NOTIFYLIBRARY

TRIP SYMPOSIUM 2017

BIOVIGILANCE

In cooperation with Belgium

The NOTIFY Library

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Italian National Transplant Centre, Rome

NOTIFYLIBRARY

NOTIFY PROJECT: HISTORY

Joint global initiative (WHO, CNT, SOHO V&S) to raise the profile of V&S of SOHO

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».*

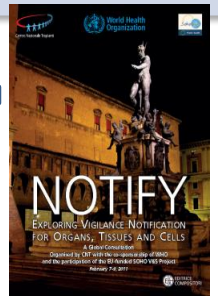
2010

The NOTIFY Google Site

2011

BOLOGNA

The Bologna Meeting



113 Experts from 36 Countries

GENEVA

BIG V&S - First Global Consultation on Vigilance and Surveillance

2012

ROME

Second Global Consultation

NOTIFYLIBRARY

2013

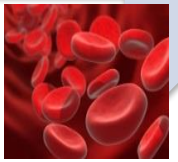
BRASILIA

Medical Product of Human Origin

2014

BARCELONA

Transfusion



2015

BARCELONA

Technical Meeting

BOLOGNA

Strategic meeting

2016

ROME

Technical Meeting

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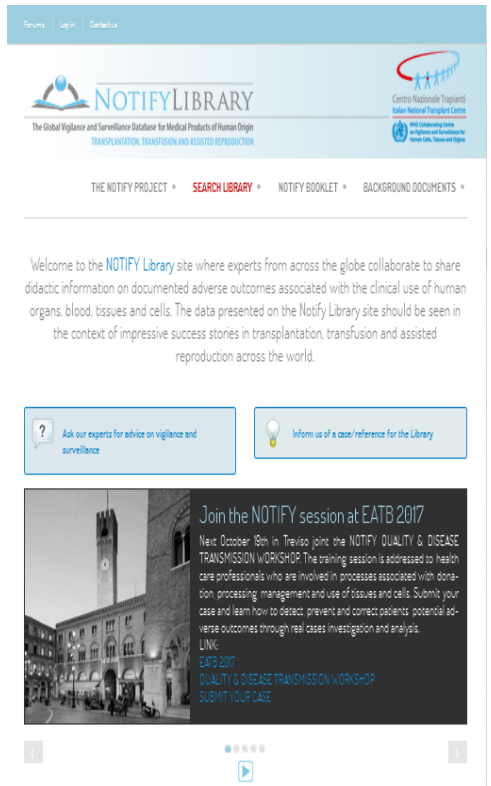
NOTIFY PROJECT: AIMS

To promote the use of vigilance and surveillance in the provision and clinical application of medical products of human origin (MPHO).

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

To provide practical support to countries that are developing vigilance systems for MPHO

NOTIFY PROJECT: MAIN TOOLS



www.notifylibrary.org

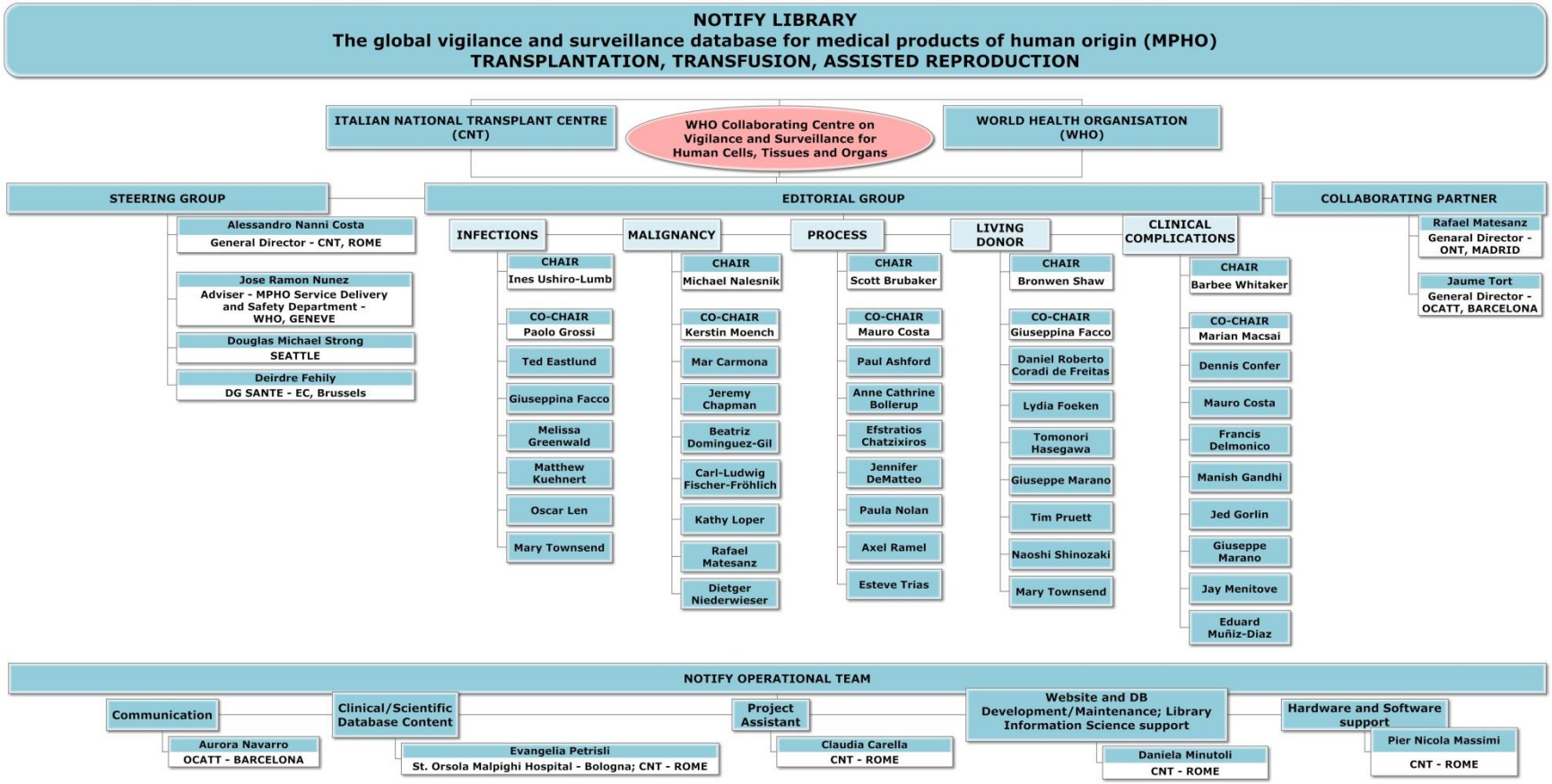
- NOTIFY Website
- NOTIFY V&S guidance Booklet
- NOTIFY Library of didactic cases of events and reactions

NOTIFYLIBRARY

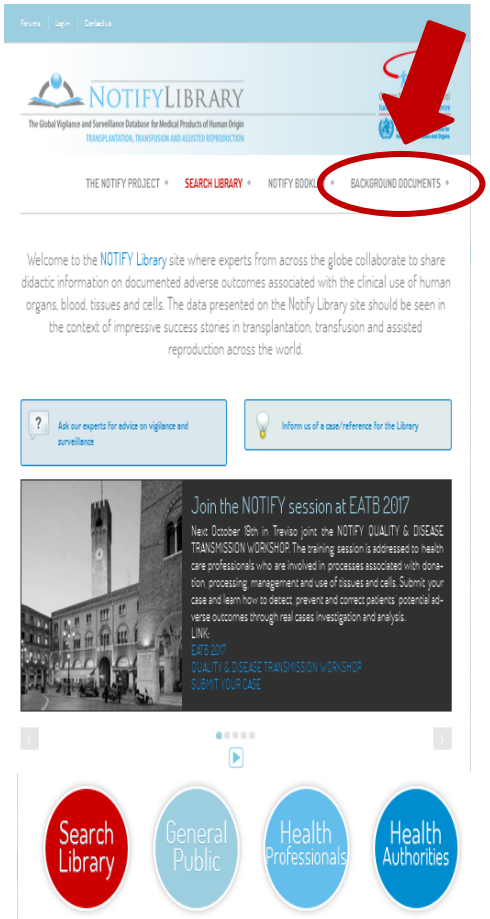
NOTIFY website: www.notifylibrary.org

NOTIFY LIBRARY

NOTIFY PROJECT: WHO WE ARE



BACKGROUND DOCUMENTS



VIGILANCE GUIDANCE DOCUMENTS

- Council of Europe – European directorate for the quality of Medicine and HealthCare (EDQM), European Centre for Disease Prevention and Control (ECDC), International Haemovigilance Network (IHN), International Society of Blood Transfusion (ISBT), etc

VIGILANCE AND SURVEILLANCE REPORTS

- European Union Annual Vigilance Reports, American Association of Blood Banks (AABB), Food and Drug Administration (FDA), Human Fertilisation and Embryology Authority (HFEA), Transfusion and Transplantation Reactions in Patients (TRIP), World Marrow Donors Association (WMDA), etc

WORLD HEALTH ORGANISATION (WHO) AND WORLD HEALTH ASSEMBLY (WHA)

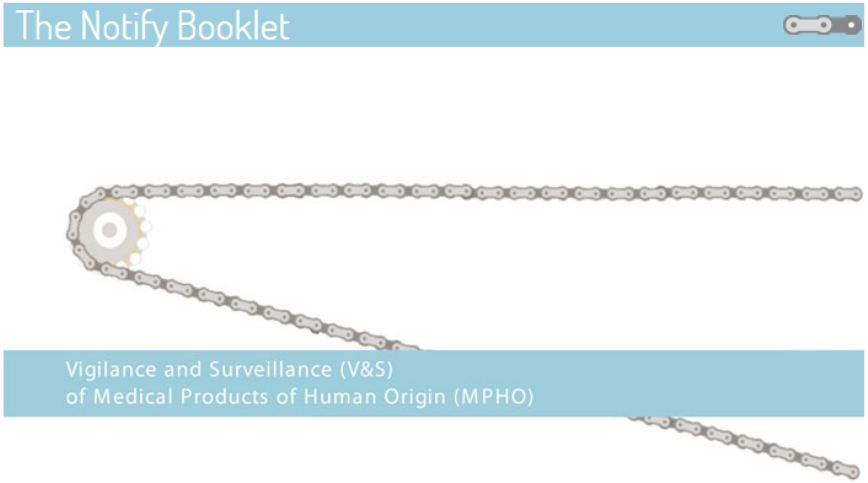
- WHO Guiding Principles on Transplantation, WHO Aide Memoire for National Health Authorities on Safety and Quality of Tissues and Cells., WHO Consultation Report – Tissues and Cells., WHA Resolution 63.22.2010

RECOMMENDATIONS FOR EPIDEMIC DISEASE OCCURRENCE

NOTIFYLIBRARY

NOTIFY BOOKLET

Download Booklet.pdf



1 Introduction
2 The V&S Chain for MPHOs
3 History of Vigilance and Surveillance
4 Medical products of Human Origin (MPHO)
5 Towards a global governance of MPHO
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

NOTIFYLIBRARY

NEW! NOTIFY CONSULTATION GROUP

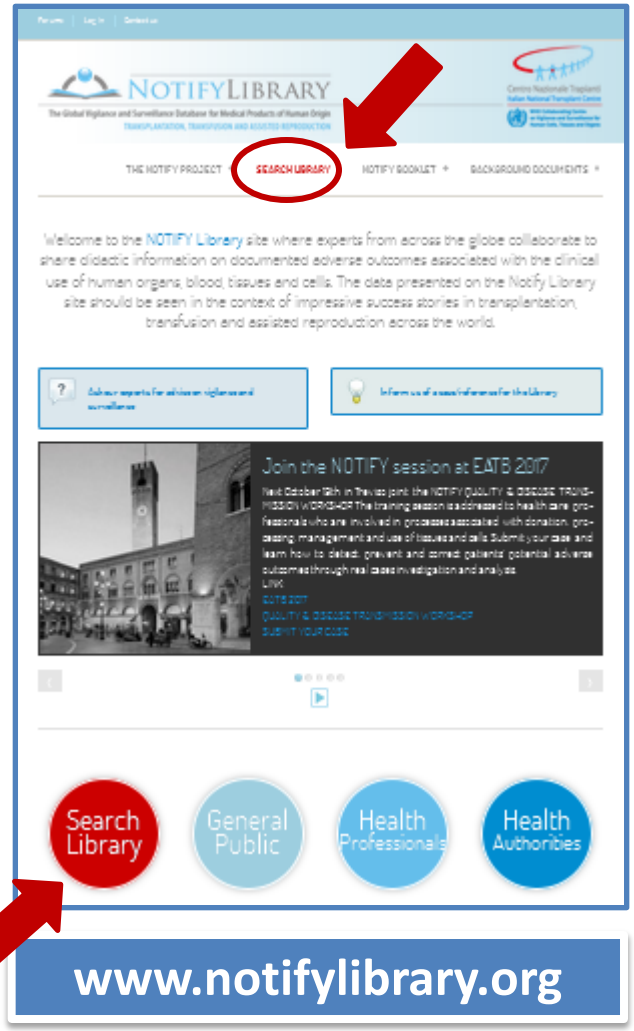
NOTIFYLIBRARY

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

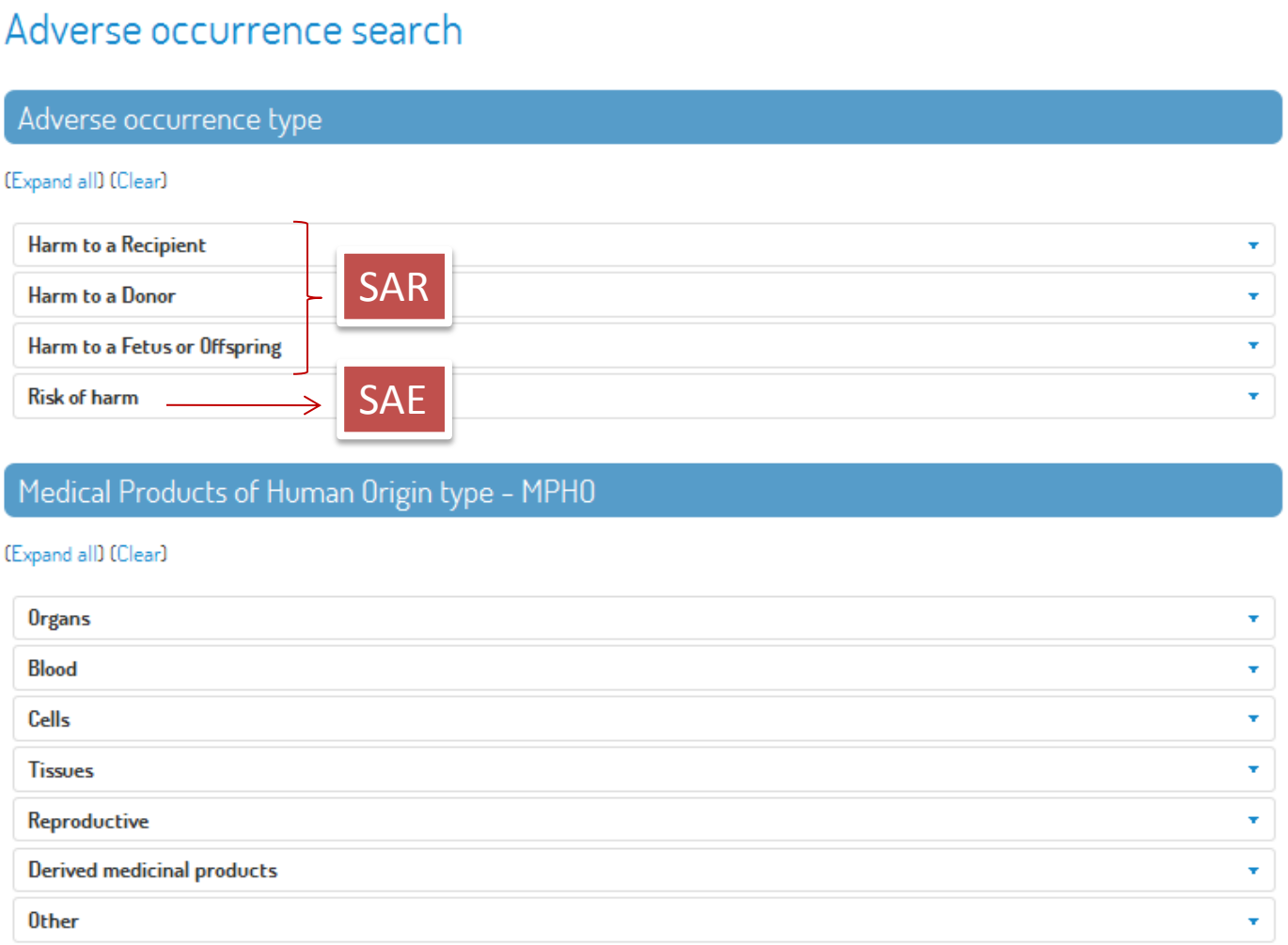
- From procurement and processing to clinical application of blood, organs, tissues, cells and other substances used in transfusion, transplantation, assisted reproduction and other applications

- Collected and analyzed by 5 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)



NOTIFYLIBRARY

ADVERSE OCCURRENCE SEARCH (1)



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ADVERSE OCCURRENCE SEARCH (2)

Keywords

thrombocytopenia

alloimmune thrombocytopenia
FNAIT (fetal and neonatal alloimmune thrombocytopenia)
HIT (heparin induced thrombocytopenia)
thrombocytopenia

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

Free text

thrombocytopenia

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

Notify Library Record ID

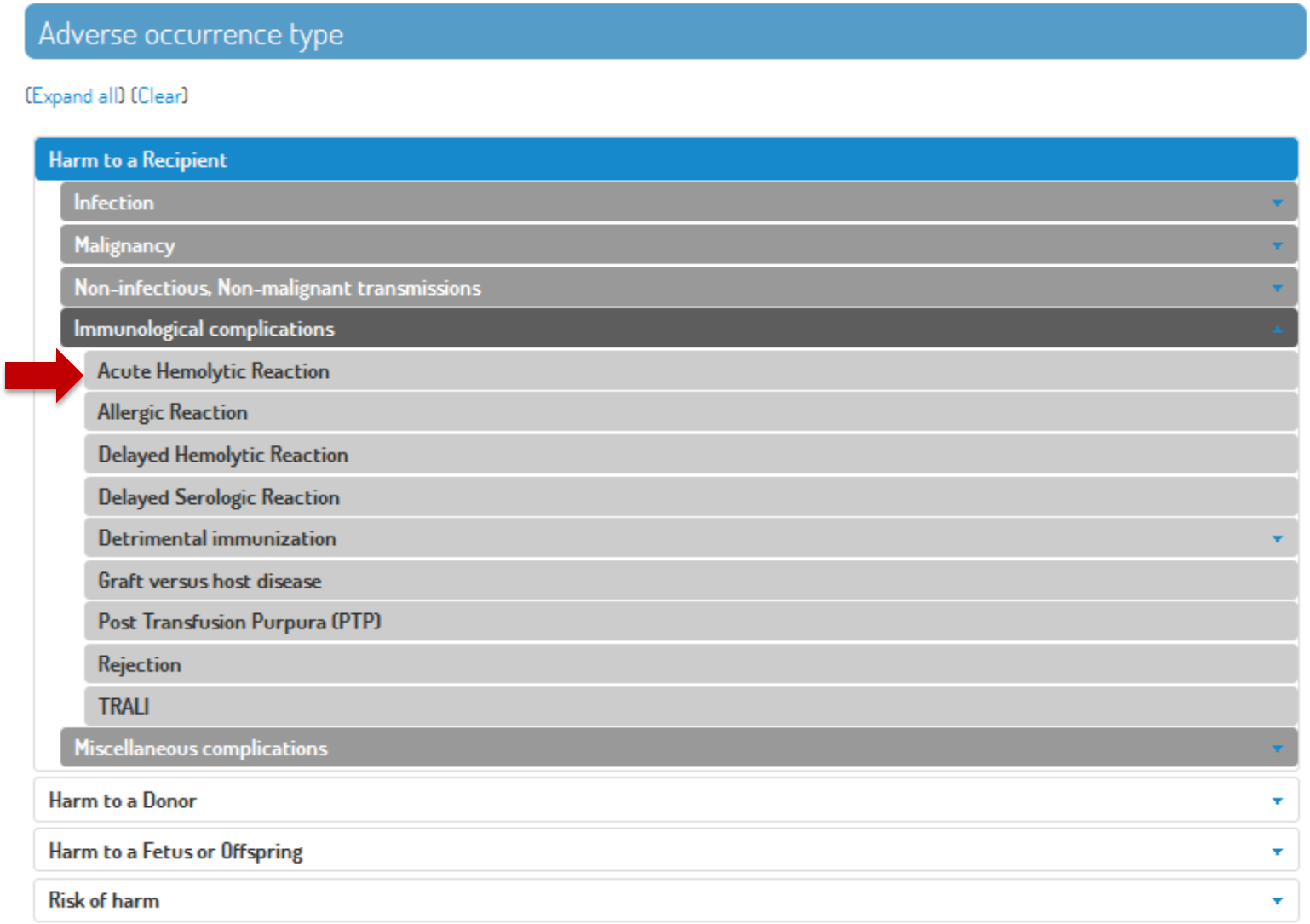
(searches by Notify Library Record ID, for multiple records separated by commas)

Limit results 100 per page

SEARCH | Reset | Print/Save selected items | Save XLS selected items | New search

NOTIFYLIBRARY

SEARCH EXAMPLE BY ADVERSE OCCURRENCE TYPE



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SEARCH EXAMPLE BY MPHO TYPE

Medical Products of Human Origin type - MPHO

(Expand all) (Clear)

- Organs
- Blood
  - Granulocytes
  - Plasma
  - Platelets
  - Red blood cells
  - Whole blood
  - Type not specified
- Cells
- Tissues
- Reproductive
- Derived medicinal products
- Other

NOTIFYLIBRARY

SEARCH RESULTS

Found 35 records (up to page top).

Search criteria:

Adverse occurrence: Harm to a Recipient >> Immunological complications >> Acute Hemolytic Reaction
Medical Product of Human Origin type - MPHO: Blood >> Red blood cells

[4449] Irani, M.S.; Figueroa, D.; Savage, G.
Acute hemolytic transfusion reaction due to anti-Le(b). Transfusion 2015; 55 (10) :2486 - 8

1662

Adverse occurrence description: Acute Hemolytic Transfusion Reaction (AHTR), anti-Le(b)
Adverse occurrence type: Harm to a Recipient => Immunological complications => Acute Hemolytic Reaction
MPHO type: Blood => Red blood cells
Time to detection: During transfusion
Alerting signals, symptoms, evidence of occurrence: A 39-year-old African-American woman with metastatic renal cell carcinoma was receiving chemotherapy. She was anemic with hemoglobin (Hb) of 7.2 g/dL and had a negative antibody detection test by the solid-phase red blood cell adherence method. She was transfused with 2 RBC units without incident. Nine days later her Hb was 7.9 g/dL again with a negative antibody detection test. Transfusion of an additional RBC unit was begun. During the transfusion she developed chills, nausea, hypertension, and red-brown urine. The posttransfusion sample plasma was grossly hemolyzed with a strongly positive direct antiglobulin test (DAT) by gel.
Estimated frequency: Case report
Demonstration of Imputability or Root cause: The pretransfusion plasma was normal appearing and the DAT was weaker. The eluate was negative on both occasions. Anti-Le(b) was detected in the posttransfusion sample by MTS gel (Ortho Diagnostics). Both RBC units she had received before the RBC unit that caused the reaction were Le(b1) as was the implicated RBC unit. The antibody was hemolytic in vitro and her phenotype was Le(a-b-). It is possible she was sensitized at the time of the first transfusions.
Imputability grade: 3 Definite/Certain/Proven
Expert comments for publication: This case illustrates that anti-Le(b) which is usually clinically insignificant can occasionally cause severe hemolytic transfusion reactions. A hemolytic transfusion reaction caused by anti-Le(b) is extremely rare. Only three other reported cases of anti-Le(b) causing hemolytic transfusion reactions could be found in the literature, two of which were abstracts.
Keywords:

AHTR (acute hemolytic transfusion reaction) | RBC (red blood cell) | chills | nausea | hypertension | dark urine | hemolysis | DAT (direct antiglobulin test) | anti-Le(b)

1 reference

NOTIFYLIBRARY

REFERENCE SEARCH

Reference 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 – MPHO

(Expand all) (Clear)

- Organs
- Blood
- Cells
- Tissues
- Reproductive
- Derived medicinal products
- Other

Years

2017
2016
2015
2014
2013
2012
2011
2010

2,378 REFERENCES INDEXED

Authors

Keywords

(searches keywords as published by the authors/editors in the articles referenced in this database)

Free text

(searches the text in titles, abstracts and keywords of published articles referenced in this database)

Notify library reference ID

;)

SEARCH | Reset | Print/Save selected items | Save XLS selected items | New search

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REFERENCE SEARCH RESULTS (1)

Found 6 records (up to page top).

Search criteria:

Authors: TRIP

Feedback questionnaire

91 - Spinal Muscular Atrophy transmission by donor sperm - Sperm
693 - Hemolytic reaction - cord blood - Cord Blood
783 - Dyspnea and diminished saturation - Apheresis
784 - Epileptic seizure - Apheresis
1153 - Processing error - Sperm
1578 - Processing error - Embryo

	Reference ID	Reference	
☐	1553	**TRIP annual report 2009 Tissue Vigilance**, TRIP , Amsterdam, the Netherlands, p.19, (2009)	6 occurrences
☐	1769	**TRIP Annual Report 2007**, TRIP , Amsterdam, the Netherlands, p.38, (2007)	1 occurrence
☐	1879	**TRIP annual report 2010 Tissue Vigilance**, TRIP , Amsterdam, the Netherlands, p.23 p., (2010)	14 occurrences
☐	1880	**TRIP annual report 2011 Tissue Vigilance**, TRIP , Amsterdam, the Netherlands, p.30 p., (2011)	17 occurrences
☐	1881	**TRIP annual report 2012 Biovigilance**, TRIP , Amsterdam, The Netherlands, p.50 p., (2012)	16 occurrences
☐	4372	**TRIP annual report 2013 Biovigilance**, TRIP , Amsterdam, The Netherlands, p.50 p., (2013)	6 occurrences

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REFERENCE SEARCH RESULTS (2)

Found 30 records (up to page top).

Search criteria:

Adverse occurrence: Harm to a Recipient >> Infection >> Parasitic
Medical Product of Human Origin type - MPHO: Organs
Years: 2017 | 2016 | 2015 | 2014 | 2013 | 2012 | 2011 | 2010

Feedback questionnaire

1359 - Plasmodium falciparum - Heart

	Reference ID	Reference	
☐	4004	**Donor-transmitted malaria after heart transplant managed successfully with artesunate.**, Sabe, N., Gonzalez-Costello J., Oriol I., Sanchez-Salado J., Ortega S., Oliver E., Manito N., and Carratala J. , //Transpl Infect Dis, 2014, Volume 16, Issue 6, (C) 2014 John Wiley & Sons A/S, p.999 - 1002, (2014)	1 occurrence
☐	4472	**Use of kidneys from trypanosoma cruzi-infected donors in naive transplant recipients without prophylactic therapy: the experience in a high-risk area.**, Cicora, Federico, Escurra Veronica, Silguero Sergio, Gonzalez Ignacio M., and Roberti Javier E. , Transplantation// Transplantation, 2014//, Volume 97, Issue 1, United States, p.e3 - 4, (2014)	9 occurrences
☐	1869	**Donor-Derived Trypanosoma cruzi Infection in Solid Organ Recipients in the United States, 2001-2011**, Huprikar, S., Bosserman E., Patel G., Moore A., Pinney S., Anyanwu A., Neofytos D., Ketterer D., Striker R., Silveira F., et al. , September, Volume 13, Issue 9, (2013)	4 occurrences

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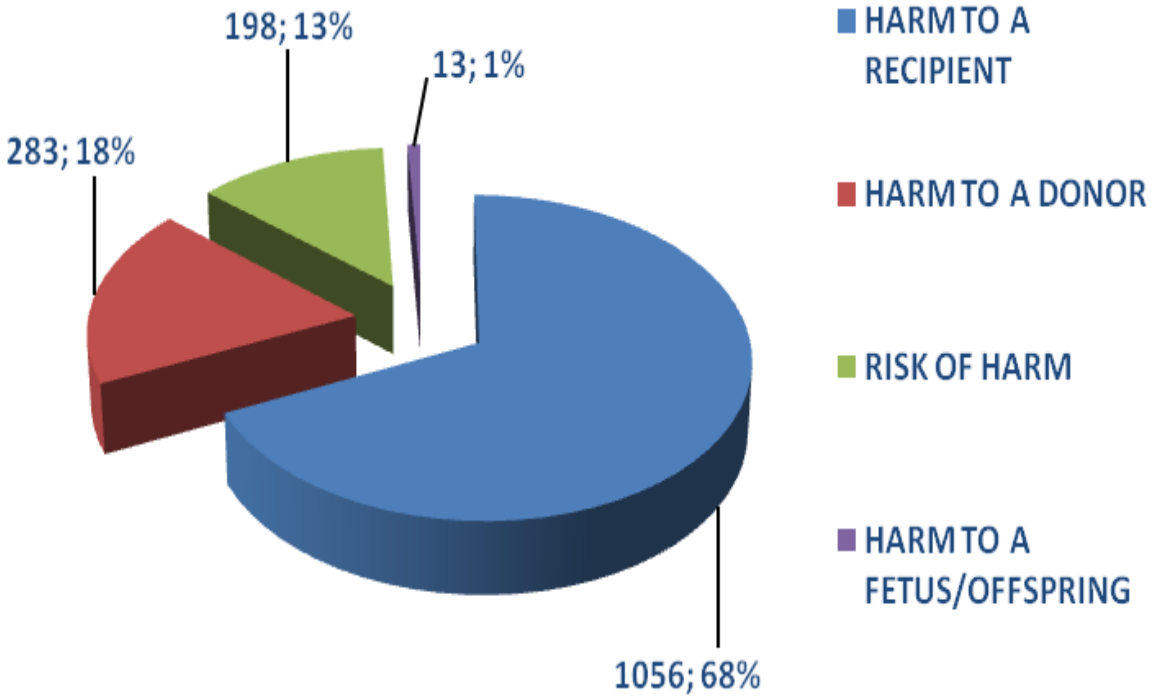
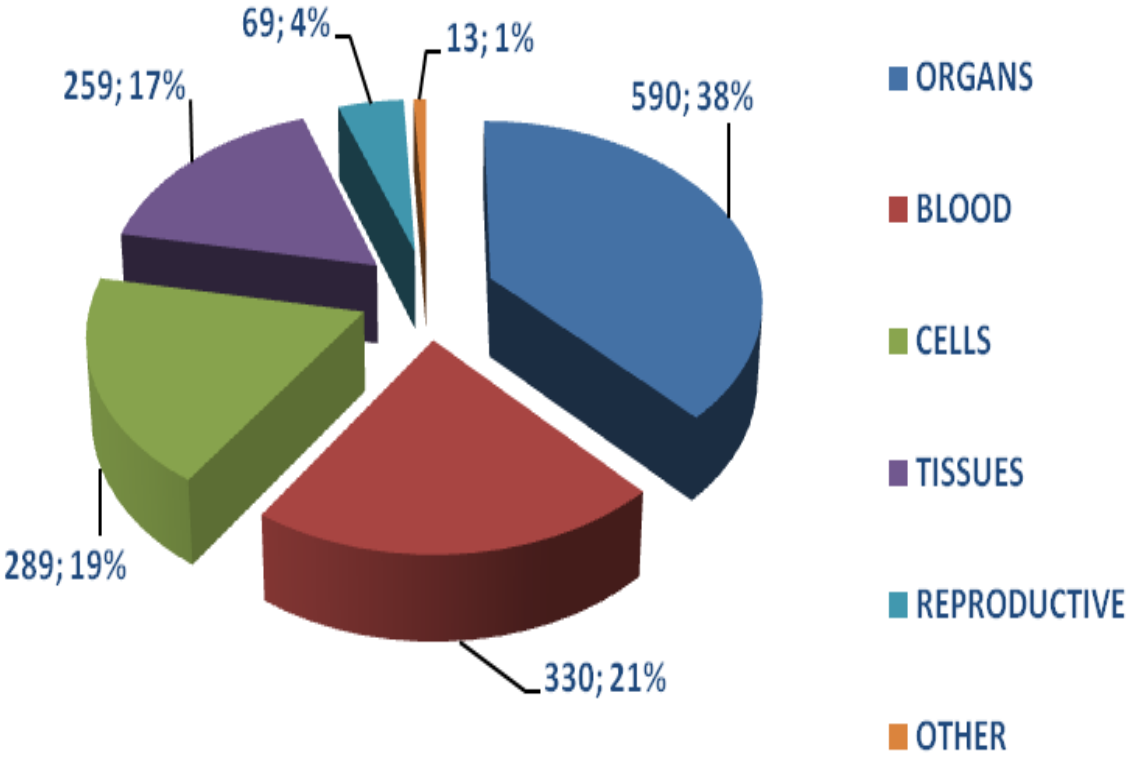
NOTIFY LIBRARY: UPLOADED RECORDS (n=1,550)

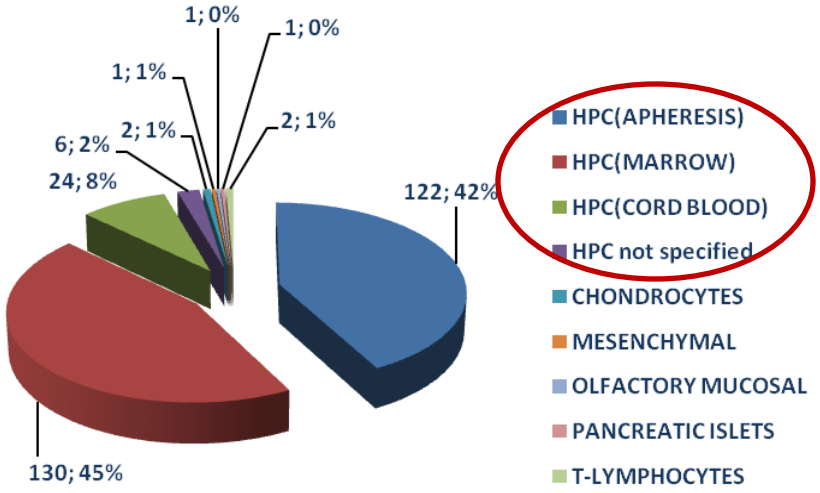


NOTIFYLIBRARY

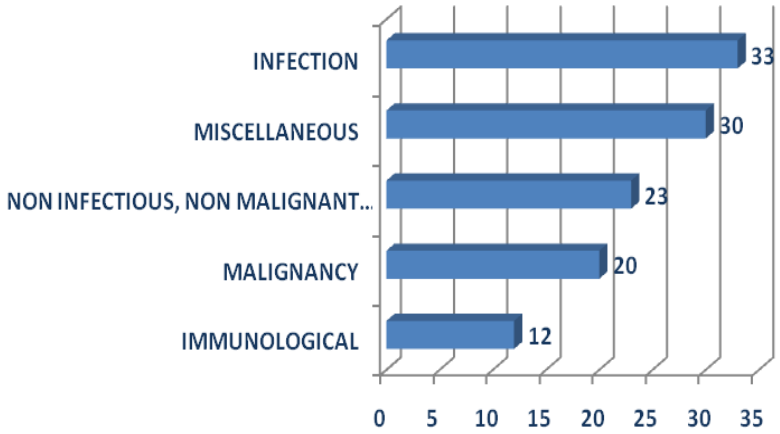
NOTIFY LIBRARY: UPLOADED RECORDS (n=1,550)



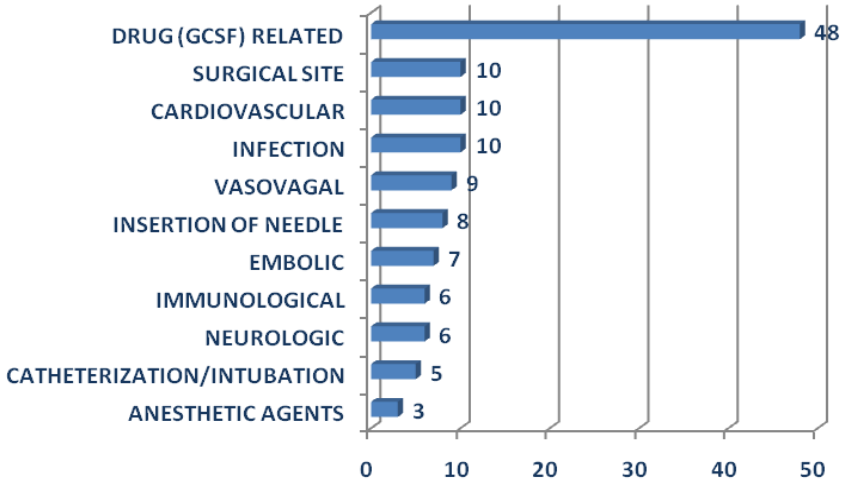
MPHO TYPE: CELLS (n=289)



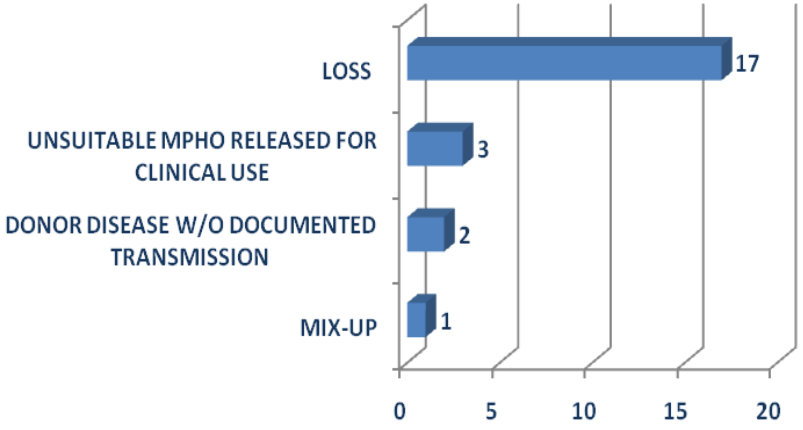
HPC - HARM TO A RECIPIENT



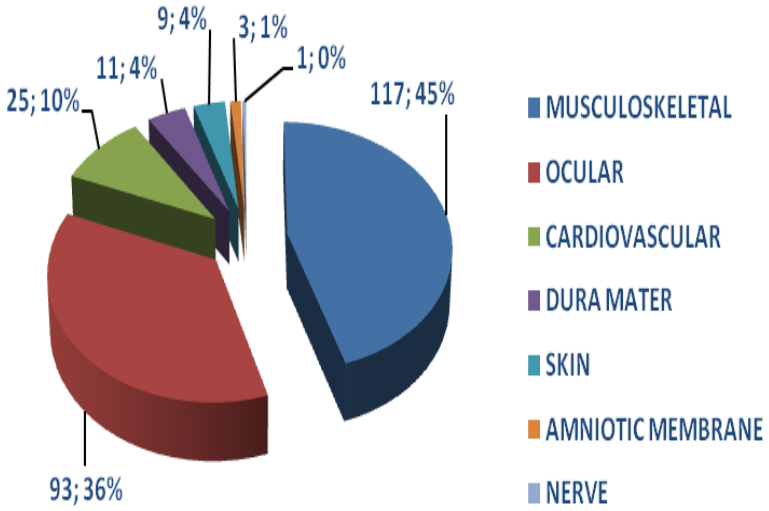
HPC - HARM TO A DONOR



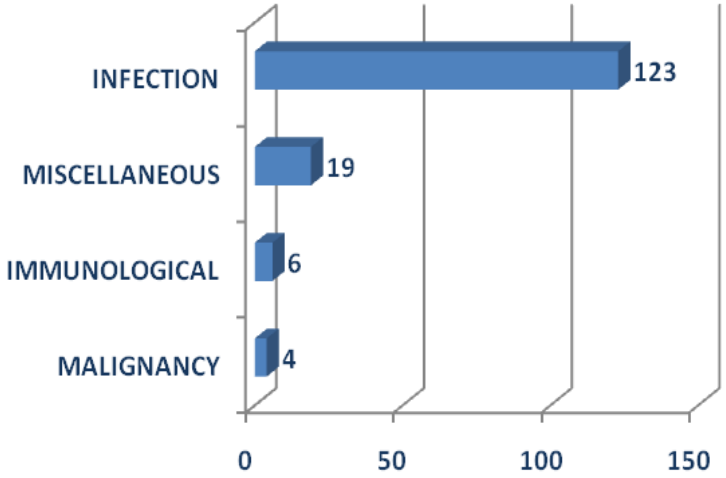
HPC - RISK OF HARM



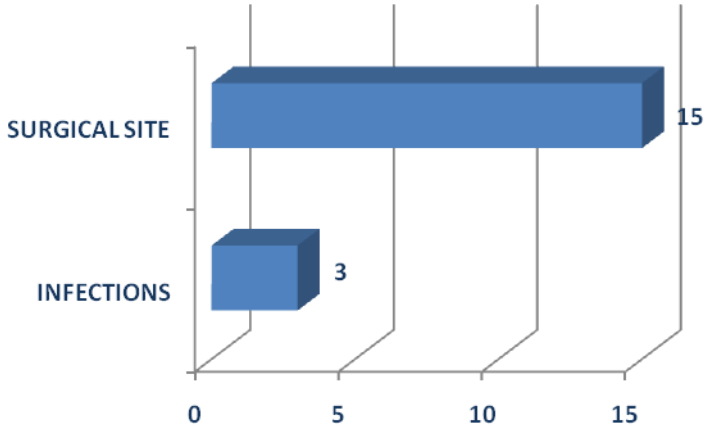
MPHO TYPE: TISSUES (n=259)



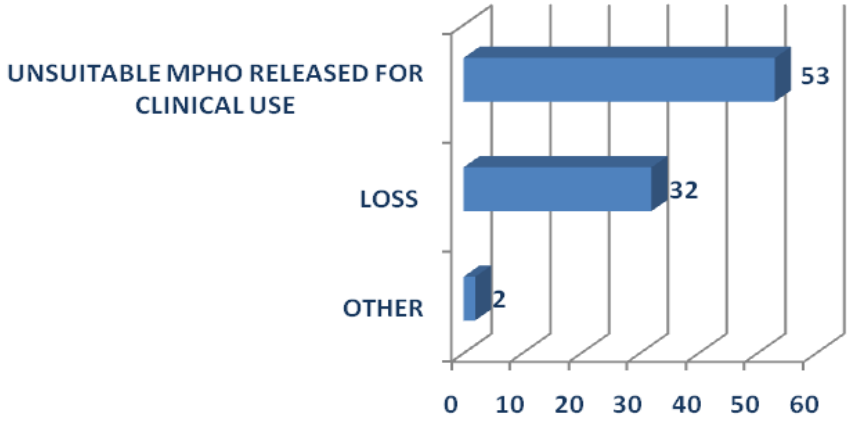
HARM TO A RECIPIENT



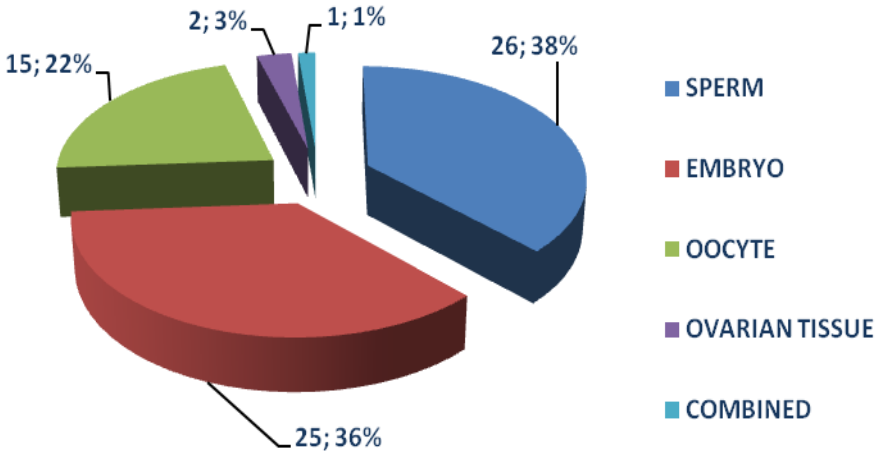
HARM TO A DONOR



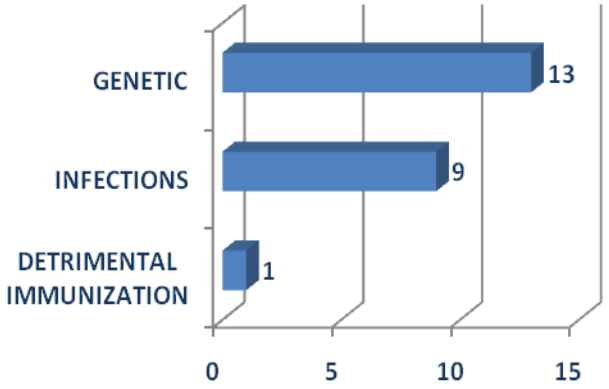
RISK OF HARM



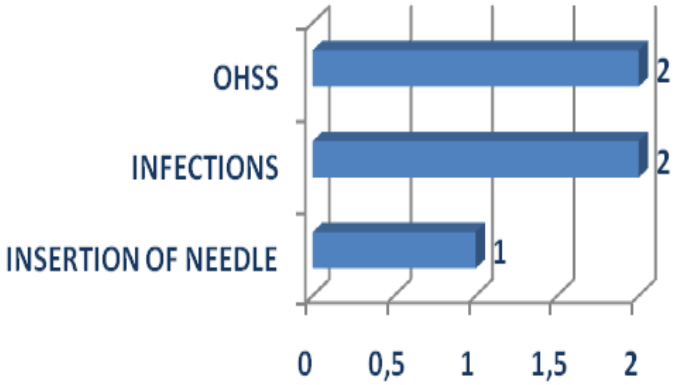
REPRODUCTIVE TISSUES AND CELLS (n=69)



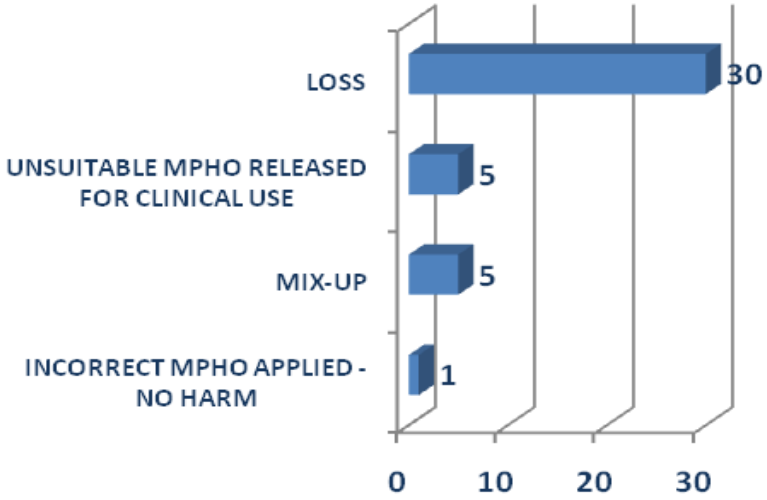
HARM TO A RECIPIENT



HARM TO A DONOR



RISK OF HARM



some case examples

HARM

[1561] Tugwell, B.D.; Patel, P.R.; Williams, I.T.; Hedberg, K.; Chai, F.; Nainan, O.V.; Thomas, A.R.; Woll, J.E.; Bell, B.P.; Cieslak, P.R.
Transmission of hepatitis C virus to several organ and tissue recipients from an antibody-negative donor
Ann Intern Med 2005; 143 (9) :648 - 54

Record ID	Adverse occurrence	
564	**Adverse occurrence description:** Hepatitis C Virus (HCV) **Adverse occurrence type:** Harm to a Recipient => Infection => Viral => Hepatitis C Virus (HCV) **MPHO type:** Tissues => Cardiovascular => Blood vessels **Time to detection:** 6 weeks **Alerting signals, symptoms, evidence of occurrence:** One of two saphenous vein recipients were found to have been infected with HCV by the transplanted tissue as part of an investigation following confirmation of transmission to a tendon recipient. The recipient was one of 8 organ and tissue allograft recipients that acquired HCV infection from a seronegative (but HCV RNA positive) recently infected donor. The index case was a patellar tendon (bone-tendon-bone) recipient, who developed "clinical HCV infection" six weeks after transplantation; the other transmissions were identified as part of the investigation that followed that case. HCV RNA testing of cadaveric donors was not required at the time of the donor's death. This publication gave clinical signs, symptoms, outcomes in only two infected recipients: the lung and patellar tendon recipients. Two years after donation, at least three recipients of organs and tissues had been diagnosed with HCV infection but their infections had not been investigated as potential transmissions. HCV transmission demonstrated in 3 of 3 organ recipients, 1 of 3 tendon recipients, 3 of 3 bone-tendon-bone recipients, 1 of 2 saphenous vein recipients, but not in any of the 16 recipients of freeze-dried irradiated bones, the 2 recipients of cryopreserved, antibiotic soaked skin or the one cornea recipient. **Estimated frequency:** N/A **Demonstration of Imputability or Root cause:** Level 4. Certain, Proven. HCV infection in donor and several tissue and organ recipients. Same genotype Ia and phylogenetic nucleic acid arrangement **Imputability grade:** 3 Definite/Certain/Proven **Expert comments for publication:** **Keywords:** HCV (hepatitis C virus) · hepatitis C infection · NAT (nucleic acid testing) · HCV RNA · vein · saphenous vein · blood vessel · cryopreservation · donor infection · lookback · donor testing · EIA (enzyme immunoassay) · allogeneic	1 reference

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HARM TO A RECIPIENT

Record ID

☐ 1154

Adverse occurrence

Adverse occurrence description: Discarded kidney in error due to labeling and storage errors

Adverse occurrence type: Harm to a Recipient => Miscellaneous complications => Undue exposure to risk-intervention

MPHO type: Organs => Kidney

Time to detection: Immediate

Alerting signals, symptoms, evidence of occurrence: Kidney accidently discarded that had just been removed from a living donor. It had been placed unlabeled in an ice bucket then inadvertently flushed down the OR hopper. Personnel did not see the kidney in the ice. The recipient, having been anesthetized but not incised has been awakened and informed of the events.

Estimated frequency: Not reported

Demonstration of Imputability or Root cause: Upon further examination, the surgical staff realized that the kidney must be discarded due to the extended warm ischemia time and loss of sterility

Imputability grade: 3 Definite/Certain/Proven

Expert comments for publication: Only reference found was from a newspaper article

Keywords:

kidney | discard error | living donor | OR (operating room) | storage | labeling

References

1 reference

[4408] Feehan, J.
UTMC review finds nurse failed to follow procedures in botched kidney transplant The blade 2012;

HAI

[4011] Eder, A.; Dy, B.; Kennedy, J.; Notari, E.; Strupp, A.; Wissel, M.; Reddy, R.; Gibble, J.; Haimowitz, M.; Newman, B.; Chambers, L.; Hillyer, C.; Benjamin, R.
The American Red Cross donor hemovigilance program: complications of blood donation reported in 2006. //Transfusion 2008; 48 (9) :1809 - 1819

1530

Adverse occurrence description: Injury related to loss of consciousness, automated red cell donation
Adverse occurrence type: Harm to a Donor => Vasovagal reactions
MPHO type: Blood => Red blood cells
Time to detection: immediate
Alerting signals, symptoms, evidence of occurrence: None specified. Usual signs and symptoms (ISBT definitions) include any injury resulting from the fall or accident in a donor with a vasovagal reaction and/or loss of consciousness (LOC).
Estimated frequency: 0.001%
Demonstration of Imputability or Root cause: Occurred during or immediately after donation.
Imputability grade: 3 Definite/Certain/Proven
Expert comments for publication: This was a review of all adverse donor reactions occurring within a one year period in the American Red Cross. The denominator was the number of satisfactory (complete) and incomplete donations. Collections included 6,914,472 whole blood (WB), 49,594 apheresis platelets and 228,183 combinations of automated red cell collections. Overall rates of adverse events were WB: 348/10,000 collections; apheresis platelets: 577/10,000 collections and automated red cells: 538/10,000 collections. Major reactions as defined by outside medical care were for WB: 3.2/10,000; automated red cells: 2.9/10,000; this data was not provided for apheresis platelet collections. No latency period was provided but is assumed to be at the time of donation or shortly after. No alerting signals were provided in the paper but were consistent with the ISBT definitions.
Keywords:

RBC (red blood cell) | automated red cell collection | LOC (loss of consciousness) | blood donation | needle insertion | hemovigilance | hemovigilance definitions | fall | vasovagal reaction

1 reference

NOTIFYLIBRARY

HARM TO A DONOR

Record ID

☐ 1798

Adverse occurrence

Adverse occurrence description: Macroscopic (frank) haematuria due to IgA nephropathy

Adverse occurrence type: Harm to a Donor => Drug related reactions => GCSF-related

MPHO type: Cells => HPC => Apheresis

Time to detection: Occurs during GCSF injections (although has been described to occur several days later in at least one case).

Alerting signals, symptoms, evidence of occurrence: Haematuria

Estimated frequency: Uncommon

Demonstration of Imputability or Root cause: Renal biopsy. Definite imputability (if biopsy-proven).

Imputability grade: 3 Definite/Certain/Proven

Expert comments for publication: Uncommon although documented causal link of haematuria provoked by GCSF injection due to underlying IgA nephropathy.

Keywords:

apheresis | G-CSF (granulocyte colony-stimulating factor) | allogeneic | hematuria | haematuria | IgA (immunoglobulin A) | nephropathy | PBSC (peripheral blood stem cells)

References

2 references

[4586] Lee, J.B.L.; Billen, A.; Lown, R.N.; Potter, M.N.; Craddock, C.F.; de Lavallade, H.; Shaw, B.E.; Sharpe, C.C.
Exacerbation of IgA nephropathy following G-CSF administration for PBSC collection: suggestions for better donor screening. Bone marrow transplantation//Bone Marrow Transplant 2016; 51 (2) :286 - 7

[4014] Funakoshi, Y.; Nazneen, A.; Nakashima, Y.; Nakashima, K.; Okada, M.; Taguchi, T.; Moriuchi, H.
Possible involvement of G-CSF in IgA nephropathy developing in an allogeneic peripheral blood SCT donor. //Bone Marrow Transplant 2010; 45 (9) :1477 - 1478

NOTIFYLIBRARY

HARM TO OFFSPRING

Record ID

☐ 102

Adverse occurrence

Adverse occurrence description: Autosomal Dominant Polycystic Kidney Disease (ADPKD) transmission by donor sperm

Adverse occurrence type: Harm to a Fetus or Offspring => Genetic

MPHO type: Reproductive => Sperm

Time to detection: N/A

Alerting signals, symptoms, evidence of occurrence: Birth of a newborn with autosomal dominant polycystic kidney disease (ADPKD) following sperm donation.

Estimated frequency: N/A

Demonstration of Imputability or Root cause: Sperm bank failed to disclose that the sperm came from a donor with a family history of Autosomal Dominant Polycystic Kidney Disease (ADPKD). Neither the woman receiving donor semen or her partner has ADPKD or a family history of the disease.

Imputability grade:

Expert comments for publication:

Keywords:

insemination | heterologous insemination | AID (artificial insemination by donor) | artificial | human donor | sperm bank | sperm donor | gamete donor | genetic testing | genetic counseling | ADPKD (autosomal dominant polycystic kidney disease) | non partner

References

2 references

[1772] Johnson v Superior Court, 80 Cal App 4th 1050 2000; 95 :864-79

[393] Daar, J.F.; Brzyski, R.G. Genetic screening of sperm and oocyte donors: ethical and policy implications. JAMA 2009; 302 (15) :1702 - 4

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RISK OF HAR

[4466] Li, J.Y.
Donors with melanoma history: the risk to ocular tissue recipients
International Journal of Eye Banking 2016; 4 (1) :1-4

Record ID	Adverse occurrence	es
1683	**Adverse occurrence description:** Subject review: Donors with melanoma history and risk to ocular tissue recipients **Adverse occurrence type:** Risk of harm => Other **MPHO 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 38-40% 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	1 reference

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RISK OF HARM

[1553] TRIP.
TRIP annual report 2009 Tissue Vigilance 2009; :19

1578

Adverse occurrence description: Processing error

Adverse occurrence type: Risk of harm => Loss => Highly matched or autologous MPHO

MPHO type: Reproductive => Embryo

Time to detection: N/A

Alerting signals, symptoms, evidence of occurrence: Only one embryo was obtained after an emergency IVF procedure for fertility preservation, that by mistake was not frozen on the usual day according to protocol. An adapted freezing procedure for later freezing should have been used but unfortunately this was not done.

Estimated frequency: Very rare

Demonstration of Imputability or Root cause: Preservation process error.

Imputability grade:

Expert comments for publication: Emergency IVF are made in oncologic patients, before chemotherapy or radiotherapy, to preserve fertility. There is usually short time, because patients have to start antineoplastic therapy. Ovarian stimulation is started at the beginning of menses, and, after oocytes retrieval, oocytes or embryos are frozen. Often this is the last opportunity for some oncologic patients who start a very toxic therapy to have some years later a pregnancy, because some antineoplastic therapies induce an irreversible damage to the ovaries. In this case, after an ovarian stimulation, the patient hasn't any embryos to freeze, and maybe she hasn't enough time to start another treatment before the beginning of antineoplastic therapy.

Keywords:

processing | lab error | embryo | freezing protocol | cryopreservation | IVF (in vitro fertilization) | fertility preservation

Reference

[4049] CDC.
Potential transmission of viral hepatitis through use of stored blood vessels as conduits in organ transplantation--Pennsylvania, 2009. MMWR. Morbidity and mortality weekly report//MMWR Morb Mortal Wkly Rep 2011; 60 (6) :172 - 4

1402

Adverse occurrence description: Hepatitis B Virus (HBV)

Adverse occurrence type: Risk of harm => Unsuitable MPHO released for clinical use - no harm

MPHO type: Tissues => Cardiovascular => Blood vessels

Time to detection: N/A

Alerting signals, symptoms, evidence of occurrence:

Estimated frequency: N/A

Demonstration of Imputability or Root cause: Error without infection; exposure to hepatitis B from vessel conduit; discovered on review of serologic discordance between vessel donor and recipient.

Imputability grade:

Expert comments for publication: Although hepatitis transmission did not occur in the two cases described in this report, the error of transplanting a vessel from a seropositive donor into a seronegative recipient was the same in these cases as it was in the case where transmission did occur; the error occurred despite appropriate labeling of vessel seropositivity. These are thus considered important "near miss" incidents in which transmission could have occurred despite appropriate safeguards being in place. Based on this investigation, CDC recommends that transplant centers discontinue the practice of storing vessels from donors with viral hepatitis markers. These markers include HBsAg, anti-HCV, or HBV or HCV detectable by nucleic acid tests. This discontinuation would apply to storage of vessels from donors seropositive or nucleic acid–positive, even if their storage was designated for use only with the original organ, because this practice still would not remove the potential for human error resulting in inadvertent use in a seronegative recipient. OPTN currently is considering a binding policy prohibiting storage of hepatitis-seropositive vessels at transplant centers.

Keywords:

HBV (hepatitis B virus) | conduit vessel | virus | asymptomatic | error

1 reference

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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**.

NOTIFYLIBRARY

VISTART JOINT ACTION

- **V**igilance and **I**nspection for the **S**afety of **T**ransfusion, **A**ssisted **R**eproduction and **T**ransplantation is a Joint Action co-funded by the European Union. The Joint Action started 10 October 2015, the duration is 36 months
- Blood, tissues and cells (including ART)
- Specific VISTART WP for Notify Library (**WP5A**)
- website: https://vistart-ja.eu/

VISTART
VIGILANCE AND INSPECTION FOR THE SAFETY OF TRANSFUSION ASSISTED REPRODUCTION AND TRANSPLANTATION

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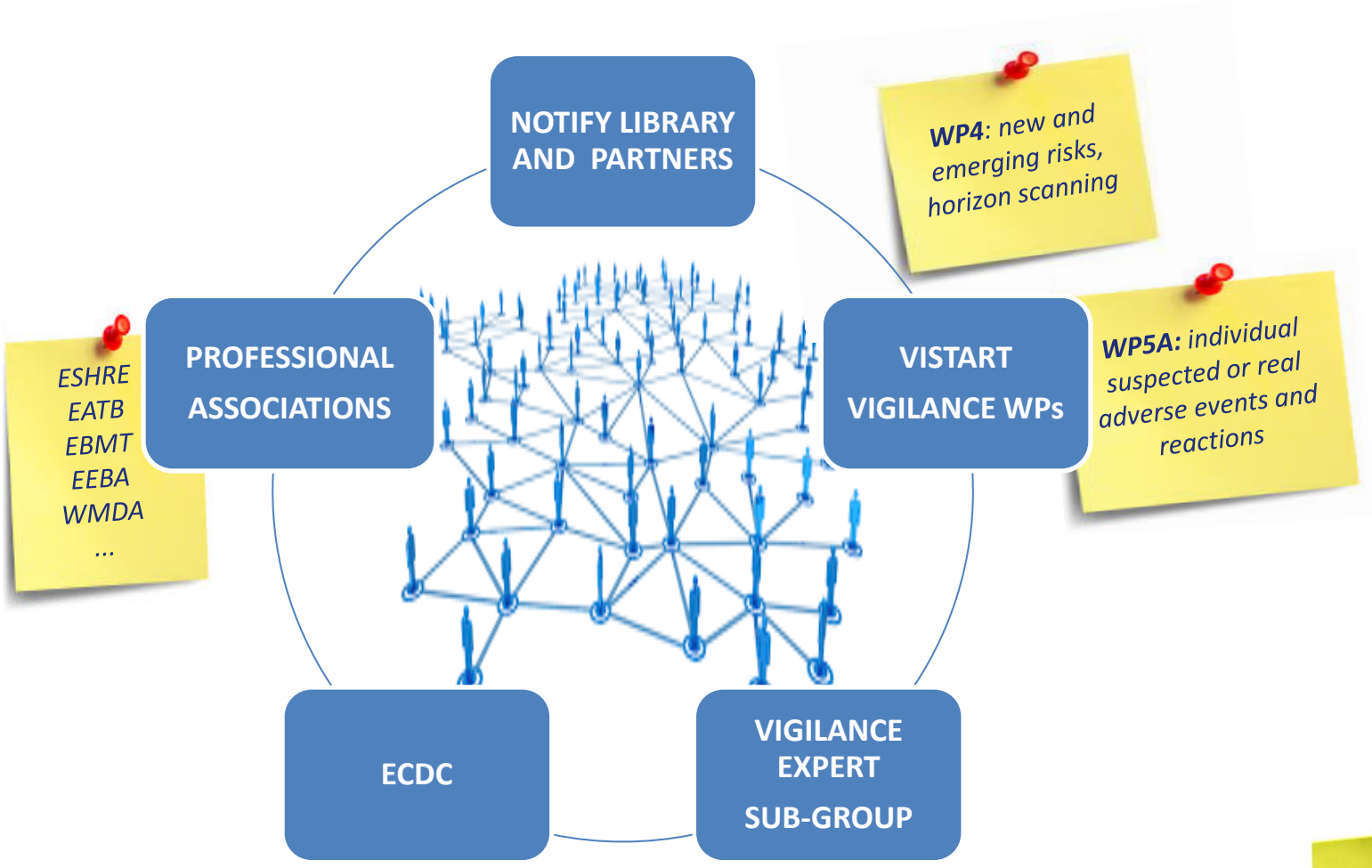
VISTART WP5A: NETWORK OF VIGILANCE



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Thank you!

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Centro Nazionale Trapianti
Italian National Transplant Centre

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