

Road to 2027

Aránzazu de Celis Miguélez

DG for Public Health and Equity in Health

Ministry of Health

Spain

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PRESENTATION

- National organization overview
- Main supervisory activities for National/Regional Competent Authorities
- Challenges





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National organisation overview



Art. 149 Spanish Constitution:

- Basis and coordination
- Basic legislation
- Foreign affairs

SoHO oversight system:

the implementation of the new EU regulation with a focus on the obligations for competent authorities



National organisation overview

National Haemotherapy Commission

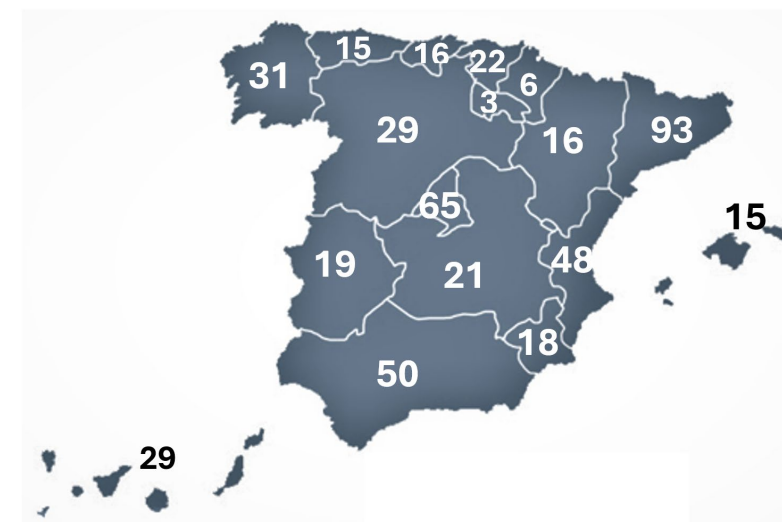
Regional Haemotherapy Commissions

Hospital Transfusion Committees

National System for Transfusional Safety



BE: 20



BB: 515

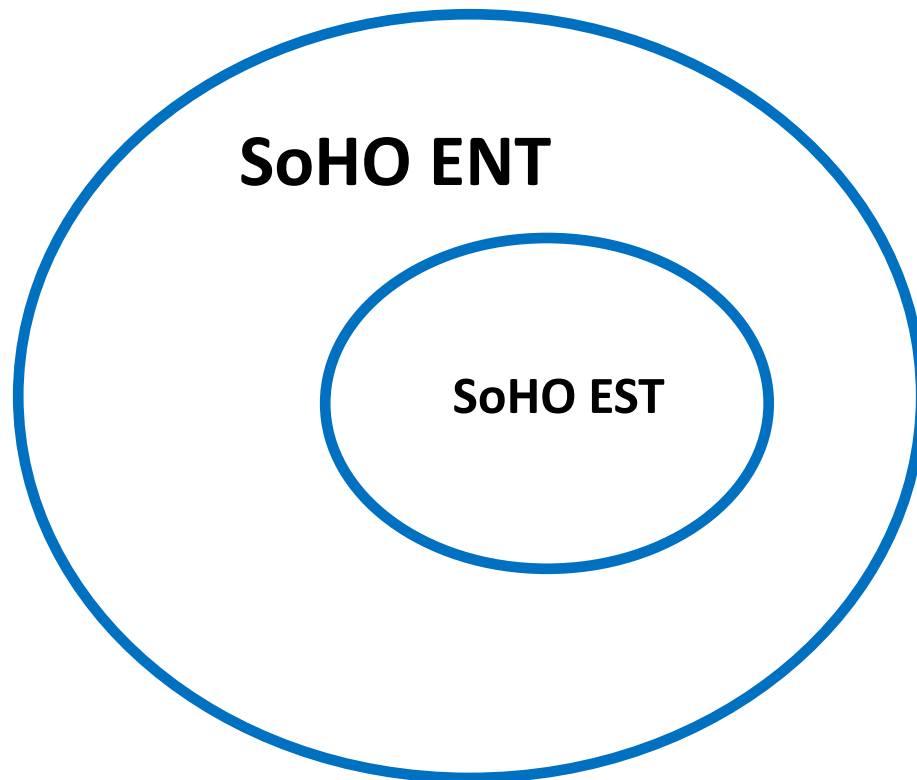


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Supervisory activities

SoHO ENTITIES&SoHO ESTABLISHMENTS



- Current BE and Hospitals: already in a national registry
- BE and Blood banks: authorisation requires by Spanish law
- New: to be authorized
- Inspections: Regional competence

Art. 16-17;24-25





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Supervisory activities

INSPECTIONS



National Committee for inspections:

- Harmonise guidelines
- Share best practices
- Identify expert in specific areas
- Joint training
- Joint Inspections

Art.27-30





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Supervisory activities

Extraction, submission and publication of ACTIVITY DATA



National registry:

- Activity data since 2006
- Highly valued IT system since 2010
- Aggregated data: national sovereignty

Art 31





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Supervisory activities

VIGILANCE

Sistema Nacional para la Seguridad Transfusional

Sistema de Información del **SISNST**

2023

Unidad de Hemovigilancia
Área de Medicina Transfusional

S.G. de Promoción, Prevención y Equidad en Salud
Dirección General de Salud Pública y Equidad en Salud

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National registry:

- Vigilance data since 2004
- Highly valued IT system since 2017
- Availability: 24h/7 d

Art.33-34



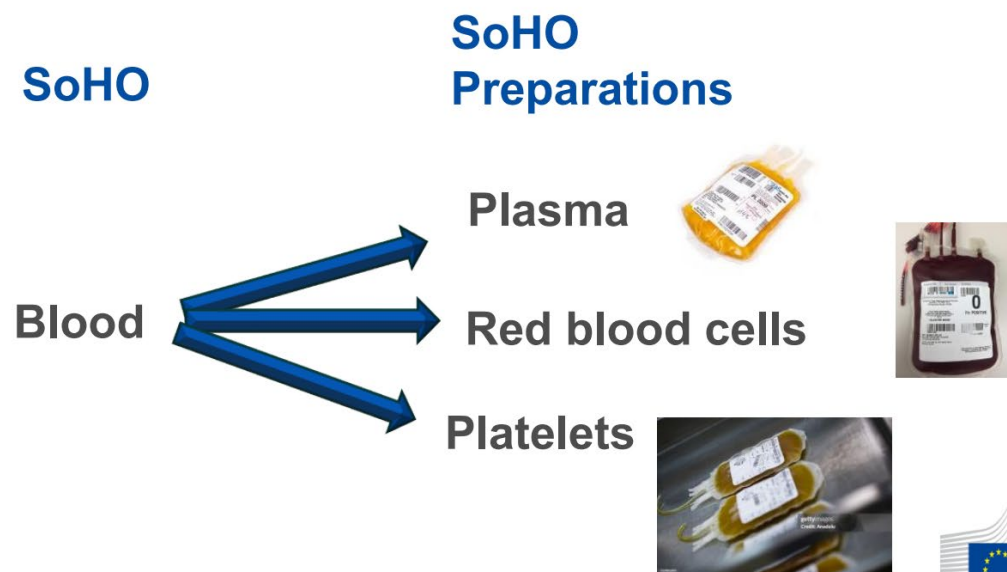


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Supervisory activities

SoHO PREPARATIONS



- New for blood
- National Committee to assess, grant or refuse authorisations and/or clinical outcome monitoring plan
- Experts from BE, hospitals,...but coordination and approval at national level.





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Supervisory activities

SUPPLY CONTINUITY



Sistema Trai
Plan de Cooperación
PANDEMIA INFLUENZA
MINISTERIO DE
SANIDAD, CONSUMO Y
BIENESTAR SOCIAL.



Virus del Nilo Occidental

(VNO)

Transfusión y CORONAVIRUS

Infección por nuevo coronavirus (COVID-19)



- Experienced sector: critical SoHO
- National emergency plans
- Transfusion network: national strategic infrastructure



SoHO oversight system:

the implementation of the new EU regulation with a focus on the obligations for competent authorities





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Challenges

Some of them....

- New entities
- Development of national legislation
- SoHO preparations
- Quality system for CA





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In brief,

