The NOTIFY project - general overview
Resolution 63.22 of the World Health Assembly was adopted in 2010 and gave WHO a mandate to facilitate Member State access to appropriate informations on donation, processing and transplantation of tissues, cells and organs, including data about serious adverse events and reactions.
Sharing vigilance experience and knowledge globally
- the NOTIFY Project (WHO)
NOTIFY PROJECT: 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 (MPHO).
During this period more than 260 international Experts contributed to the content of the NOTIFY Project, its goals and in the improvement of the Notify Library.
NOTIFY PROJECT: MAIN COMPONENTS

1. NOTIFY website: [http://www.notifylibrary.org](http://www.notifylibrary.org)

2. NOTIFY Booklet

3. NOTIFY Library
The website is maintained and updated on this platform and is intended as a communication hub for institutions and organisations worldwide collaborating in the facilitation of access to Vigilance and Surveillance information.

Welcome to the NOTIFY Library site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation, transfusion and assisted reproduction across the world.
Welcome to the NOTIFY Library site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation, transfusion and assisted reproduction across the world.
Interactive Booklet through an index
• publically accessible online database of didactic cases of severe adverse reactions and events

• from procurement and processing to clinical application of blood, organs, tissues and cells used in transfusion, transplantation and assisted reproduction

• collected and analyzed by dedicated editorial groups of international experts, regulators and clinicians and linked to their source reference:
  ✓ literature review (published articles in scientific journals and/or books)
  ✓ case reports from regulatory or professional vigilance programs (grey literature)
WHO WE ARE

NOTIFY LIBRARY
The global vigilance and surveillance database for medical products of human origin (MPHO)
TRANSPLANTATION, TRANSFUSION, ASSISTED REPRODUCTION

ITALIAN NATIONAL TRANSPLANT CENTRE (CNT)
WHO Collaborating Centre on Vigilance and Surveillance for Human Cells, Tissues and Organs
WORLD HEALTH ORGANISATION (WHO)

STEERING GROUP
- Alessandro Nanni Costa
  General Director - CNT, ROME
- Jose Ramon Nunez
  Adviser - MPH0 Service Delivery and Safety Department - WHO, GENEVE
- Douglas Michael Strong
  SEATTLE
- Deirdre Fehily
  DG SANTE - EC, Brussels

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  Mauro Costa
  Francis Delmonico
  Manish Gandhi
  Giuseppe Marano
  Jay Menillo
  Eduard Muffiz-Diaz

NOTIFY OPERATIONAL TEAM
- Communication
  Aurora Navarro
  OCATT - BARCELONA
- Clinical/Scientific Database Content
  Evangelia Petrisi
  St. Orsola Malpighi Hospital - Bologna; CNT - ROME
- Project Assistant
  Claudia Carella
  CNT - ROME

Website and DB Development/Maintenance/Library Information Science support
- Daniela Minutoli
  CNT - ROME

Hardware and Software support
- Pier Nicola Massimi
  CNT - ROME
NOTIFY LIBRARY: ADVERSE OCCURRENCE DEFINITIONS

1. **Severe Adverse Event (SAE)**: any untoward occurrence, associated with the chain, from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalization or morbidity. *In the NOTIFY project these are referred to as cases of ‘Risk of Harm’.*

2. **Severe Adverse Reaction (SAR)**: any unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalization or morbidity. *In the NOTIFY project these are referred to as cases of ‘Harm to Donor’, ‘Harm to Recipient’ or ‘Harm to Fetus/Offspring’.*
### NOTIFY LIBRARY: SEARCH PAGE

#### Adverse occurrence search

<table>
<thead>
<tr>
<th>Adverse occurrence type</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Expand all) (Clear)</td>
</tr>
<tr>
<td>Harm to a Recipient</td>
</tr>
<tr>
<td>Harm to a Donor</td>
</tr>
<tr>
<td>Harm to a Fetus or Offspring</td>
</tr>
<tr>
<td>Risk of harm</td>
</tr>
</tbody>
</table>

#### Medical Products of Human Origin type - MPH0

<table>
<thead>
<tr>
<th>(Expand all) (Clear)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organs</td>
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<tr>
<td>Blood</td>
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<tr>
<td>Cells</td>
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<tr>
<td>Tissues</td>
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<tr>
<td>Reproductive</td>
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<tr>
<td>Derived medicinal products</td>
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<tr>
<td>Other</td>
</tr>
</tbody>
</table>

#### 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

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**Search Options:**
- Search
- Reset
- Print/Save selected items
- New search
NOTIFY LIBRARY: SEARCH RESULTS

Search criteria:

**Adverse occurrence:** Risk of harm
**Medical Product of Human Origin type - MPH0:** Tissues >> Ocular

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[4466] Li, J.Y.
*Donors with melanoma history: the risk to ocular tissue recipients*

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**Record ID:** 1683

**Adverse occurrence description:** Subject review: Donors with melanoma history and risk to ocular tissue recipients
**Adverse occurrence type:** Risk of harm >> Other
**MPH0 type:** Tissues >> Ocular >> Cornea
**Time to detection:** 2 months
**Alerting signals, symptoms, evidence of occurrence:** Recipient developed ocular melanoma within two months of surgery.
**Estimated frequency:** Rare; Review article written in response to single case report of melanoma transmission following keratolimbal allograft. No existing reports in literature documenting melanoma transmission from corneal transplant. Based on the case report a moratorium on use of ocular tissue from donors with melanoma (restricted from all use) and donors with metastatic solid tumors (not to be released for use of vascular components) was issued in February 2016 to be reviewed by the Eye Bank Association of America in October 2016.
**Demonstration of Imputability or Root cause:** Donor had history of malignant melanoma.
**Imputability grade:**
**Expert comments for publication:** Article was written as a review at the time of active discussion regarding the appropriate response to the cited case report. It is pointed out that donors with solid tumors constitute 30-40% of the ocular donor pool. In the case of melanoma, micrometastases raise concern for the possibility of transmission, but in practice this has not been seen. Possible factors contributing to the absence of known transmissions include the avascular nature of cornea and absence of immunosuppressive drugs. It is also noted that vascularized ocular components (such as keratolimbal allografts) also require immunosuppression and may have tumor transmission risks more similar to solid organ transplants. The article discusses the need to balance restoring sight and patient safety in the difficult setting of limited available evidence.
**Keywords:** cornea transplantation, cornea, melanoma, subject review, keratolimbal, metastasis, exclusion criteria
NOTIFY LIBRARY: ADVERSE OCCURRENCE TYPE TAXONOMY (extract)
NOTIFY LIBRARY:
UPLOADED RECORDS BY ADVERSE OCCURRENCE TYPE (n=1,586)

2,472 REFERENCES INDEXED

Last update September 2018
NOTIFY LIBRARY:
UPLOADED RECORDS BY MPHO TYPE (n=1,586)

- ORGANS: 615; 39%
- BLOOD: 340; 22%
- CELLS: 290; 18%
- TISSUES: 259; 16%
- REPRODUCTIVE: 13; 1%
- OTHER: 69; 4%

2,472 REFERENCES Indexed

Last update September 2018
CONCLUSION

Notify is a joint Global initiative that supports the sharing of published vigilance information for teaching purposes and greater public transparency on the use of Medical Products of Human Origin.

The Notify Library is the first database that aims to organize the current knowledge about serious adverse events and reactions of organs, blood, tissues, cells and ART available globally in a single, publically accessible database.
THANK YOU

notifylibrary@iss.it