REGULATION OF CORD BLOOD BANKING: GLOBAL IMPLICATIONS

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European Directives ≠ National Laws

In the case of blood and blood components & tissues and cells

- European Directives
  - Quality & safety requirements
    - Concern “what to do” to adequately and homogeneously manage defined activities
    - Involve essential healthcare services and quality assurance

- National laws
  - Provisions aimed at guaranteeing essential healthcare services delivery
    - May concern “where” and “by whom” the activities must/should be managed
    - Involve technical and political choices
Advances in stem cell research over the last two decades have coincided with large increases in haemopoietic stem cell transplantation using either bone marrow, peripheral blood or cord blood-derived stem cells.

In parallel, the role played by regulatory bodies, both institutional and professional, has increased in order to ensure that specialists undertake the above procedures in a manner so as to minimize the risk to patients and guarantee high quality levels.
European Directives concerning tissues and cells

2004/23/EC


2006/86/EC

implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells

2006/17/EC

on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
Directive 2004/23/EC of CoE sets standards that ensure a comparable level of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells throughout the EU. The directive had to be transposed into the legislation of member states within 2 years of its adoption by the EU.
Two Directives of the European Commission - derived from Directive 2004/23/EC - were published in 2006 providing more detailed requirements: **Directive 2006/17/EC** which provides detailed requirements for donation, procurement and testing and **Directive 2006/86/EC** including coding, processing, preservation, storage and distribution requirements.
The European regulation on cells and tissues

The European regulation designs an appropriate comprehensive framework and establishes detailed technical requirements for tissue and cell banking, to be applied to CB banking in all member states, according to the specificity of this activity.
Each member state has to harmonize/update its national regulation with the Community’s provisions so as to guarantee equal quality and safety levels for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells throughout the EU. This is hopefully to be realized in all member states soonest possible.
Cord Blood Banking

- European directives
- National provisions
- International standards

Safety and quality requirements
International standards

Collection
Processing
Testing
Banking
Selection
Release
The Italian regulation of cord blood banking authorisation and accreditation
National provisions
(who and where)

**Blood**

- Law n. 219
  New discipline of transfusion medicine activities and national production of blood derivatives of 21 October 2005

**Tissues and cells**

- Decree n.16 of December 2010 implementing Directives 2006/17 and 2006/86/EC
Law n. 219
New discipline of transfusion medicine activities and national production of blood derivatives of 21 October 2005

... By a decree of the Minister of Health, a project for the institution of a national network of cord blood banks (CBBs) aimed at cord blood preservation for haematopoietic stem cells (HSC) transplantation is implemented; the project provides for annual plans of development of relevant activities ...
... By a decree of the Minister of Health, the Italian Cord Blood Network (ITCBN) of cord blood banks (CBBs) has been instituted in 2009.
The **National Blood Centre**, entrusted with the co-ordination and technical and scientific control of all issues ruled by this law, coordinates the **ITCBN**.

(Compiti del Centro nazionale sangue)

4. Il Centro nazionale sangue, nelle materie disciplinate dalla presente legge, svolge le funzioni di coordinamento e di controllo tecnico scientifico, di intesa con la Consulta.
Blood and blood components donation, peripheral HSC collection and CB collection, are allowed within the Blood Transfusion Services licensed by regional authorities.
Italian Cord Blood Network (ITCBN)

17/19 CBBs operate in Blood Establishments
No. of CB units banked and released by Italian CBBs during 1994-2010

Center Nazionale Sangue
Banche di sangue di cordone ombelicale – Report 2010

Total No. Banked Units

- Non Fam-rel
- Directed
- Auto

Total No. Rel. Units 1994-2010

- Non Fam-rel
- Directed
- Auto

23098 listed at IBMDR

25824 HLA-typed
6308 Not yet typed
1035

2

32132
2176
115
has been transposed into:

Decree n. 191
of 6 November 2007
Art. 2
(Definitions)

«Tissue institute»: a tissue bank
a unit of a public hospital
a blood establishment section
another body no profit

where activities of processing, preservation, storage and distribution of human tissues and cells are undertaken.
Art. 6.
Authorisation and accreditation of tissue establishments

Tissue institutes must be authorized and accredited by the designated competent authorities that in Italy are the Regional Competent Authorities supported by the National Competent Authorities

- National Blood Centre (NBC)
- National Transplant Centre (NTC)
The Italian regulation of Cord Blood Banking

AUTHORISATION REQUIREMENTS

• General requirements
• Organization
• Human resources
• Quality management
• ISO 9000 certification
• Technology requirements
• Information technology
• Specific requirements for the processing laboratory (premises and equipment)
• Management of cord blood collection centers
• Management of outsourced cryogenic services (where applicable)
The Italian regulation of Cord Blood Banking

TECHNICAL & SCIENTIFIC STANDARDS
(ITCBN COOPERATIVE WORKING GROUPS)

Technical and scientific standards have been approved as mandatory for all Italian Cord Blood Banks
The Italian regulation of Cord Blood Banking

ACCREDITATION

PROCESS AND PROCEDURES MANAGED AT THE REGIONAL LEVEL, COMPLYING WITH SPECIFIC NATIONAL GUIDELINES AND ASSISTED BY THE NATIONAL COMPETENT AUTHORITIES

LINEE GUIDA PER L’ACCREDITAMENTO BANCHE DI SANGUE CORDONALE (SCO)

Approved by State/Regions agreement
National Accreditation Guidelines for CBBs have been defined:

- according to the indications from the competent authorities (NBC, NTC)
- with the CBBs agreement
- focusing on quality requirements for CB banking activities
- in compliance with most international standards
- shall be updated by the national competent authorities according to the evolution of science in the specific field
The IBMDR (Italian Bone Marrow Donors Registry) is entrusted with the search for CB units in Italian and foreign CBBs, besides its activity of HSC donors search in national and foreign registries, following requests from healthcare organizations performing HSC transplantation.
The Italian Network of Cord Blood Banks - ITCBN

**Institutional framework**

- **Regional Blood Centres**
- **Blood Transfusion Centres**
- **ITCBN**
  - Hematology services hosting CBBs
- **National Blood Centre**
- **National Co-ordination of ITCBN**
- **National Transplant Centre**
- **Cooperation with national Co-ordination of ITCBN**
- **“Sportello Unico” IBMDR**
- **HSC Transplantation Services**
- **National Technical Blood Conference**
- **Ministry of Health**
  - National Institute of Health
- **Regional Transplant Centres**
Italian Network of Cord Blood Banks

System Governance

National Transplant Centre
- Cooperation with national Coordination CBBsN

National Blood Centre
- National Coordination of CBBs Network

CBBs Conference

HSC Transplantation Services

“Sportello Unico” IBMDR

Scientific Board
- Technical & Operative Co-ordinating Centre

Cord Blood Banks
## Italian Cord Blood Network
designations, certifications, accreditations
as of May 2011

### 19 Cord Blood Banks

<table>
<thead>
<tr>
<th>Designations Certifications Accreditations</th>
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<th>NO</th>
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<tr>
<td>Regional designation</td>
<td>18</td>
<td>1</td>
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<tr>
<td>ISO 9001 Certified</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>EFI/ASHI Accredited</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>NetCord-FACT accredited</td>
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<td>17</td>
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<td>NetCord-FACT application</td>
<td>8</td>
<td>11</td>
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The NetCord-FACT accreditation has become the “gold standard” of good quality in CB banking and a sort of “priority flag” in international HSC registries.

Yet it must be considered that European member states have to sustain considerable commitment and guarantee significant resources in order to comply with the new EU requirements and lead their CB banks to national licensing/accreditation.

Should any European CB bank seeking for best qualification and consequent optimization of its global “market share” run for the NetCord-FACT accreditation, beyond accomplishing the mandatory national licensing/accreditation process?
Voluntary accreditation is considered an important opportunity for improving quality and standardization in CB banking.

The overall quality of CB banks throughout the world is not well known.

The new European provisions on tissues and cells may lead member states to implement institutional CB banking accreditation programs which include most internationally accepted standards and envisage that accreditation be guaranteed by national competent authorities as independent third parties.
The new EU regulatory framework should hopefully lead to cooperation between European national competent authorities and voluntary accreditation agencies, with the aim to assess institutional requirements’ suitability on one side and voluntary standards’ [i.e. NetCord-FACT’s] sustainability on the other side.

Experimental cooperative programs could be hypothesized aimed at minimizing interpretative options and application variability inevitably affecting even the most vigorous and sound standards.