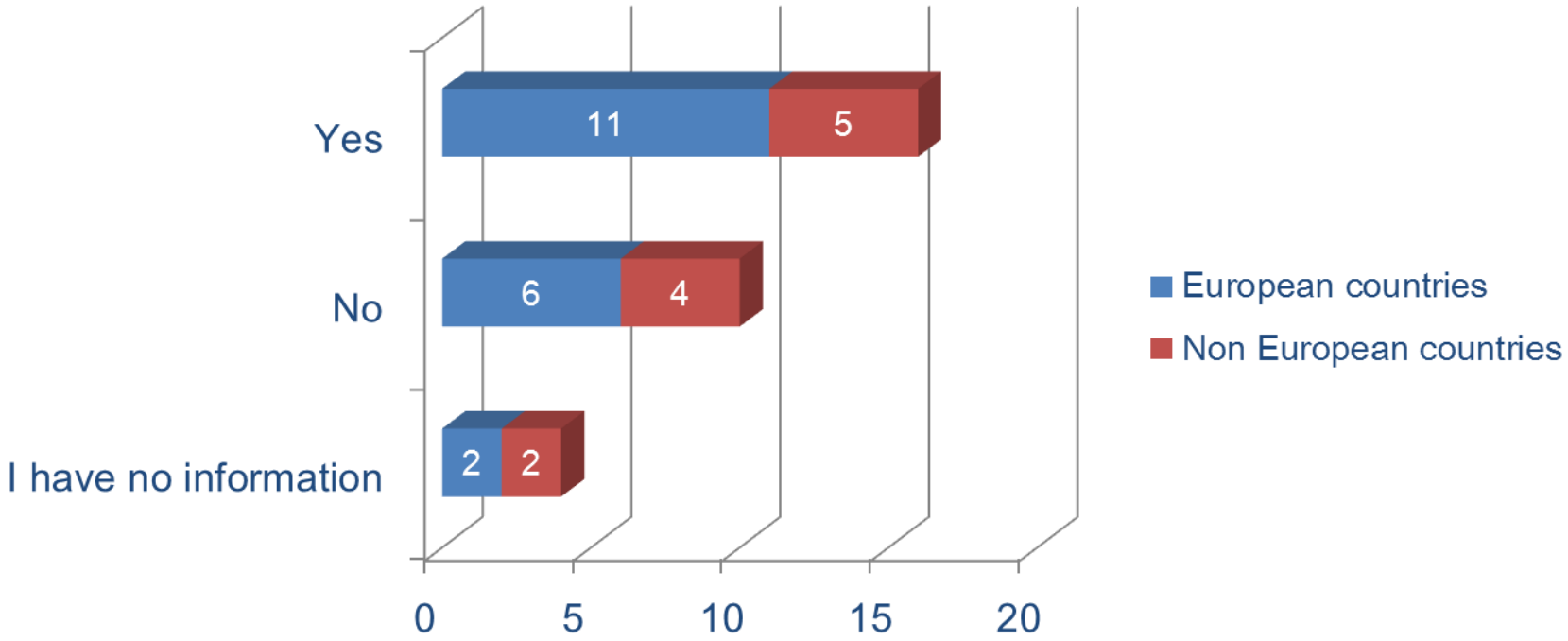
- ✓ Collected data – 46.7% (57.9% EU countries)
- ✓ Official reports – 10% (10.5% EU countries)
- ✓ Estimated data - 43.3% (31.6% EU countries)

Traceability responsibilities

	European countries	Non European countries	Total	%
I have no Information	2	0	2	6.7
No	4	2	6	20
Yes	13	9	22	73.3
Total	19	11	30	100

In 73.3% (68.4% in the EU) of the cases the traceability responsibilities of Blood Establishments and the Hospital Blood Banks (including the hospital and treatment facilities) are covered by contracts between them.

Verification/ confirmation procedure



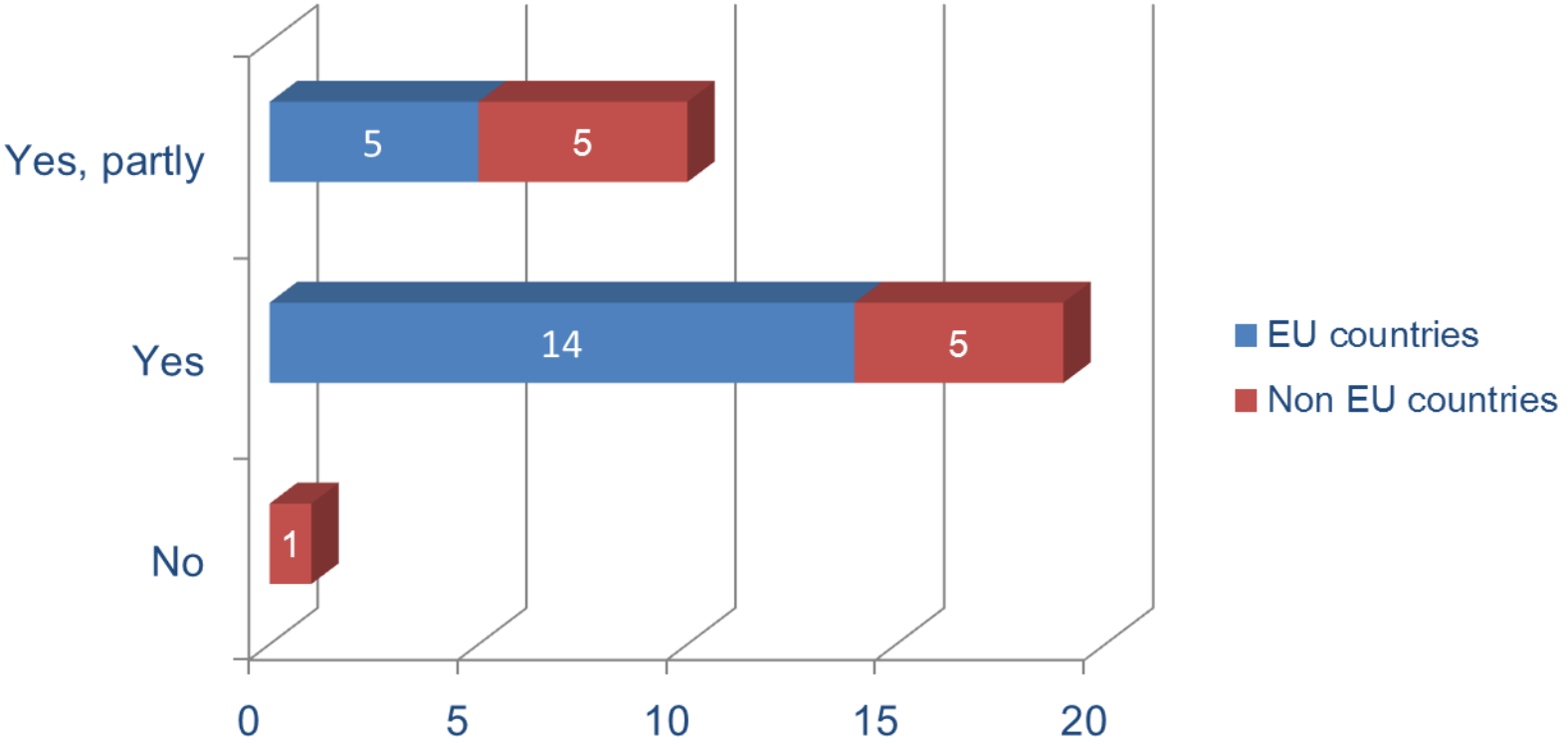
53.3% (57.9% in the EU) of the respondents have procedures in place to receive information that each unit issued has been transfused to the intended recipient.

Methods by which the transfusion confirmation is received

- 14 countries didn't answer this question.
- 4 (UK, France, USA , Brazil) answered *"The method varies between hospitals"*
- The answers from the remaining 11 were:

Total	European countries	Non European countries	
11	9	2	Paper form returned to Hospital Blood Bank
7	6	1	Electronic information relayed by device used at bedside
6	5	1	The method varies between hospitals
4	3	1	Empty bags returned to Hospital Blood Bank
4	2	2	Clinical departments are instructed to return unused units so transfusion is presumed to have taken place if the unit does not come back

Procedure to verify components' subsequent disposal



If the unit has not been transfused 63.3% (73.7% in the EU) of the respondents have procedures to verify components' subsequent disposal, i.e. whether the unit has been discarded or returned to the distributing BE or issuing HBB.

Blood identification system/ Identification procedures /Record of data on traceability

- All the respondent countries' Blood establishments, Hospital Blood Banks and facilities have a system for identification of each blood donation and each component made from it.

- All the respondent countries' Blood establishments and facilities record data comprising:blood establishments identification, blood donor identification, blood unit identification, individual blood component identification, date of collection,facilities to which blood units or blood components are distributed or subsequent disposition, issued blood component identification,date of transfusion or disposition.

- All facilities but one record blood component supplier identification, transfused recipient identification.

- For blood units not transfused, confirmation of subsequent disposition is recorded by 86.6% of responding countries (84.% in the EU).

Component label information

Component label information	EU countries	Non EU countries	Total
Official name of the component	100%	100%	100%
Volume, weight or number of cells in the component	89.5%	90,9%	90%
Unique numeric or alphanumeric donation identification	100%	100%	100%
Name of producing establishment	100%	100%	100%
ABO Group	100%	100%	100%
Rh D Group	100%	100%	100%
Date or time of expiry	100%	100%	100%
Storage temperature	89.5%	81.8%	86.6%
Name, composition and volume of anticoagulant and/or additive solution	100%	72.7%	90%

Labeling system

- 70% (73.3% in the EU) use a single national coding system for blood components.
- 50% (57.9% in the EU) apply ISBT128.

Record of data on traceability

- Data record on traceability is kept by Quality managment system or quality policy in 70% of the respondents (73,7% 14/19 at EU level).

- Data storage is organized both in paper and electronic forms by all non European countries. At European level 73,7%, 14 respondents organize data storage both in paper and electronic forms, 4 only in electronic forms and one only in paper.

- When electronic forms are used the access levels are granted by function or job descripton in 63,3% of the respondents (57,9% at EU level) in 16,6% by organization CEO.

- For all the respondents but two (one EU country and one non EU), back-up procedures are in place.

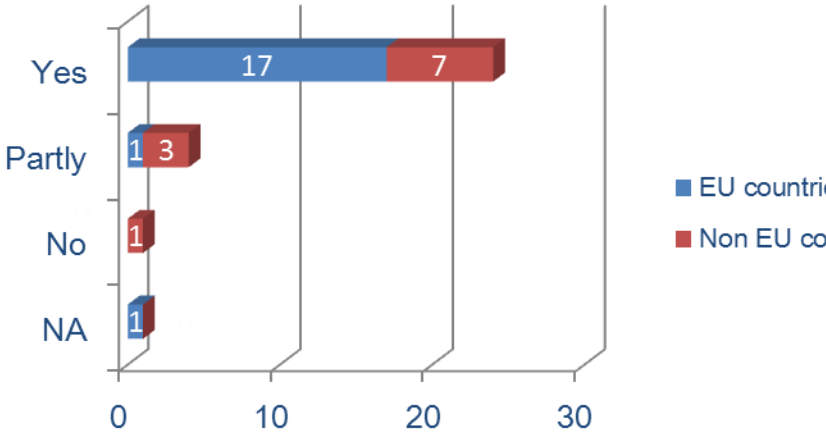
Record of data on traceability

- For all the respondents but one at European level, and two at non European level the same rules that apply for Blood Establishments apply to Hospital Blood Banks.

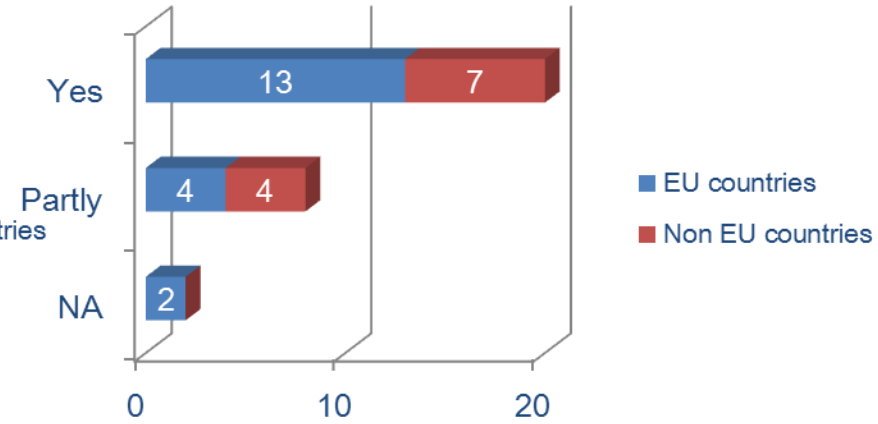
- 30 years data storage requirement is ensured mainly by regular inspections and audits.

Goods traceability

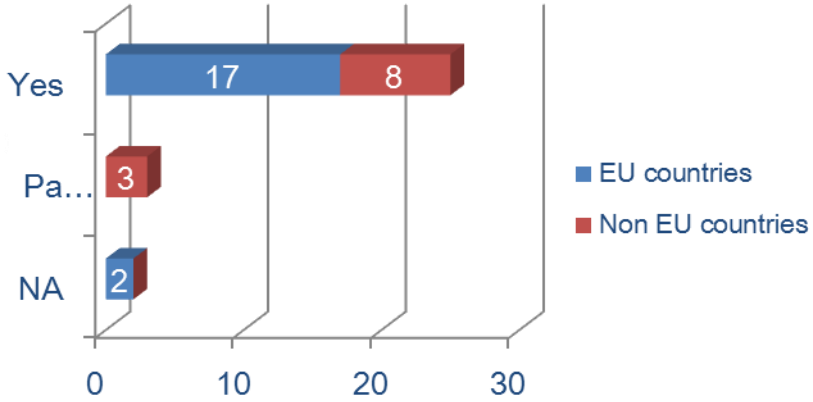
Stock Requisitions



Non Stock Requisitions



Delivery notes



✓80% (89.5% EU) have documented procedures to maintain records of stock requisitions received and dispatched.

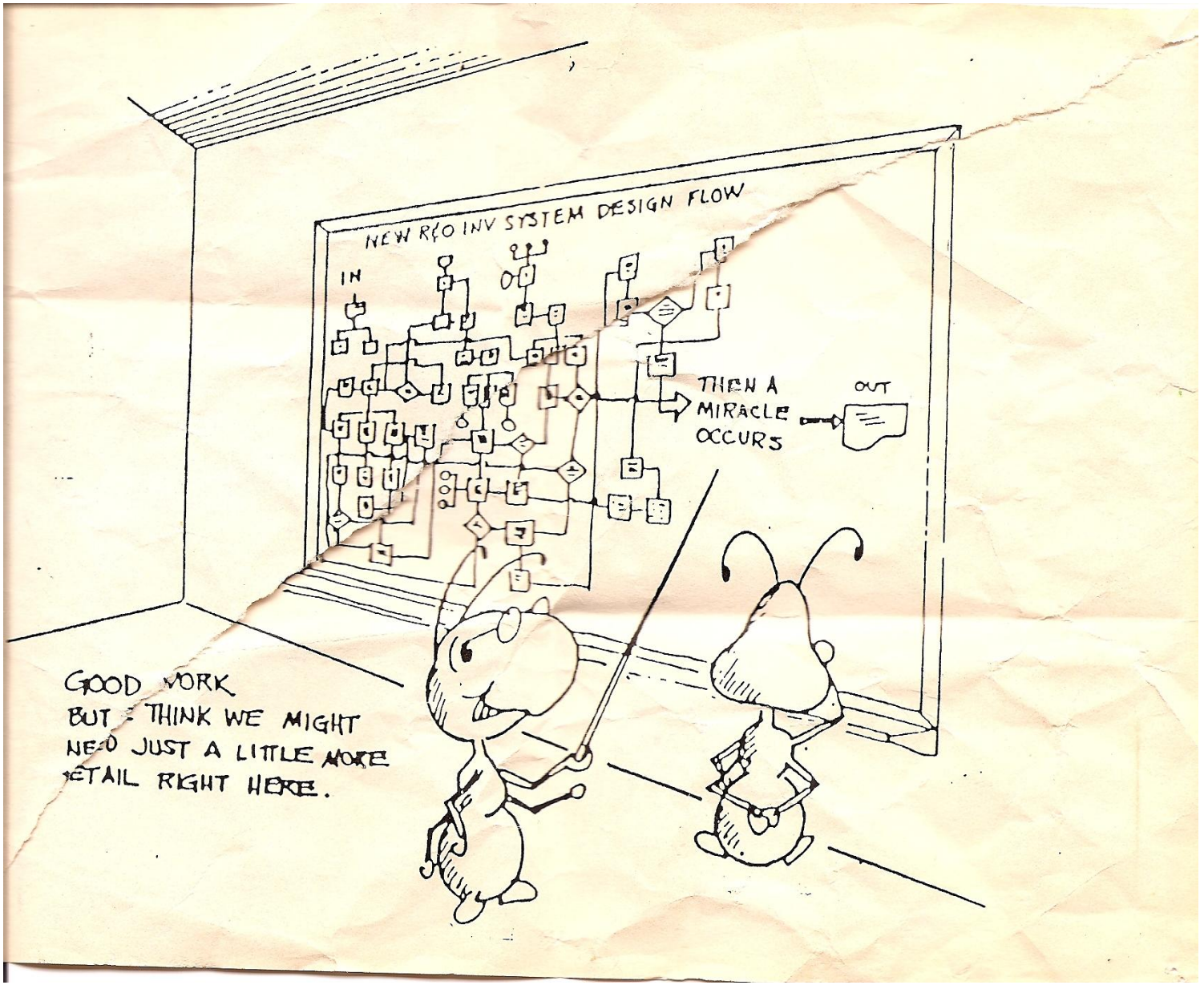
✓66.7% (68.4 EU) for non stock requisitions.

✓83.3% for delivery notes (89.5% EU countries)

Conclusions

- Blood components are majority traceable from the donor to recipient and vice versa through unmistakable identification procedures and requirements, record maintenance and appropriate labeling systems.

- The critical point on traceability is the fact the legal requirements to confirm the final destination of blood components is currently not always met.



Future Directions

- A more detailed survey is needed to obtain insight into the various methods used by hospitals to control the final destiny of blood components.

- The same way the reports of adverse reactions and events, official reports on traceability, should also be disclosed.

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