Developing a National Haemovigilance Programme

Established Programme – more than 20 years

Professor Constantina Politis

Scientific Advisor for the National Public Health Organisation

Hellenic Coordinating Haemovigilance Centre and Surveillance of Transfusion

Background

- SKAEM, founded in **1995** by the Hellenic Centre for Disease Control (KEEL)
- 2011 it was appointed by the Ministry of Health as the competent authority for haemovigilance in Greece
- By the virtue of the Law 4633/16-10-2019 KEELPNO has been upgraded to National Health Organization (EODY) and SKAE has also undertaken the task of the **epidemiological surveillance of transfusion** – and is therefore referred to as SKAEM
- Working through 6 regional centres, its multidisciplinary team undertakes epidemiological surveillance of transfusion in the broader sense of the term within the National Health Organization (EODY) and Ministry of Health infrastructure, in support of the National Blood Centre
- SKAEM's national epidemiological surveillance contributes to blood safety and quality by highlighting and preventing risks to the lives of transfused patients due to human errors and deviations from Good Practice Guidelines
- All untoward adverse reactions (ARs) and adverse events (AEs) in patients and donors are recorded, irrespective of severity, using standardized recording and reporting mechanisms

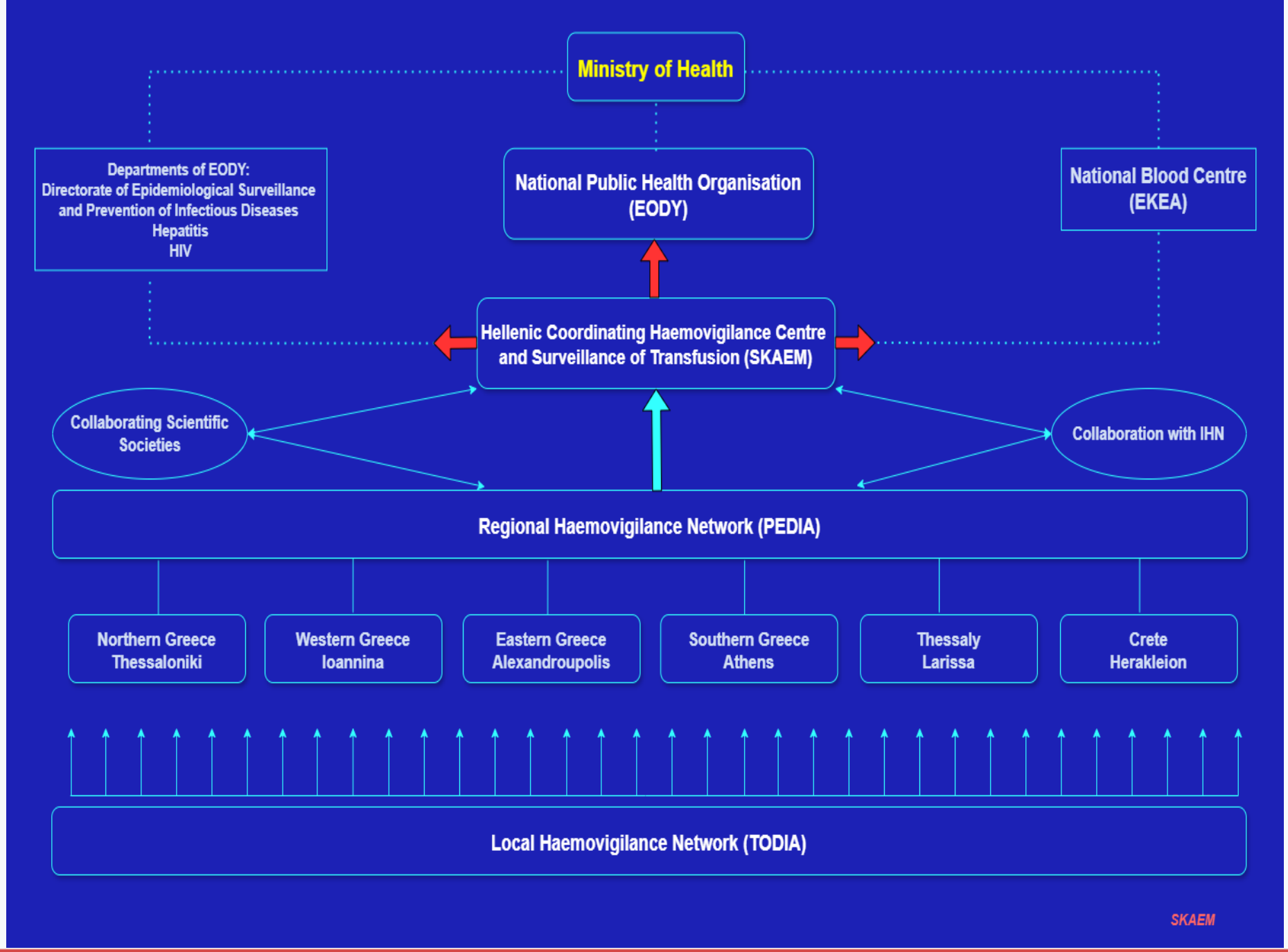
SKAEM

Planning a surveillance system

- Establish objectives
- Develop definitions
- Determine data sources
- Determine the data collection mechanism
- Construct data collection instruments
- Carry out field testing of methods
- Develop and test the analytic approach
- Develop a dissemination mechanism
- Ensure that analysis and interpretation are sustainable
- Assure protection and confidentially of data
- Develop a system for notifying information to the relevant authorities

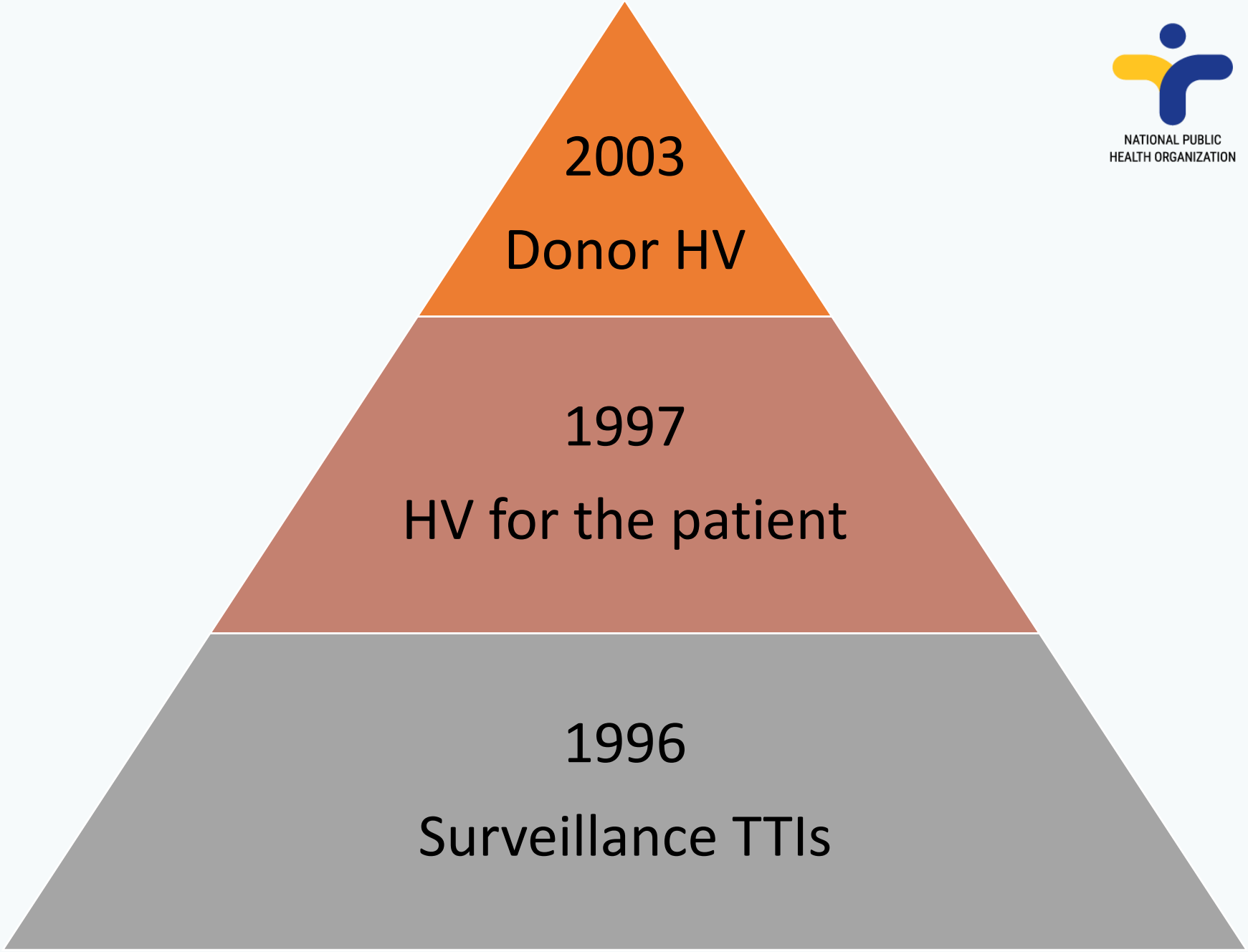
SKAEM

The Greek National Haemovigilance Network



NATIONAL PUBLIC HEALTH ORGANIZATION

The Hellenic Holistic Approach to Blood System Surveillance



SKAEM's Basic Functions

NATIONAL PUBLIC HEALTH ORGANIZATION

Surveillance of transfusion transmissible Infections TTIs

Traceability
Retrieval of potential infectious donations
Post donation Information
Look back

Surveillance of adverse reactions and adverse events associated with blood transfusion

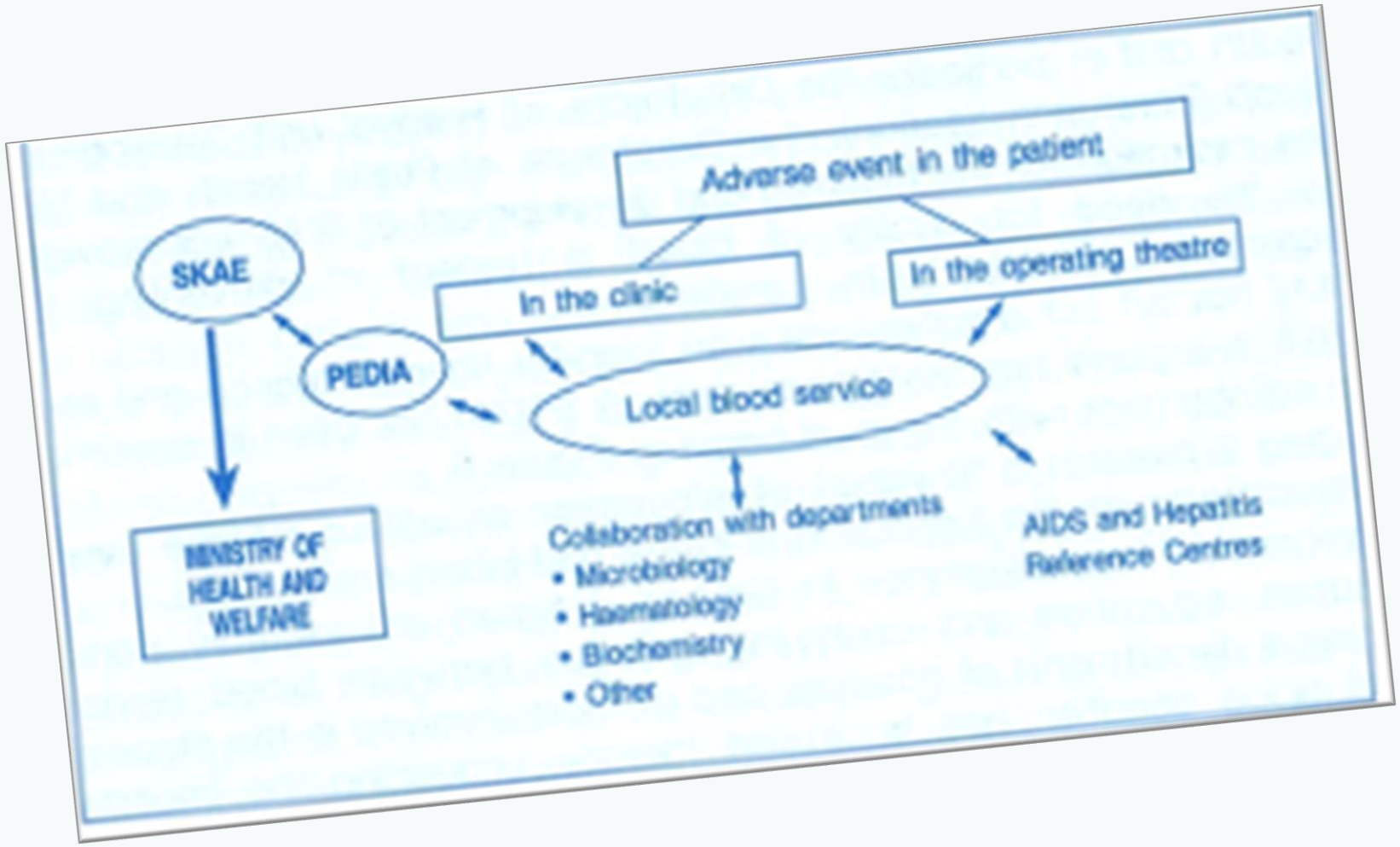
Reporting to the competent authorities
Recommending preventive and corrective measures
Warning BTS and hospitals
Informing the medical community about the risk of transfusion

Surveillance of adverse reactions and events in blood donors during or after donation

Alerts
Crisis management
Cost-effective studies
Education
Research - Publications

Constant cooperation between all stakeholders: Health Authorities, Blood establishment and Clinicians

Flow Chart of Information



SKAEM

Methods

Seroprevalence of mandatorily screened HBsAg, anti-HCV, anti-HIV, anti-HTLV, Syphilis infections as well as molecular testing for HIV-RNA, HCV-RNA, HBV-DNA, **Estimation of residual risks for TTIs**

Retrospective screening (**Look-back**) and post-donation information procedure

All transfusion–associated ARs and AEs, **Root Cause Analysis** per blood component, type of reaction, imputability, severity and outcome of the event and post-transfusion information procedures

Recording of serious and “near-miss” adverse events, as well as errors without serious consequences which may affect the safety and the quality of the transfused component

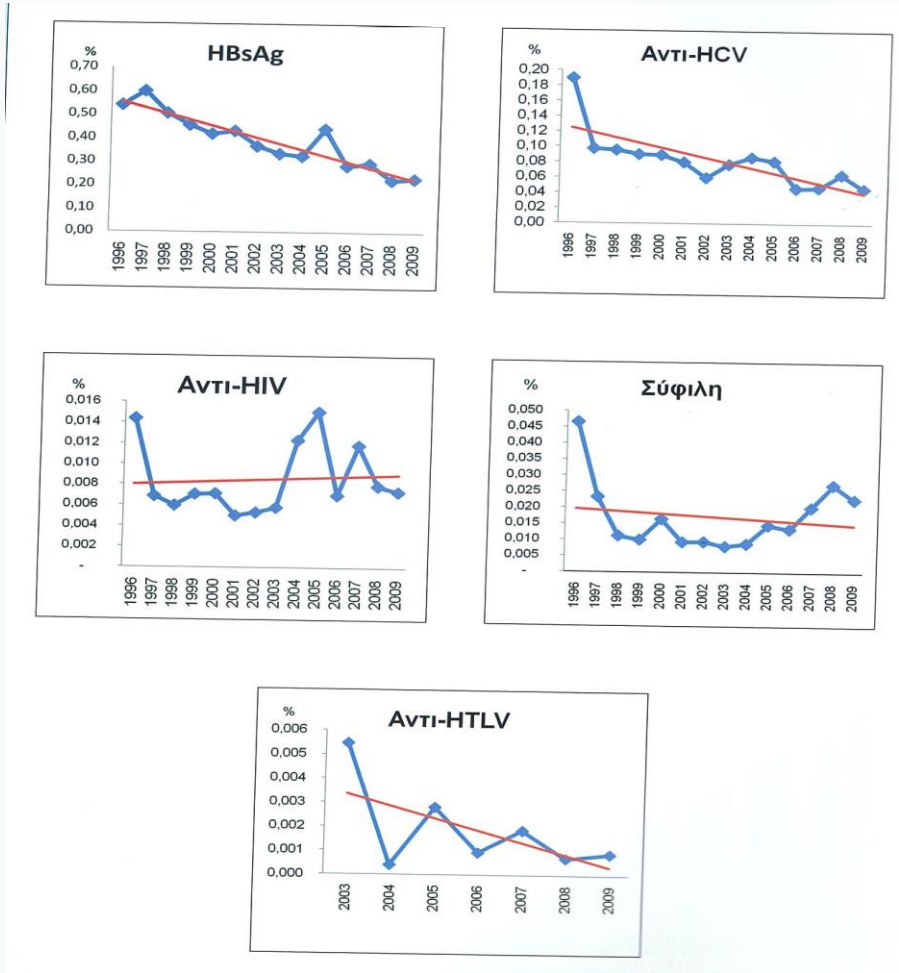
Analysis of the AEs in connection with a defective component, equipment failure, human error and more. Reporting ARs and AEs in blood donors by type of reaction/event - serious, life-threatening clinical symptoms, or fatal outcome

SKAEM

Surveillance of Transfusion Transmitted Infections (TTIs) in 14,100,268 tested blood units, 1996-2023

Seroprevalence of TTIs in 7,203,951 blood donations, 1996-2009

NATIONAL PUBLIC HEALTH ORGANIZATION

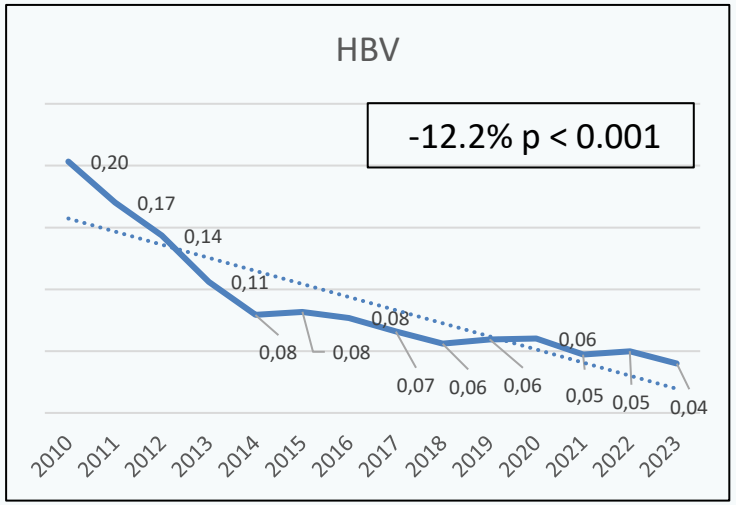


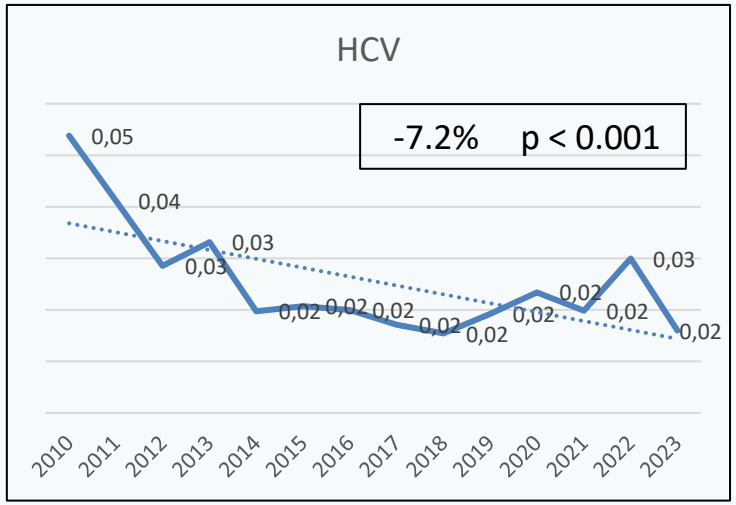
- Total annual reduction: - 0,033%
- HBsAg: - 0.026 % (statistically significant reduction)
- Anti- HCV: -0.006 % (statistically significant reduction)
- Anti-HIV, Syphilis, Anti- HTLV: not statistically significant reduction

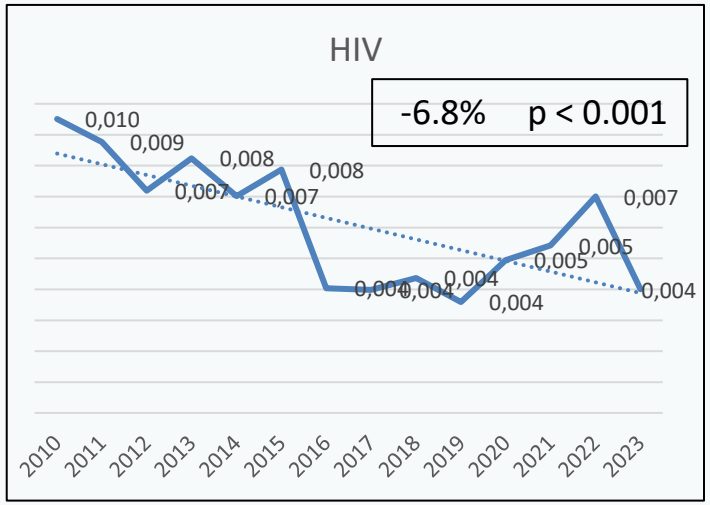
SKAEM

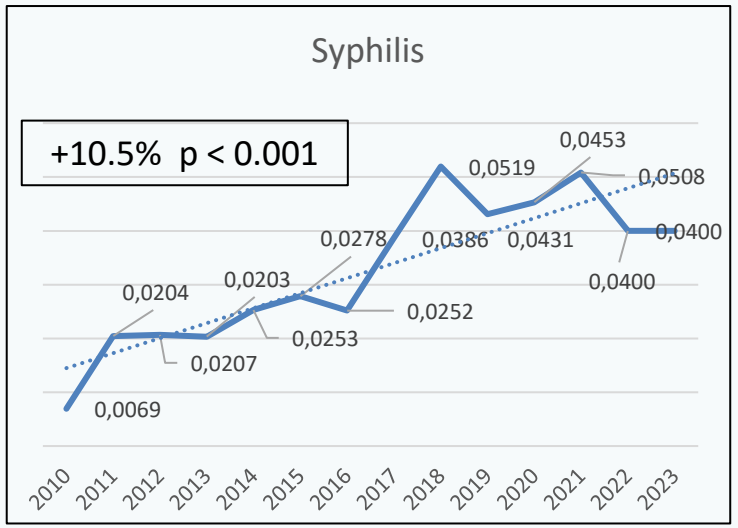
Seroprevalence of TTIs in 6,896,317 blood donations, 2010-2023

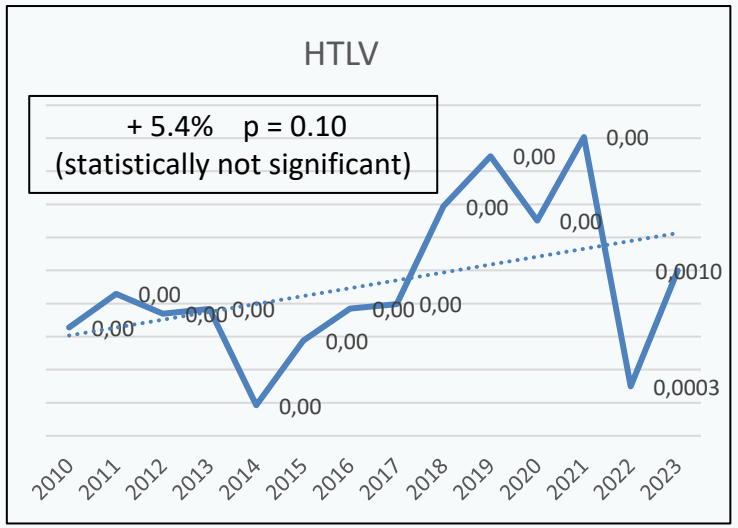
NATIONAL PUBLIC HEALTH ORGANIZATION











SKAEM

Molecular Blood Testing in 8,389,862 blood donations, 2007 - 2023

NATIONAL PUBLIC HEALTH ORGANIZATION

HIV-RNA	**n=20**
HCV-RNA	**n=52**
HBV-DNA	**n=1,321**
Total TTIs	**n=1,393**

Frequency	
HBV-RNA	1: 6,351 blood units
HCV –RNA	1: 161,344 blood units
HIV-RNA	1: 419,493 blood units
Total	1:6,023 blood units

Prevention of 3,482 Potentially Transfusion Transmitted Infectious Diseases

SKAEM

Changes in the deferral criteria for donor eligibility

NATIONAL PUBLIC HEALTH ORGANIZATION

Common Ministerial Decision Number G.P. fin. 900/2022 Official Gazette No 36/B/10-1-2022

WHO SHOULD NOT DONATE BLOOD

1. **Anyone who has had many sexual partners without consistently using a condom in the last 12 months.**
2. **Anyone who has used intravenous or inhaled drugs in the last 12 months.**
3. **Anyone who has had sexual intercourse with a partner who receives money or drugs in exchange for sex in the last 12 months.**
4. **Anyone who has taken Prep / Truvada or PEP to prevent HIV infection before or after sexual intercourse respectively.**
5. **Anyone who has used psychoactive substances before and during sexual intercourse (chemsex).**
6. **Anyone who has had sexual intercourse with a partner positive for syphilis, HIV, hepatitis B or hepatitis C in the last 12 months**
7. **Sexual partners of multi-transfused individuals**
8. **Generally anyone who thinks he/she may have been exposed to the virus that causes AIDS or is at risk for another sexually transmitted disease.**

If any of the above concerns you, you can discuss it with the screening Physician.
BUT DO NOT BECOME A BLOOD DONOR

SKAEM

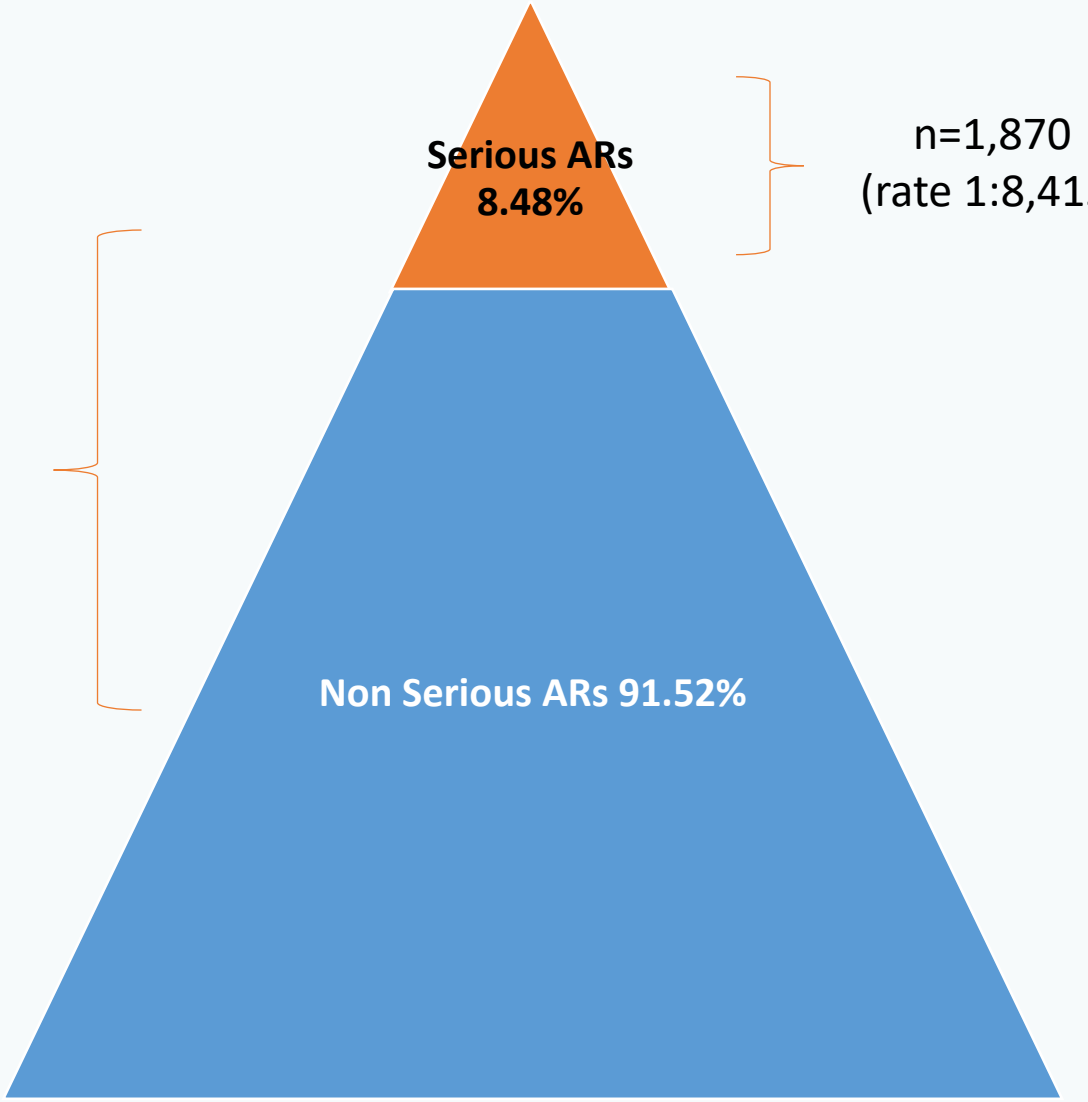
Surveillance of Adverse Reactions (ARs) and Adverse Events(AEs) associated with blood transfusion 1997-2023

Definitions and Grading of Severity and Imputability in accordance with:

- IHN/ISBT/AABB → (all ARs & AEs)
- Directives 2002/98/EC, 2005/61/EC → (serious ARs & AEs)

ARs associated with transfusion of 15,736,498 BCs, 1997- 2023

NATIONAL PUBLIC HEALTH ORGANIZATION



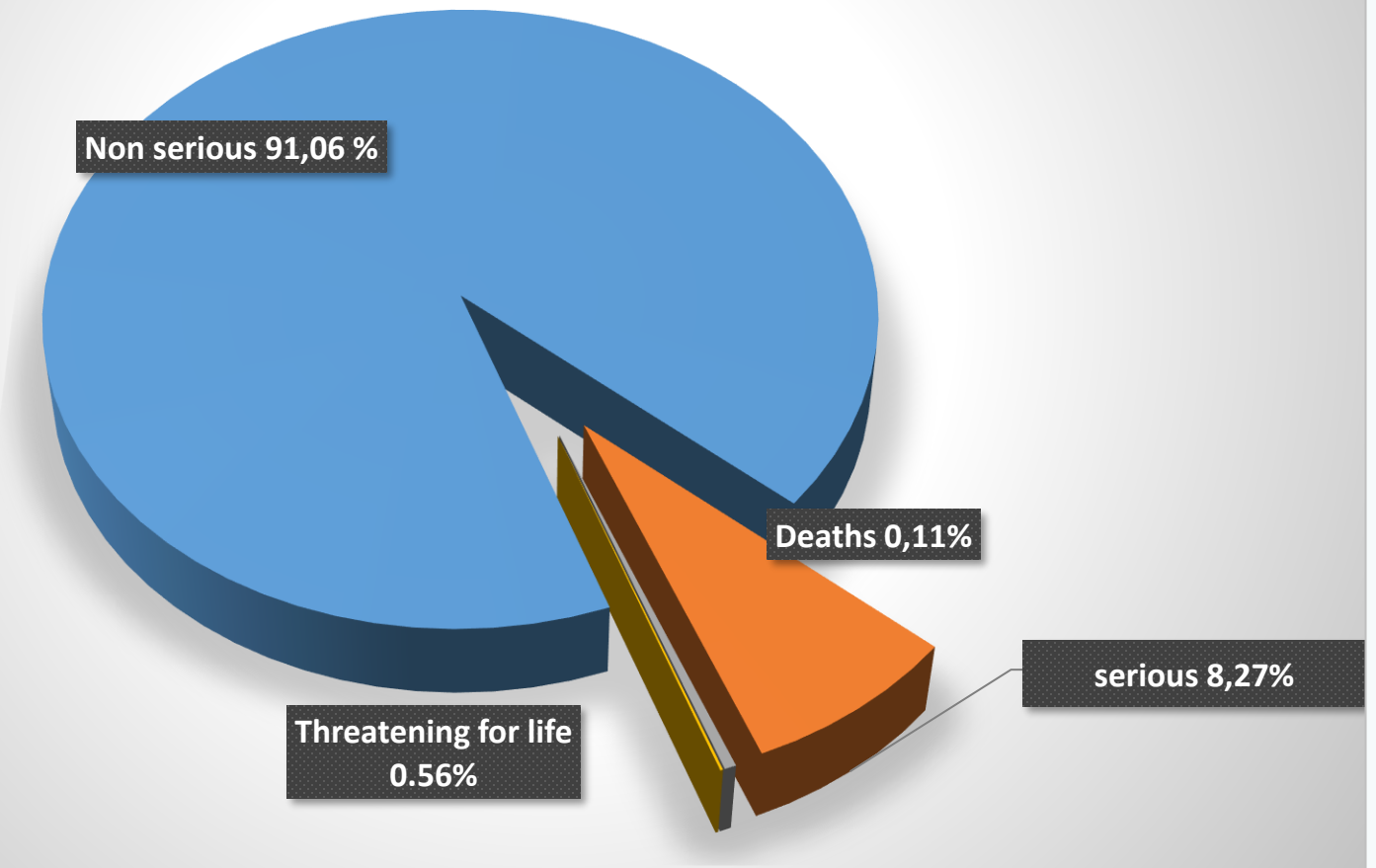
n=1,870
(rate 1:8,415)

Total
n=22,026
(rate 1:714)

SKAEM

NATIONAL PUBLIC HEALTH ORGANIZATION

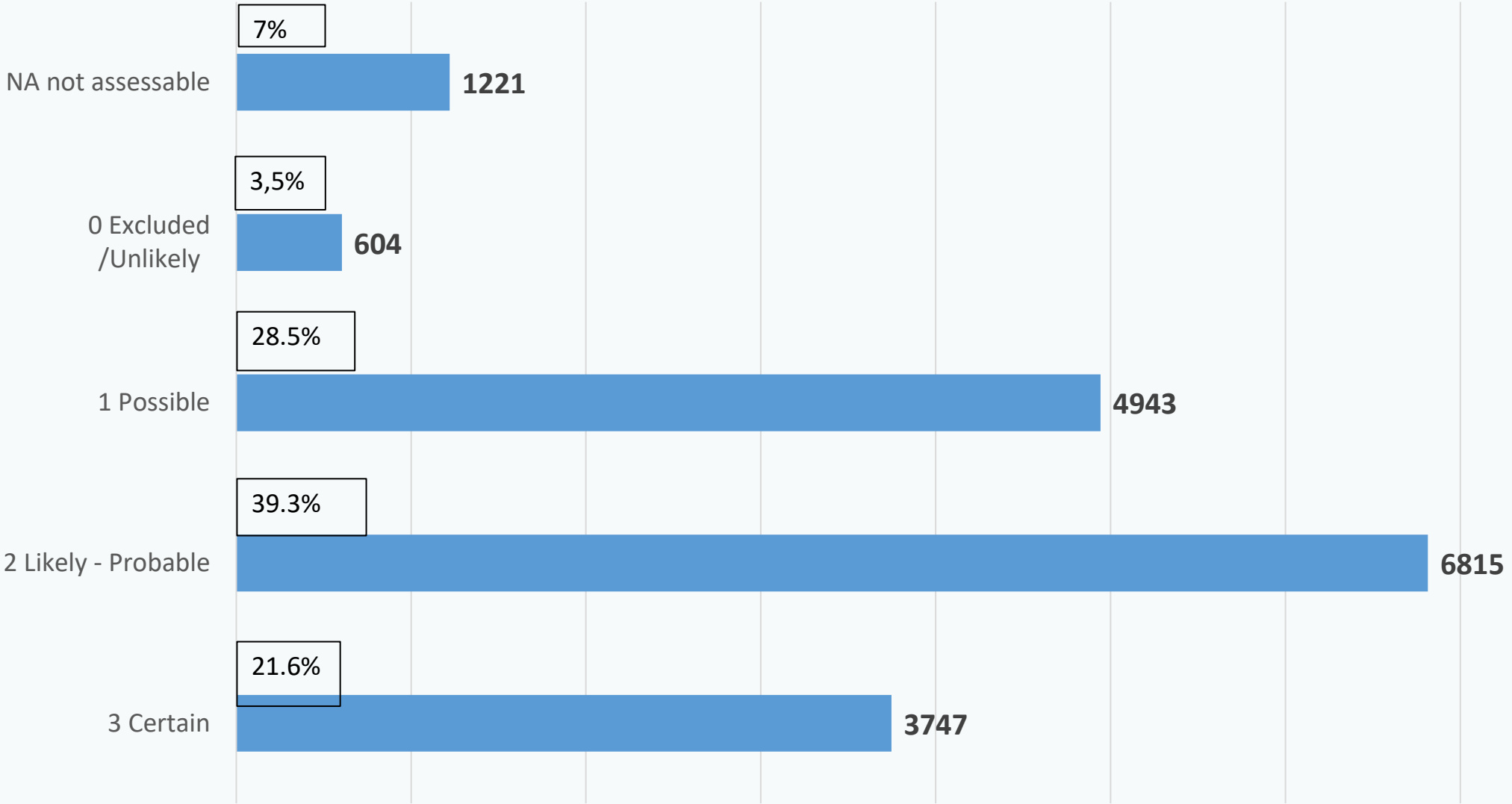
2010-2023
Adverse Reactions broken down by severity
n=15,978



SKAEM

ARs by Imputability 2010-2023 , n=17330

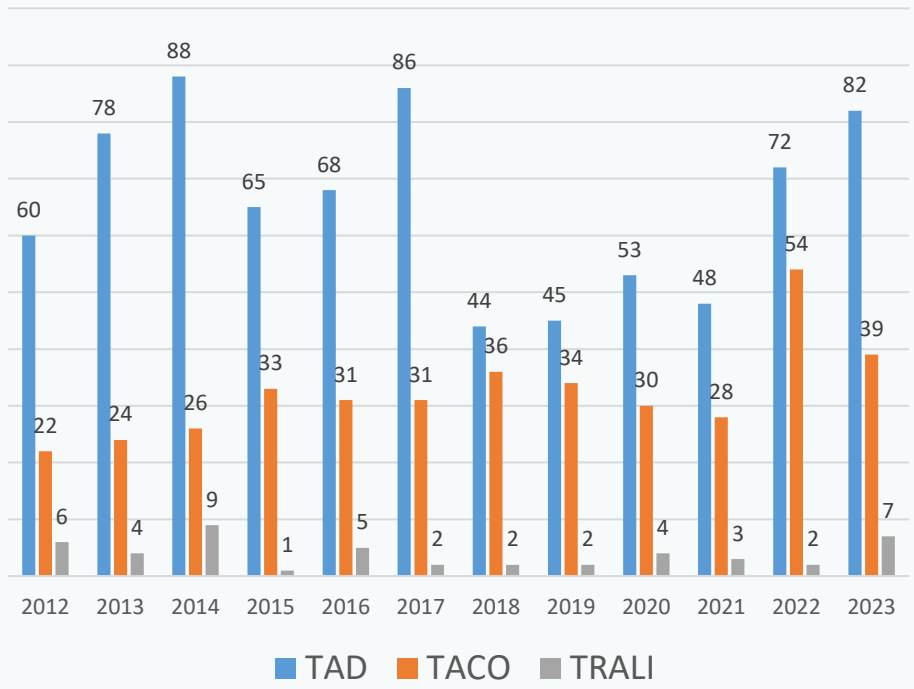
NATIONAL PUBLIC HEALTH ORGANIZATION



SKAEM

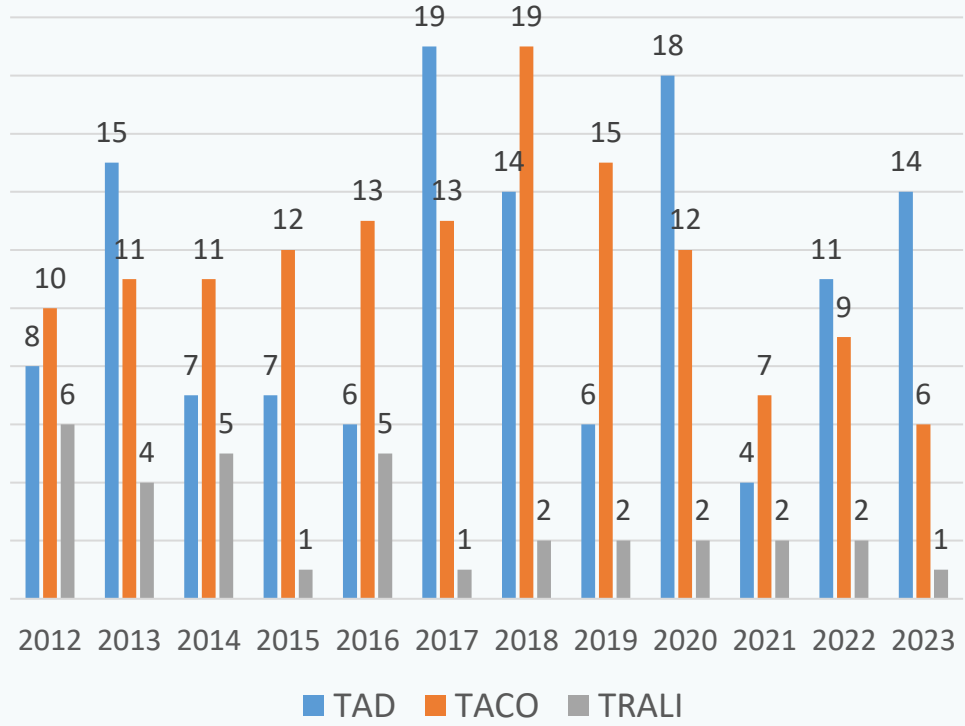
TACO-TAD-TRALI, 2010 - 2023

ALL



TAD	+2.3%	p = 0.030(statistically significant)
TACO	+9.5%	p < 0.001 (statistically significant)
TRALI	-0.3%	p = 0.95

SERIOUS



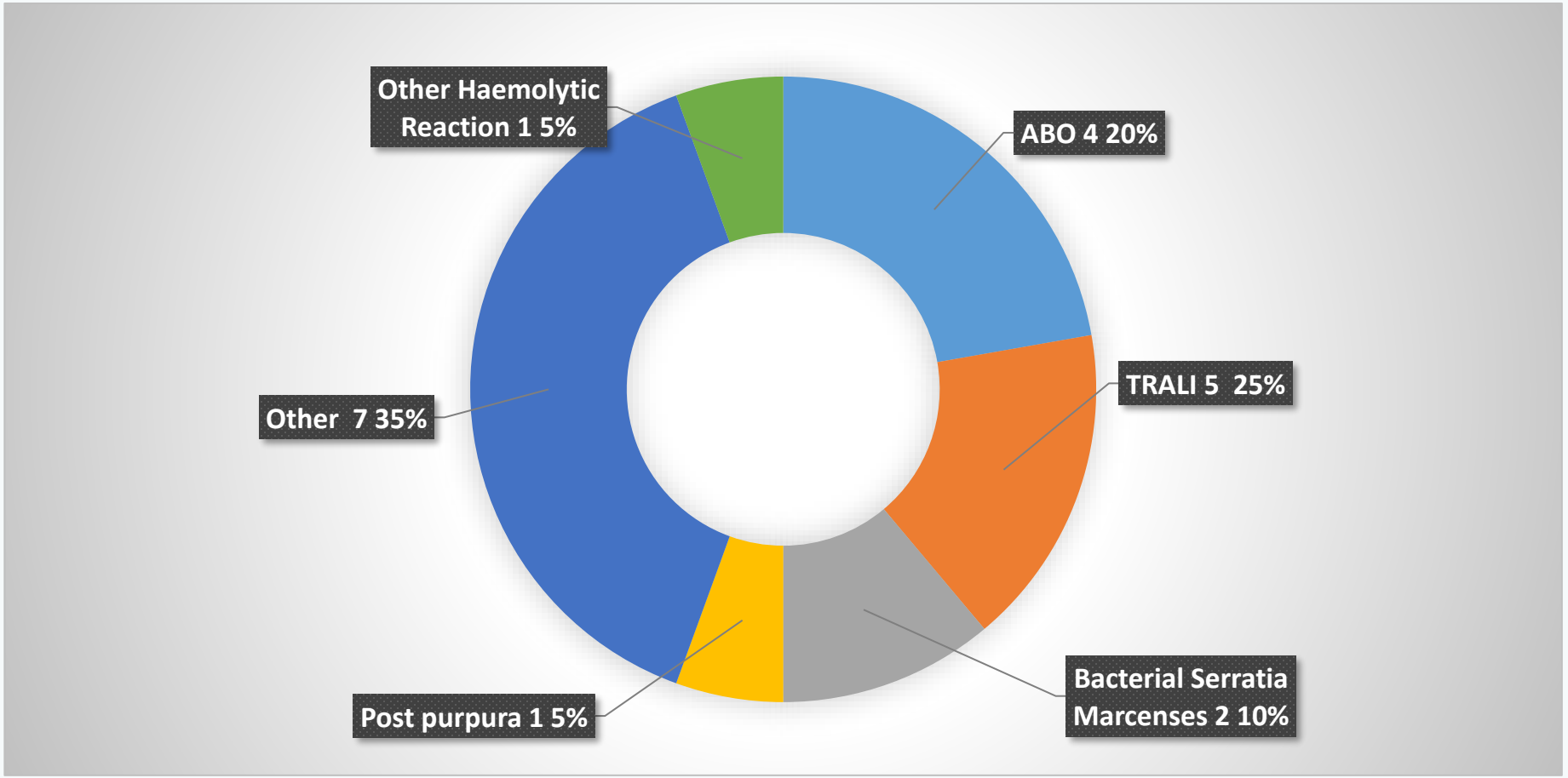
TAD	+ 5.9%	p = 0.027(statistically significant)
TACO	+ 1.3%	p = 0.62
TRALI	- 9.3%	p = 0.070

SKAEM

Deaths associated with transfusion of 15,736,498 BCs, 1997-2023

NATIONAL PUBLIC HEALTH ORGANIZATION

n=20
Rate 1: 786,824



SKAEM

The Infectious Risk of Transfusion associated with 13,551,474 issued BCs

• 2005 HIV	2 Cases → 1 associated with RBCs; 1 associated with Plasma (From the same blood unit)
• 2005 Malaria**	3 Cases (All *P. malarae, traceability was possible only in one case)*
• 2014 HCV	1 Case
• 2015 HCV	1 Case
• 2015 HBV	1 Case
• 2016 HEV	1 Case
• 2019 *Brucella melitensis*	1 Case
• 2023 Parvovirus 19	1 Case
• 2011-2023 WNV	4 Cases
Total	**15 Cases**

Rate: 1:903,431

** *the implicated donor was 42 year-old Greek woman born in a previous epidemic area who reported having had fever of unknown origin in 1945 before the eradication of malaria in Greece*

Alloimmunisation and Other ARs in Thalassaemia Syndromes *Before* and *After* COVID -19

NATIONAL PUBLIC HEALTH ORGANIZATION

Rate of Alloimmunization

- Up to 2010

11.6% of 983 patients with history of alloimmunization (highest TI followed by SCD-thal and TM)

- 2011-2014

New alloimmunization 1.4% (risk of 1:9,405 of RBCs transfused)

(C. Politis, E. Hassapopoulou, et. al. ISBT Science Series (2016) 11 Suppl 1)

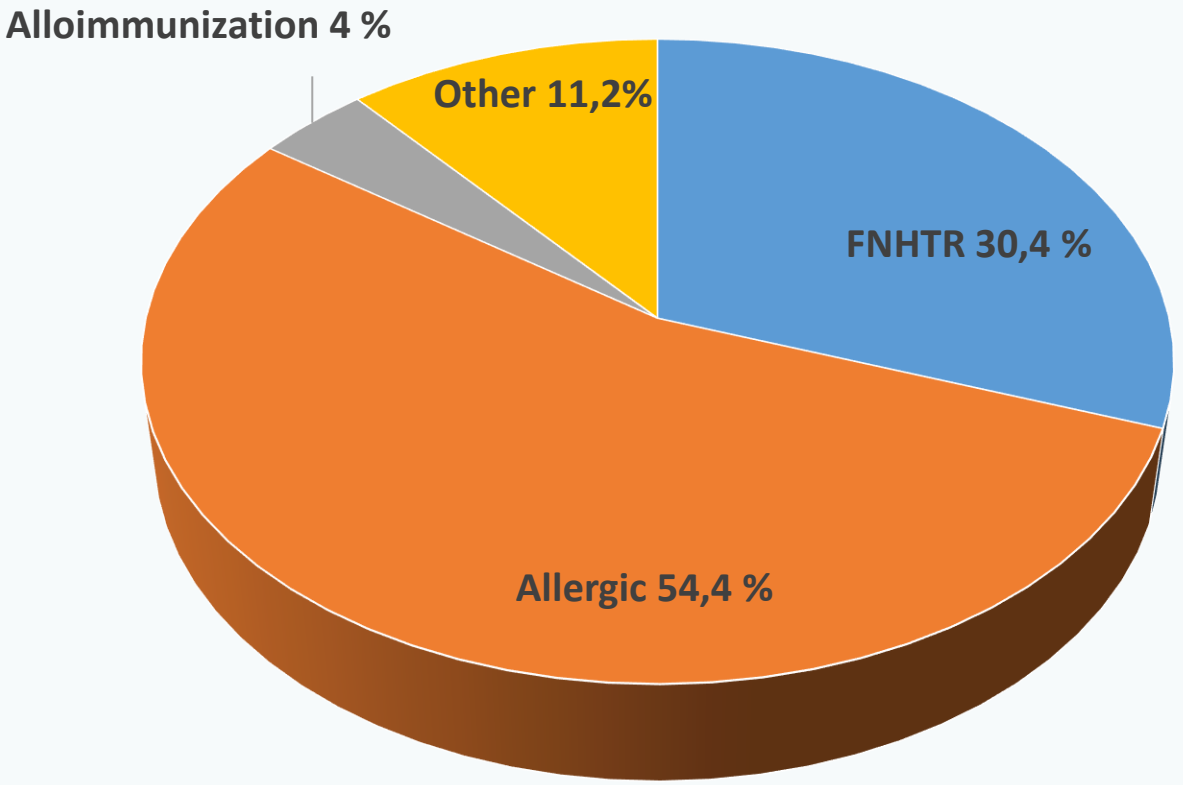
- 2018

0.4% of 1,196 patients (risk of 1:19,270 of RBCs transfused)

Conclusion

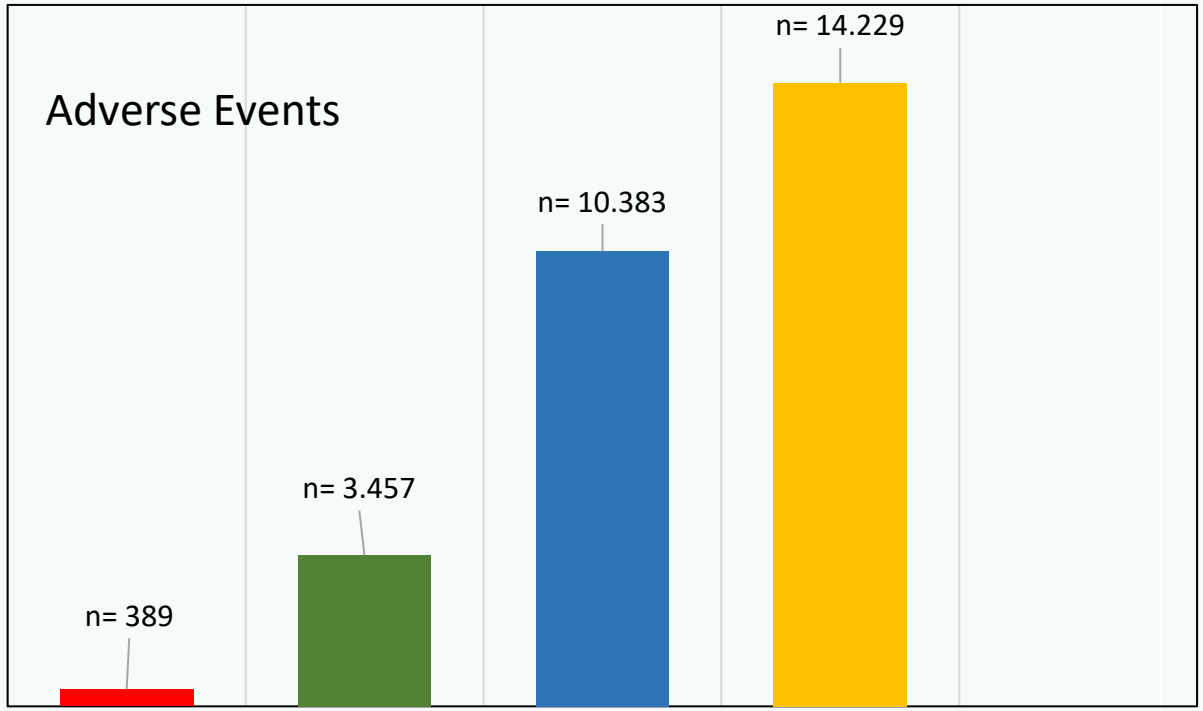
- The use of *extended matched donor blood* is proven effected in reducing the rate of alloimmunization
- DHTR + Hyperhaemolysis is a major problem especially during the gestational period and delivery in patients who escape expert medical follow up

ARs n=401



SKAEM

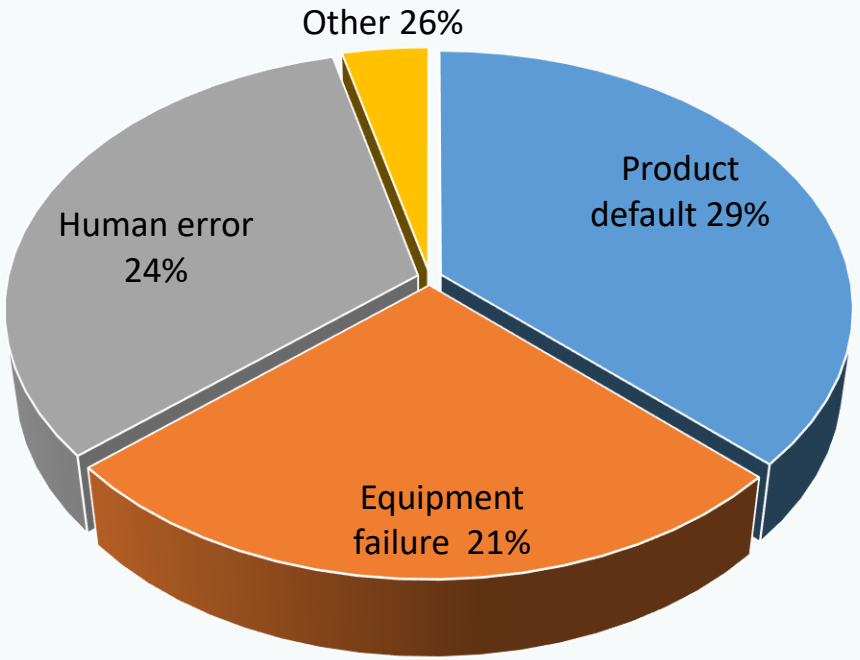
Adverse Events associated with 10,295,718 processed BCs, 2010-2023



Incidence			
Serious	Near-Miss	Uneventful	Total
4/100,000	34/100,000	101/100,000	138/100,000

Adverse events associated by specification

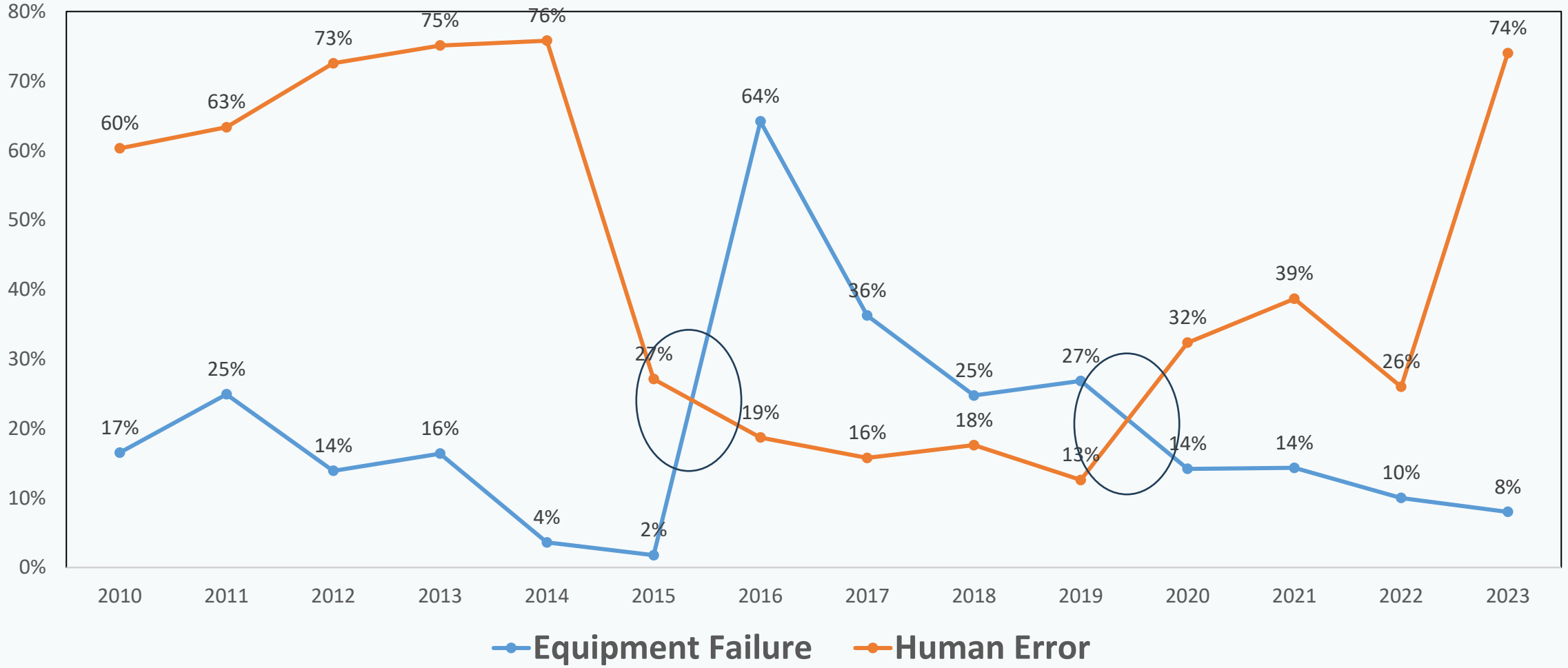
n=14,229



SKAEM

NATIONAL PUBLIC HEALTH ORGANIZATION

Adverse Events 2010-2023



SKAEM

Haemovigilance in Donors

2023: 375,584
- 360,207 Whole blood donors
- 15,377 PLT aphaeresis donors

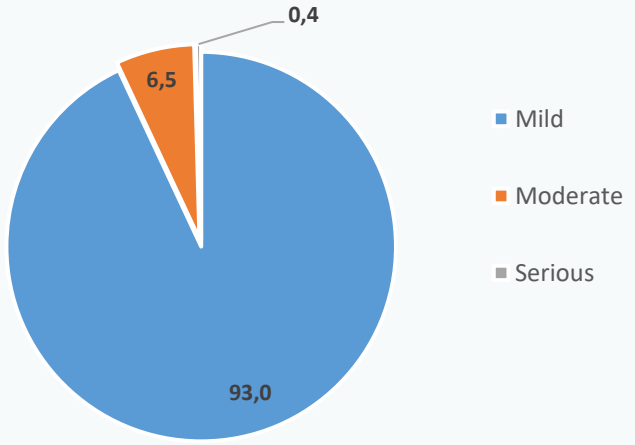
Reactions **Total n=4,653 (1:81 blood units)**

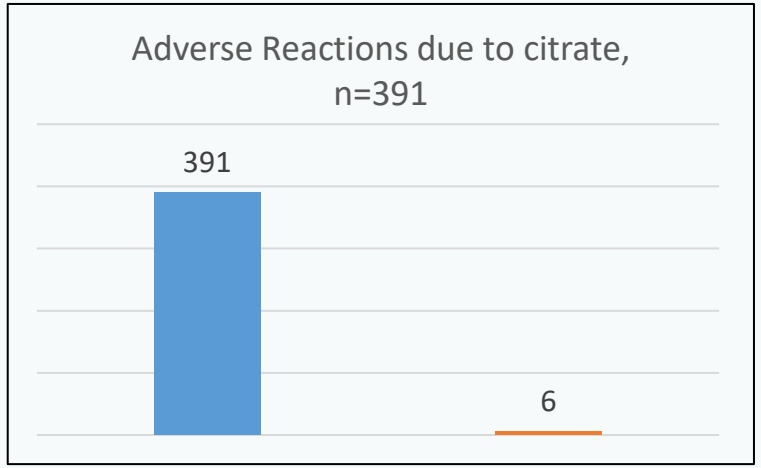
Serious ARs n=20 (0.5%)
(rate 1:18,779 blood donation)

Vasovagal ⇨ n=3,573 (77%) Serious n=20 (0.6%)

Haematoma mild / moderate n=426
Arterial puncture n=8 (6 mild, 2 moderate)
Nerve puncture n=14 (13 mild,3moderate)

Adverse Events in Donors associated with severity





SKAEM

Achievements

- Better reporting and improved compliance with the definitions and better understanding of the differential diagnosis between ARs of the respiratory system
- Reduction of Incorrect Blood Component Transfused
- No case with TT-HIV infection has been diagnosed since 2005
- NAT testing of blood has prevented the issue and use of seronegative but NAT positive blood units for HBV,HCV and HIV infections
- SKAEM's data provided the epidemiological evidence for the policy change of permanent deferral criteria of potential blood donors in relation to sexual behaviour, including **MSM**
- Seasonal surveillance and Haemovigilance measures for West Nile Virus infection and Malaria in the blood donor population have contributed in the prevention of transmission of these infections to the recipient of blood

Challenges

- Wrong Blood to the wrong patient
  - Night transfusions
  - Inadequate staff and lack of reliable ID system
  - Equipment defect
- New emerging infectious diseases
- Better Compliance with Good Practice Guidelines
- Improvement of blood processing and safety by automation should be a national priority

SKAEM

Conclusions

NATIONAL PUBLIC HEALTH ORGANIZATION

❖Twenty-seven years of haemovigilance in Greece demonstrate coordinated progress towards better quality and safety in blood donation and transfusion

❖The climate change and immigration should be taken into consideration in National HV Systems

❖B-SPEC to be applied

❖Empowerment of all stakeholders

SKAEM

Special thanks:

NATIONAL PUBLIC HEALTH ORGANIZATION

SKAEM Staff

Marina Assariotou

Eleni Rapti

Eleftherios Konstantinidis

Urania Sakka

Athanasios Kalos

SKAEM Contributors

Eleftheria Zervou

Giorgios Martinis

Maria Hatzitaki

Panayiota Halkia

Elisavet Grouzi

Anthi Gafou

Lilian Kavallierou

Myrsini Parara

Panagiotis Damaskos

Clive Richardson

ALL Fellow Members of the Hellenic Blood Transfusion Services and National Public Health Organisation

SKAEM

IHN International Haemovigilance Network

Thank you for your attention!!!