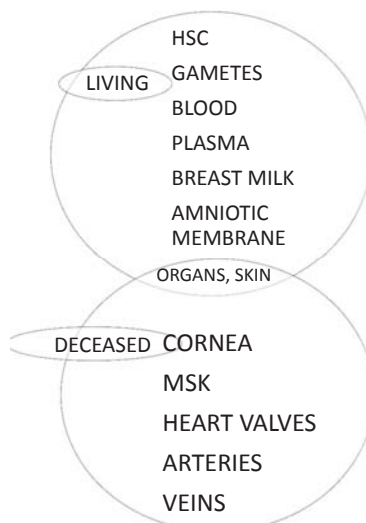


PROJECT NOTIFY

Sharing vigilance experience and knowledge globally

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University of Washington, School of Medicine
Seattle, Washington

Medical Products of Human Origin (MPHO)



Medical products of human origin are derived wholly or in part from the human body and intended for clinical application.

They include blood and blood products, organs, bone marrow, cord blood, corneas, tissues and other derivatives.

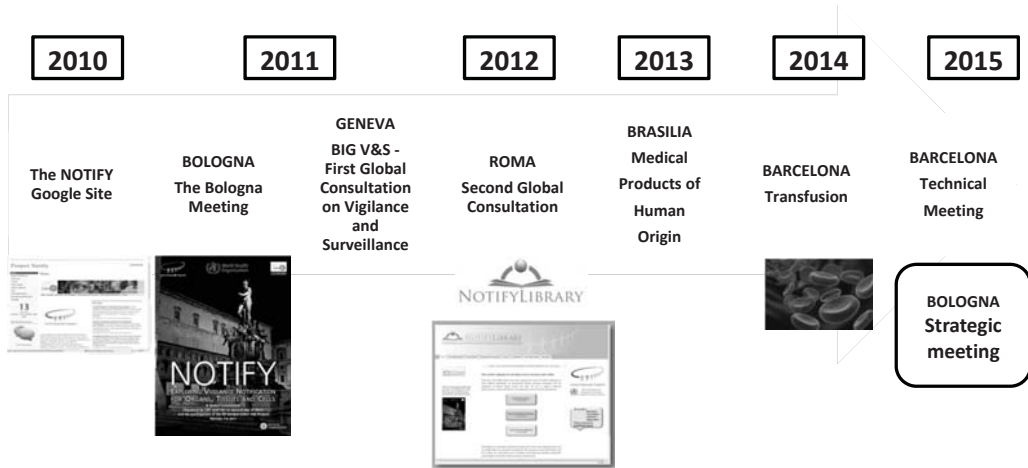
The human origin of these products gives rise to a high level of complexity, hence health systems and health-care providers have a responsibility to assess and assure safety.

NOTIFY – HISTORY

113 Experts from 36 Countries

Adoption of Resolution 63.22 by the World Health Assembly in 2010

- *Provide all Member States information about donation, processing, transplantation of tissues, cells and organs, including data about serious adverse events and reactions».*



AIMS

To provide professionals with relevant information helpful for determining the suitability of a potential donor.

To draft common guidelines supporting the implementation of effective vigilance and surveillance.

To provide practical support to countries that are developing vigilance systems for medical products of human origin.

The NOTIFY Tools

- NOTIFY Website <http://www.notifylibrary.org>
- NOTIFY Library of didactic cases of events and reactions



- NOTIFY Booklet
- NOTIFY Consultations
- NOTIFY Network for horizon scanning ECDC+ USCDC+ ...
- NOTIFY Journal (TBD)

WHAT IS THE NOTIFY LIBRARY?

- **Publically accessible online database of didactic cases** of adverse reactions and events that have caused harm or risk of harm
- **From procurement and processing to clinical application** of blood, organs, tissues, cells and other substances used in transfusion, transplantation, assisted reproduction and other applications
- Collected and analyzed by dedicated editorial groups of international experts, regulators and clinicians and **linked to their source references**:
 - ✓ literature review (published articles in scientific journals and/or books)
 - ✓ case reports from regulatory or professional vigilance programs (grey literature)



Adverse occurrence search

Adverse occurrence type

(Expand all) (Clear)

Harm to a Recipient

Harm to a Donor

Harm to a Fetus or Offspring

Risk of harm

Medical Products of Human Origin type - MPH0

(Expand all) (Clear)

Organs

Blood

Cells

Tissues

Reproductive

Derived medicinal products

Other

Keywords

(Searches keywords identified by the Notify editors)

Free text

(Searches the text in the database cases and includes alerting signals, imputability and keywords)

Notify Library Record ID

(Searches by Notify Library Record ID, for multiple records separated by commas)

Limit results 100 per page

NOTIFY LIBRARY: SEARCH RESULTS

Found 2 records (up to page top).

Search criteria:

Adverse occurrence: Harm to a Recipient >> Infection >> Bacterial >> Staphylococcus

Medical Product of Human Origin type - MPH0: Tissues

<input type="checkbox"/> Record ID	Adverse occurrence	References
<input type="checkbox"/> 634	<p>Adverse occurrence description: Staphylococcus epidermidis</p> <p>Adverse occurrence type: Harm to a Recipient => Infection => Bacterial => Staphylococcus</p> <p>MPH0 type: Tissues => Ocular => Cornea</p> <p>Time to detection: 3 - 14 days</p> <p>Alerting signals, symptoms, evidence of occurrence: This study of culture results of 469 donor corneal scleral rims correlated positive findings with clinical outcomes.</p> <p>Estimated frequency: Transmission of a bacterial infection is rare (0.4% or likely even less)</p> <p>Demonstration of Imputability or Root cause: Level 2, Possible, but unlikely. These 2 cases had Staph epi found in the corneal ulcer and on the donor tissue, suggesting a</p> <p>Imputability grade:</p> <p>Expert comments for publication:</p>	1 reference
<input type="checkbox"/> 27	<p>Adverse occurrence description: Staphylococcus epidermidis</p> <p>Adverse occurrence type: Harm to a Recipient => Infection => Bacterial => Staphylococcus</p> <p>MPH0 type: Tissues => Musculoskeletal => Bone</p> <p>Time to detection: 6 months</p> <p>Alerting signals, symptoms, evidence of occurrence: serous discharge positive, increased ESR, CRP</p> <p>Estimated frequency: N/A</p> <p>Demonstration of Imputability or Root cause: Proven</p> <p>Imputability grade:</p> <p>Expert comments for publication:</p>	1 reference

NOTIFY LIBRARY: SEARCH RESULTS

Found 2 records (up to page top).

Search criteria:

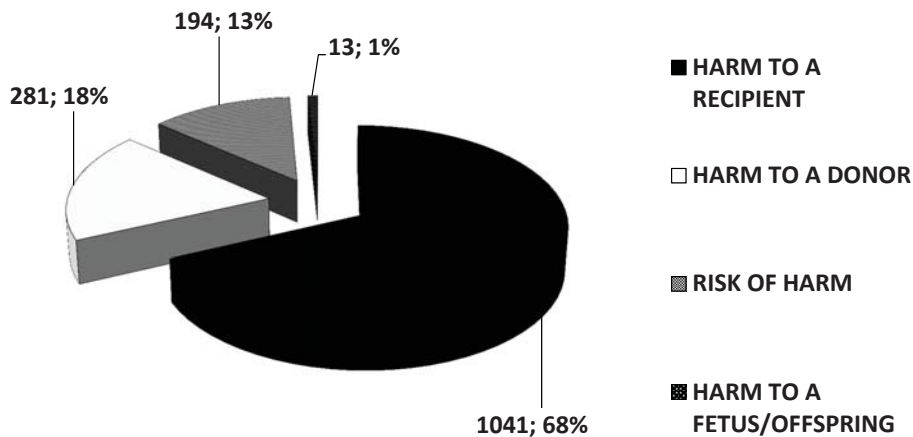
Adverse occurrence: Harm to a Recipient >> Infection >> Bacterial >> Staphylococcus
Medical Product of Human Origin type - MPH0: Tissues

[Feedback questionnaire](#)

[1305] Rehany, U.; Balut, G.; Leifer, E.; Rumelt, S.
 The prevalence and risk factors for donor corneal button contamination and its association with ocular infection after transplantation *Cornea* 2004; 23 (7):649 - 54

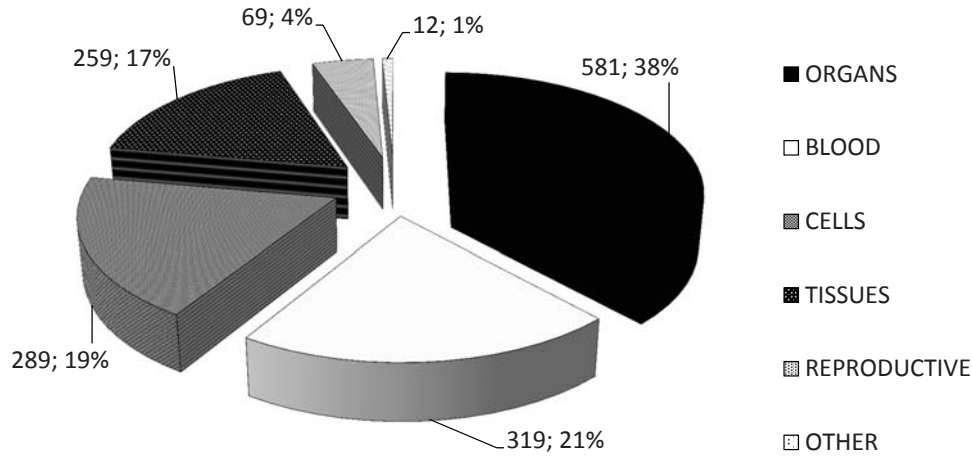
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NOTIFY LIBRARY: UPLOADED RECORDS BY ADVERSE OCCURRENCE TYPE (n=1,529)



2,356 REFERENCES INDEXED

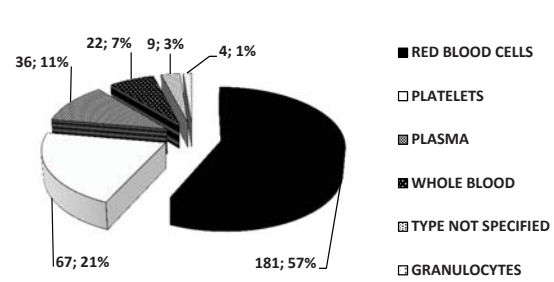
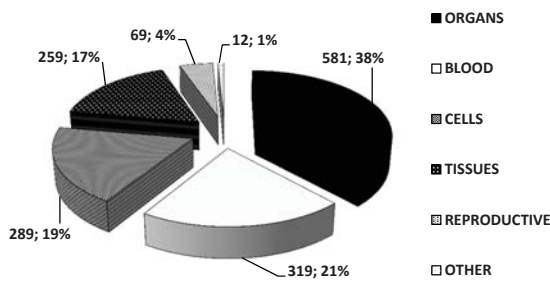
NOTIFY LIBRARY: UPLOADED RECORDS BY MPHO TYPE (n=1,529)



2,356 REFERENCES INDEXED

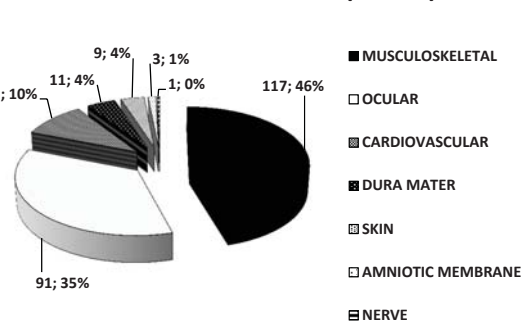
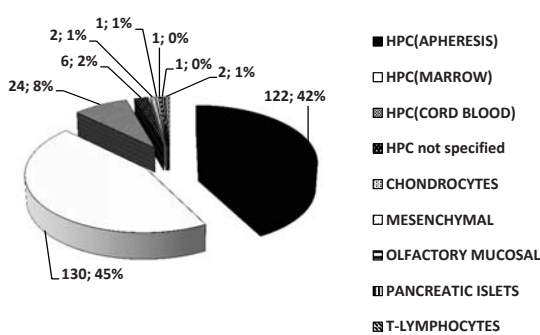
MPHO TYPE (n=1,529)

MPHO TYPE: BLOOD (n=319)



MPHO TYPE: CELLS (n=289)

MPHO TYPE: TISSUES (n=257)



Forum Login


NOTIFYLIBRARY
 The Global Vigilance and Surveillance Database for Medical Products of Human Origin
 TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION


 Centro Nazionale Trapianti
 Italian National Transplanters Centre

 WHO Collaborating Centre
 for Vigilance and Surveillance for
 Human Cells, Tissues and Organs

THE NOTIFY PROJECT + SEARCH LIBRARY NOTIFY BOOKLET BACKGROUND DOCUMENTS

Welcome to the NOTIFY Library site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the application of human organs, blood, tissues and cells. We aim to support continued improvements in safety and efficacy in transplantation, transfusion and assisted reproduction. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation and assisted reproduction across the world.



World Health Assembly Executive Board Acknowledges Exceptional Nature of MPH0
 At the 136th meeting of the WHA Executive Board (EB) in January 2015, a proposal from Italy, Lithuania, Malta, Slovenia and Spain to work towards consensus on the principles for the donation and management of blood and other Medical Products of Human Origin (MPHO) was **DOCUMENTED**. The discussion was based on a **REPORT** submitted to the EB for possible future consideration by the full WHA. This important initiative raises the acknowledgement of the exceptional nature of MPH0.

Search Library General Public Health Professionals Health Authorities

Download Booklet.pdf

The Notify Booklet

1 Introduction
 2 The V&S Chain for MPH0s
 3 History of Vigilance and Surveillance
 4 Medical products of Human Origin (MPHO)
 5 Towards a global governance of MPH0
 6 The V&S system is primarily a responsibility for health authorities
 7 Organization for a comprehensive Vigilance & Surveillance System
 8 Vigilance & Surveillance – Recognition relies on health care staff
 9 Investigating occurrences that could cause harm – Learning from Errors
 10 Project NOTIFY
 11 The NOTIFY Database – Learning from Vigilance
 12 Risks Associated with Living Donation
 13 Investigating Harm to Recipients – Infections
 14 Investigating Harm to Recipients – Malignancy
 15 Investigating Harm to Recipients – Genetic Transmissions – HPSG
 16 Investigating Harm to Offspring – Genetic Transmissions – Gametes and Embryos
 17 Characteristics, handling and clinical errors
 18 Traceability: an absolute pre-requisite for MPH0 safety





Vigilance and Surveillance (V&S) of Medical Products of Human Origin (MPHO)

- 1 Introduction
- 2 The V&S Chain for MPH0s
- 3 History of Vigilance and Surveillance
- 4 Medical products of Human Origin (MPHO)
- 5 Towards a global governance of MPH0
- 6 The V&S system is primarily a responsibility for health authorities
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- 10 Project NOTIFY
- 11 The NOTIFY Database – Learning from Vigilance
- 12 Risks Associated with Living Donation
- 13 Investigating Harm to Recipients – Infections

The site: BACKGROUND DOCUMENTS

European Union Standards and Training for the Inspection of Tissue Establishments Project (EUSTITE)

EUSTITE was an EU-funded project (2006-2009) led by the Italian National Transplant Centre in which the World Health Organisation participated. In one of its work-packages, it conducted the first pilot programme of collecting and analysing adverse occurrences associated with tissues and cells used in transplantation and assisted reproduction in 20 EU Member States. Many of the cases evaluated in the pilot study have been inserted in the NOTIFY library.

Attachment	Size
 EUSTITE Final Recommendations.pdf	169.98 KB
 EUSTITE V&S Pilot Report.pdf	1.38 MB
 EUSTITE Vigilance Tools Wallchart.pdf	116.87 KB

The site: BACKGROUND DOCUMENTS

Vigilance and Surveillance of Substances of Human Origin Project (SOHOV&S)

SOHOV&S was an EU-funded project (2009 – 2012) that developed a number of guidance documents for vigilance and surveillance of tissues and cells for transplantation and for assisted reproduction.

Attachment	Size
 SOHO V&S Guidance on V&S in ART in the European Union.pdf	507.64 KB
 SOHOV&S Survey of European Vigilance and Surveillance Systems.pdf	1.76 MB
 SOHO V&S Communication and Investigation Guidance.pdf	2.88 MB
 SOHO V&S Deliverable 9 - The VS Training Model.pdf	5.3 MB
 SOHOV&S Vigilance Guidance for Healthcare Professionals - Part 1 Tissues.pdf	332.44 KB
 SOHO V&S Vigilance Guidance for Healthcare Professionals - Part 2 HPCs.pdf	338.11 KB

The site: BACKGROUND DOCUMENTS

European Union Annual Vigilance Reports

The European Commission (Directorate General for Health and Consumer Protection) receives annual vigilance reports for different MPHD types from the Competent Authorities of its 28 Member States. It publishes collated summaries of these reports.

Attachment	Size
 EU SANCO Blood_Adverse_Events_2013_en.pdf	558.98 KB
 EU SANCO Report on the Rapid Alert system for human Tissues and Cells (RATC) (2010-2012).pdf	231.48 KB
 EU SANCO Tissues_Cells_Adverse_Events_2012_en.pdf	405.41 KB
 EU SANCO Tissues_Cells_Adverse_Events_2011_en.pdf	171.32 KB
 European Commission_blood_sare_2014_en.pdf	281.23 KB
 European Commission_RATC_report_2013_en.pdf	241.46 KB
 European Commission_tissues_cells_SARE_2013_en-1.pdf	635.81 KB

The site: BACKGROUND DOCUMENTS

Transfusion and Transplantation Reactions in Patients (TRIP)

TRIP is a national vigilance organisation in the Netherlands that gathers adverse occurrence reports in transfusion, transplantation and assisted reproduction on behalf of the Dutch Health Authority. It publishes an annual summary of the reports it receives. TRIP collaborates with the NOTIFY library, selecting and analysing cases of didactic value for insertion in the database.

Attachment	Size
 TRIP Biovigilance 2013.pdf	1.88 MB
 TRIP Biovigilance 2012.pdf	733.18 KB
 TRIP tissuevigilance 2011.pdf	1.7 MB
 TRIP tissuevigilance2010.pdf	164.86 KB
 TRIP Tissuevigilance2009.pdf	581.53 KB

GOOGLE ANALYTICS RESULTS: SITE VISITS FOR WHO REGIONAL OFFICES 2012 - 2015

