



CENTRO NAZIONALE
TRAPIANTI



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



EIOS and the NOTIFY MPHO Safety Network

Evi Petrisli
on behalf of the Notify team

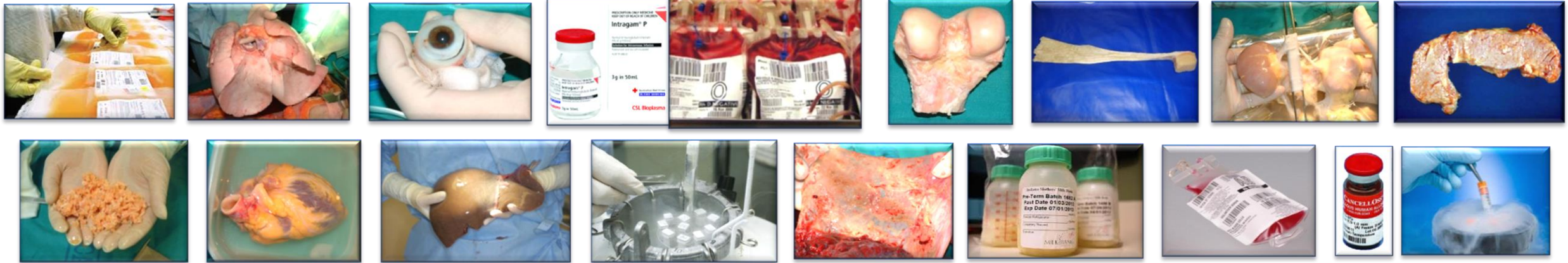
EIOS Global Technical Meeting
Luxor, November 27th – 29th 2022

Medical Products of Human Origin (MPHO)

Substances that are derived wholly or in part from the **human body** and intended for **clinical application**

From donation to the follow-up care of the recipient, MPHOs have a **shared exposure to risks** with a potential undesirable outcome

Vigilance and surveillance systems → monitoring of severe adverse occurrences, improved mitigation or prevention measures



Adverse occurrences

Centers for Disease Control and Prevention

MMWR

Weekly / Vol. 60 / No. 50

Morbidity and Mortality Weekly Report

December 23, 2011

Transmission of Hepatitis C Virus Through Transplanted Organs and Tissue — Kentucky and Massachusetts, 2011

Brauns et al. *World Allergy Organization Journal* (2016) 9:3
DOI 10.1186/s40413-016-0093-4

World Allergy
Organization Journal

CASE REPORT

Open Access

A lurking threat: transfer of peanut allergy through peripheral blood stem cell transplantation

Birka Brauns^{1,5*}, Michael P. Schön^{1,2}, Gerald Wulf³ and Martin Mempel^{1,2,4}



Molecular Insights in Transmission of Cancer From an Organ Donor to Four Transplant Recipients

Chloe E. Atreya, MD, PhD^{1,2}; Eric A. Collisson, MD^{1,2}; Meyeon Park, MD, MAS³; James P. Grenert, MD, PhD^{4,5}; Spencer C. Behr, MD^{2,6}; Amalia Gonzalez, BA⁷; Jonathan Chou, MD, PhD^{1,2}; Samantha Maisel, BA¹; Terence W. Friedlander, MD^{1,2}; Chris E. Freise, MD⁸; Jun Shoji, MD³; Thomas J. Semrad, MD⁹; Jessica Van Ziffle, PhD^{5,10}; and Peter Chin-Hong, MD¹¹

Evidence for Transmission of Zika Virus by Platelet Transfusion

N ENGL J MED 375;11 NEJM.ORG SEPTEMBER 15, 2016

Notes from the Field

Tuberculosis Outbreak Linked to a Contaminated Bone Graft Product Used in Spinal Surgery — Delaware, March–June 2021

Ruoran Li, ScD^{1,2,*}; W. Wyatt Wilson, MD^{1,2,*}; Noah G. Schwartz, MD^{1,3}; Alfonso C. Hernandez-Romieu, MD^{1,2}; Janet Glowicz, PhD²; Emily Hanlin, MPH⁴; Malikah Taylor, MPH⁴; Heather Pelkey⁵; Carol A. Briody⁵; Lija Gireesh, DNP⁵; Mark Eskander, MD³; Kenneth Lingenfelter, DO⁵; Sandy P. Althomsons, MA³; Rebekah J. Stewart, MSN³; Rebecca Free, MD²; Pallavi Annambhotla, DrPH²; Sridhar V. Basavaraju, MD²; Jonathan M. Wortham, MD³; Sapna Bamrah Morris, MD³; Isaac Benowitz, MD²; Maryam B. Haddad, PhD³; Rick Hong, MD⁴; Marci Drees, MD⁵

Received: 6 December 2020

DOI: 10.1111/ajt.16532

CASE REPORT

Donor to recipient transmission of SARS-CoV-2 by lung transplantation despite negative donor upper respiratory tract testing

Daniel R. Kaul¹ | Andrew L. Valesano¹ | Joshua G. Petrie² | Rommel Sagana³ | Dennis Lyu³ | Jules Lin⁴ | Emily Stoneman¹ | Lane M. Smith⁵ | Paul Lephart⁶ | Adam S. Luring⁷

AJT

NOTIFY project: aims

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

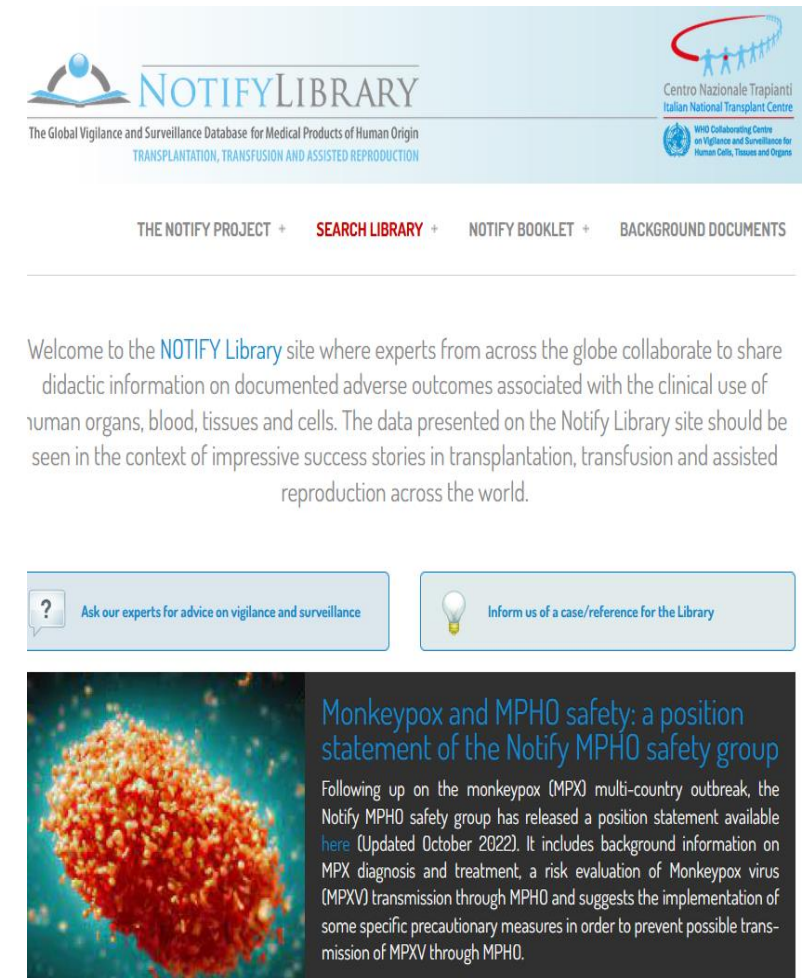
To draft common guidelines supporting the implementation of effective vigilance and surveillance

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

Notify Library

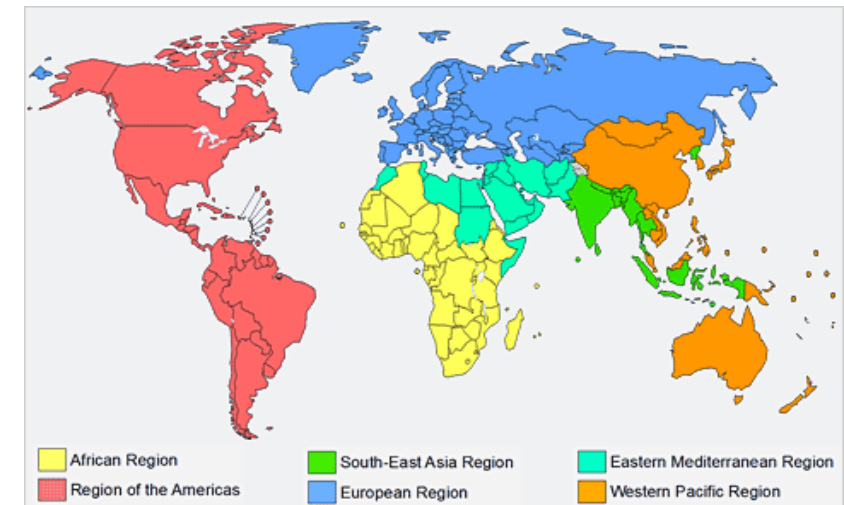
<http://www.notifylibrary.org>

- **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)



Notify website visits by WHO regional office

	2018 (users; sessions)	2019 (users; sessions)	2020 (users; sessions)	2021 (users; sessions)
EURO	2,790; 4,742	3,733; 5,558	9,922; 10,962	8,311; 8,881
SEARO	964; 1,022	2,023; 2,143	3,035; 4,030	5,599; 5,705
WPRO	884; 991	1,702; 1,838	3,948; 4,030	5,060; 5,236
EMRO	290; 300	629; 674	1,225; 1,262	1,455; 1,284
AFRO	151; 161	496; 525	917; 929	1,347; 1,405
PAHO	4,184; 4,877	8,496; 9,166	22,765; 23,071	15,737; 16,175
OTHER	138; 142	115; 120	169; 171	214; 227
TOTAL	9,371; 12,235	17,194; 20,024	41,981; 43,522	37,559; 38,913



MPHO Safety Network: background

To strengthen global sharing of **surveillance information** on the microbiological safety of MPHO supply, the CNT and the European Centre for Disease Prevention and Control co-organised a virtual meeting of the Notify project group in October 2020.



Centro Nazionale Trapianti
Italian National Transplant Centre



WHO Collaborating Centre
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Participants discussed the **need to address new emerging disease threats to MPHO rapidly**, allowing a wider proactive approach.



To tackle MPHO safety needs, participants took the initiative to establish an **international network** that could support the identification of threats posed by infectious diseases to the safety of MPHO supply and use the Notify infrastructure to share this information with colleagues around the world

MPHO Safety Network

October 2020

Keeping MPHO safe
- monitoring adverse
outcomes and
scanning for new
threats. A Joint
ECDC and WHO
Notify project
meeting

July 2021

All Notify project
experts and
meeting attendees
were invited to
volunteer, or to
nominate an
alternative local
expert in the field of
microbiological
safety of MPHO

November 2021

First discussion on
action steps
between WHO
and Notify team

November 2022

Translation of
identified
keywords in other
languages



January 2021

Redesignation of
CNT as WHO-CC
and definition of
new TOR

August 2021

Registration of
MPHO Safety
Network on the
EIOS platform

June 2022

MPHO related
category definition

EIOS EPIDEMIC INTELLIGENCE
FROM OPEN SOURCES

M P H O Safety
Network

Identifying
potential threats
(ECDC)

Identifying
potential threats
(EIOS, WHO)

Identifying
potential threats
(CDC? Others?)

Uploading possible records for
evaluation
(Notify team)

Review and creation of
records
(Expert group)

PUBLISH RECORDS in the
MPHO Safety Outbreak
Register
(Notify team)

Inputs: Search
criteria
Output: long list

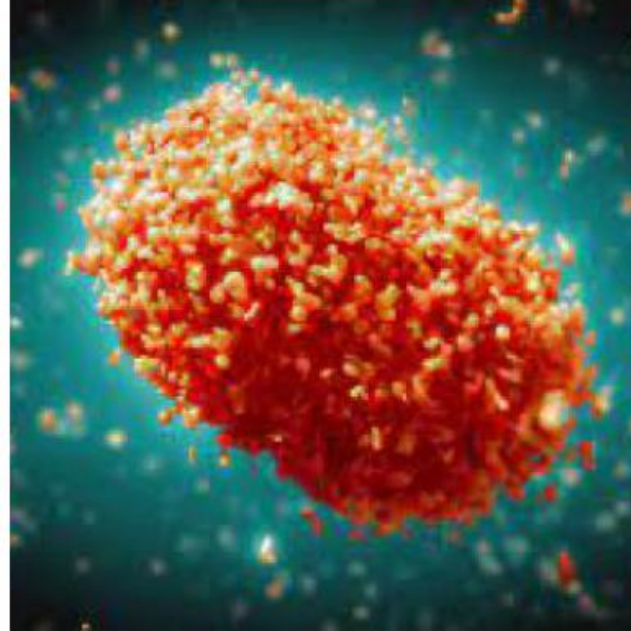
Input: Selection
criteria
Output: shortlist

Management tool
similar to the EG
management record
tool

Register of records:
Standard format

MPHO Safety Network Output

To provide useful information to be shared with the Notify MPHO safety network, thus to prepare specific alert to prevent disease transmission through MPHO transfusion and transplantation.



Monkeypox and MPHO safety: a position statement of the Notify MPHO safety group

Following up on the monkeypox (MPX) multi-country outbreak, the Notify MPHO safety group has released a position statement available [here](#) (Updated October 2022). It includes background information on MPX diagnosis and treatment, a risk evaluation of Monkeypox virus (MPXV) transmission through MPHO and suggests the implementation of some specific precautionary measures in order to prevent possible transmission of MPXV through MPHO.

Learning from Vigilance

From Latin “vigilare”,
to watch, to stay awake,
to paying close and
continuous attention



Interested parties can contact us
e.petrisli@yahoo.com
notifylibrary@iss.it



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Commentary

Donor-derived Disease—Who to Notify?

Jeremy R. Chapman, AC, FRACP, MD¹

Review

Vigilance for Medical Products of Human Origin—Progress on the Notify Library's Global Effort to Share Information and Learning

Evangelia Petrisli, MD,¹ Claudia Carella, MA,² Aurora Navarro, MD,³ Deirdre Fehily, PhD,^{2,4}
Douglas Michael Strong, PhD,⁵ and Massimo Cardillo, MD²; on behalf of the Notify Editorial Board*

*Thank you for
your attention!*