



International Haemovigilance Network: ISTARE



Constantina Politis

On behalf of the working group

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DFK - Deutsches Rotes Kreuz
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European Blood Inspection System
Established under the Public Health Programme of the EC
Director: Edelmar SANCO - 1996, 2000

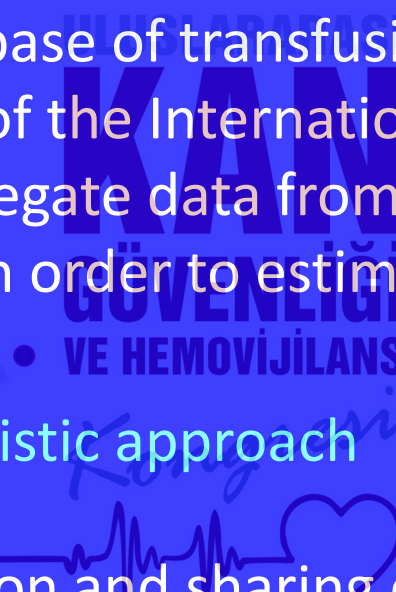
International Congress of Blood Safety and Haemovigilance
Antalya 2-5 November, 2019

Background I

ISTARE is the international database of transfusion adverse reactions (ARs) and adverse events (AEs) of the International Haemovigilance Network (IHN) is collecting aggregate data from member national haemovigilance systems (HVS) in order to estimate the morbidity and mortality of blood transfusion

in a holistic approach

ISTARE aims to unify the collection and sharing of information with view to harmonizing best practices for Haemovigilance systems around the world



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IHN promotes a holistic haemovigilance approach

The rationale of ISTARE is to avoid restricting our observations to only the tip of the iceberg

i.e. not only serious events (unlike EU and Council of Europe)



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Background II

- The ultimate goal is to contribute to improving the safety of transfusion by close monitoring throughout the chain from “vein to vein”
- Historically, the ISTARE was established in 2008 by IHN on the grounds of European Haemovigilance Network (EHN) that was set up in 1998 with the aim of developing as a major contributor to increase blood safety at the European level
- Later on it was expanded and renamed as the IHN – in collaboration with the ISBT working party on Haemovigilance

Background III

- IHN brings together individuals and organizations from around the world with an interest in haemovigilance, for the purposes of education and support
- It holds international scientific seminars, and provides a forum for developing definitions and for sharing and analysing data for benchmarking and practice improvement
- IHN also supports developing and established national haemovigilance systems by participation in their scientific and educational activities

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Mission, Vision & Strategic goals

IHN's vision

Health services around the world will have effective haemovigilance systems in place.

IHN's mission statements (purpose)

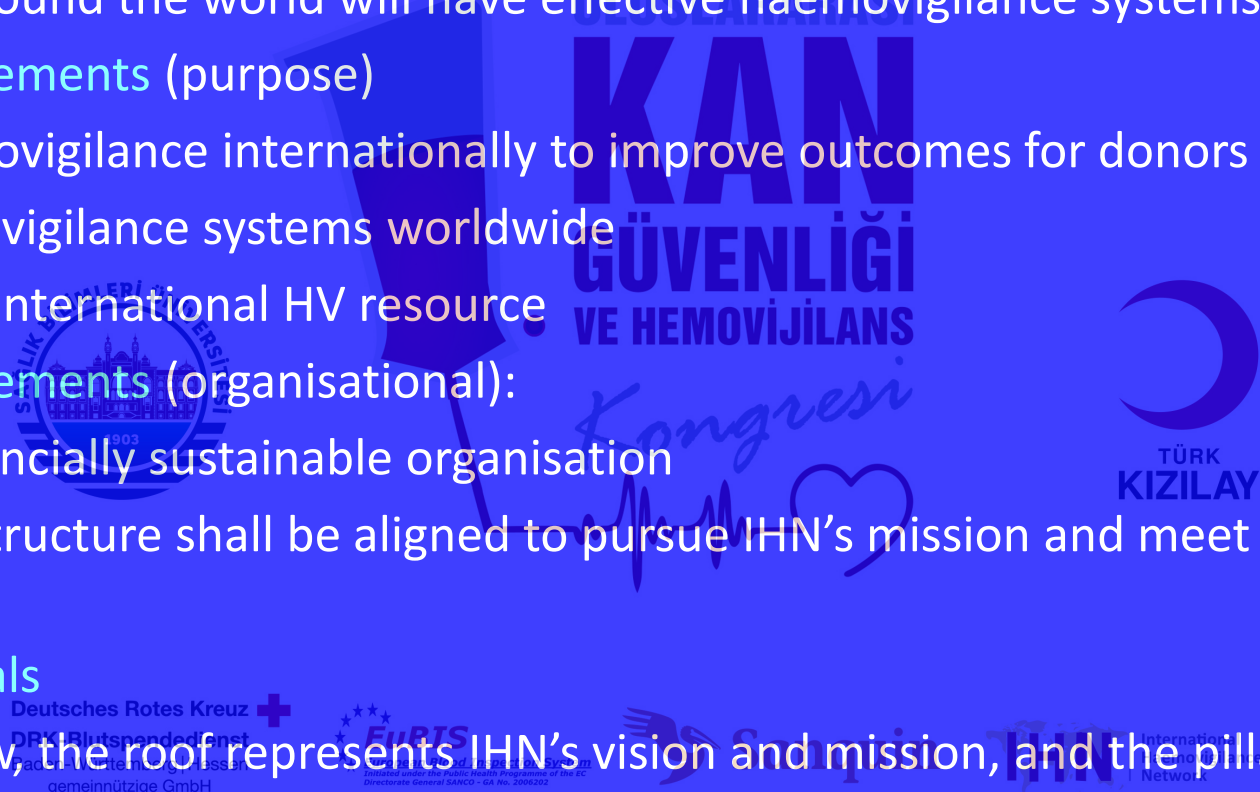
- To promote haemovigilance internationally to improve outcomes for donors and patients
- To support haemovigilance systems worldwide
- To be the leading international HV resource

IHN's mission statements (organisational):

- IHN shall be a financially sustainable organisation
- The governance structure shall be aligned to pursue IHN's mission and meet its strategic goals

IHN's strategic goals

In the figure below, the roof represents IHN's vision and mission, and the pillars indicate strategic goals towards fulfilling the mission. The beam represents connecting organisational structures, ensuring sustainability and feasibility.



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Working Methods

Definitions

Haemovigilance

A set of **surveillance procedures** covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

Types of Adverse Reactions:

Are defined by **IHN/ISBT** standard definitions. Detailed instructions are provided in ISTARE's help facility.

For certain items for which international standard definitions do not exist, such as transfusion transmitted infections ARs, the National Haemovigilance Systems, the user has the option to submitting the total for each main type of blood component

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ISBT-Basel 2019

- Acute haemolytic (AHTR)
- Delayed haemolytic (DHTR)
- Delayed serologic reaction (DSTR)
- Allergic reaction
- Febrile non-haemolytic (FNHTR)
- Transfusion-associated circulatory overload (TACO)
- Transfusion-related acute lung injury (TRALI)
- Transfusion-associated dyspnoea (TAD)
- Transfusion-transmitted viral infection (TTVI): Hepatitis B, C
Human immunodeficiency virus (HIV)
- Transfusion-transmitted parasitic infection (TTPI)
Malaria, Other
- Transfusion-transmitted bacterial infection (TTBI)
- Hypotensive reaction
- Transfusion-associated graft versus host disease (TA-GVHD)
- Post-transfusion purpura (PTP)
- Hyperkalemia, Hypocalcaemia
- Other transfusion reaction
- Unclassifiable complication of transfusion (UCT)



Types of ARS in the recipient

defined by
IHN/ISBT Standard
Definitions



Access to ISTARE

Four categories of users have access to the ISTARE tool via their individual usernames and passwords, defining their access level

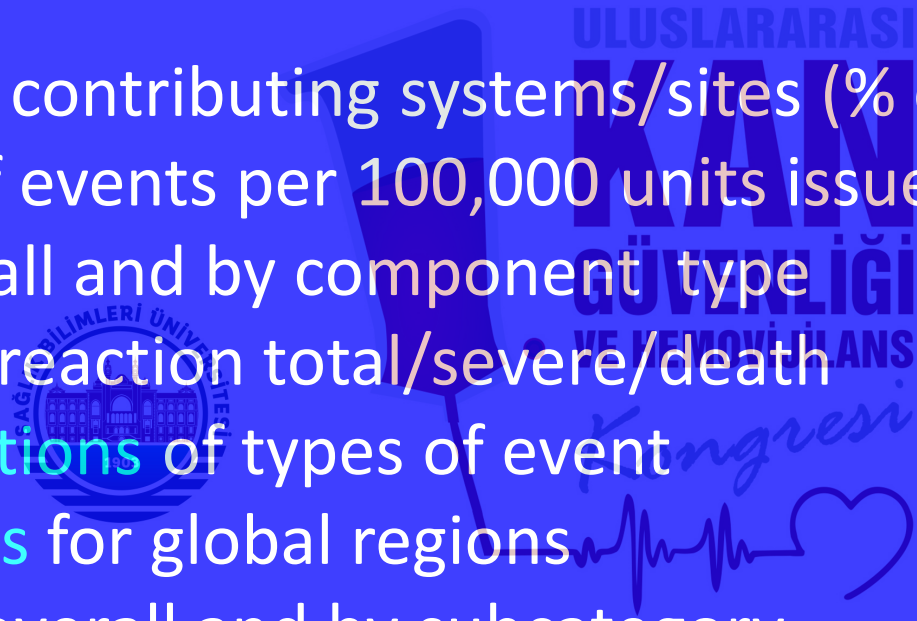
- **Level 1 (Local user)**
 - *Enters. Edits and saves national data but cannot submit it*
- **Level 2 (National super-user)**
 - *Enters and edits data, Submits national data, Requests registration of national users, Views national reports and general reports, Extracts national data*
- **Level 3 (ISTARE Working Group)**
 - *Views and Extracts all data, Does NOT edit data, Views all reports, Communicates with national süper-users about data issues and annual closure*
- **Level 4 (Administrator (International super-user))**
 - *Registers countries, users, issues passwords. Extracts all data, Does NOT edit data*
 - *At request of ISTARE or national super-user, unlocks data for correction.*

Submission of data

- Annual aggregate haemovigilance data are submitted confidentially online using **IHN/ISBT standard definitions** and detailed instructions
- ISTARE automatically provides **rates and ratios** of ARs for analysis of national data and produces charts comparing international data for one or more years
- Interactive **graphs** compare country data with total data
- Data are disseminated only in anonymized form each country is marked in tables and diagrams by a code number

Areas to be covered by the analysis

- Data on contributing systems/sites (% coverage)
- Rates of events per 100,000 units issued/transfused overall and by component type
- Type of reaction total/severe/death
- Distributions of types of event
- Averages for global regions
- Trends overall and by subcategory

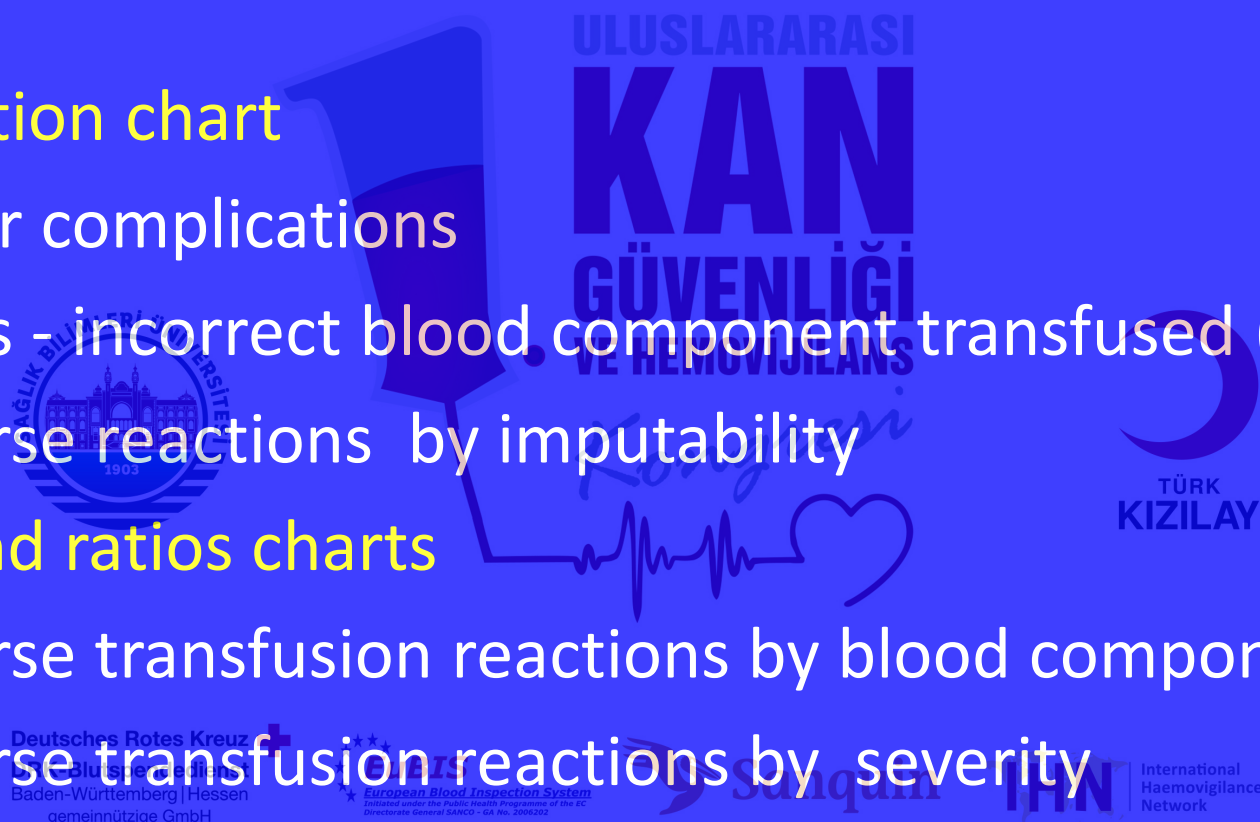


Note: If the HV system does not record events according to component subtype, the user has the option of submitting the total for each main type of component



Charts available within ISTARE for national use

- **Distribution chart**
 - Donor complications
 - Errors - incorrect blood component transfused (IBCT)
 - Adverse reactions by imputability
- **Rates and ratios charts**
 - Adverse transfusion reactions by blood component
 - Adverse transfusion reactions by severity
 - Incidence of all ARs



What data ?

- **General information:** *structure and coverage of the HV system*
- **General denominators:** *data on numbers of donors/donations and main categories of blood components issued, transfused, % leukoreduced*
- **Specific denominators:** *data on specific types of blood components standard, aphaeresis, pathogen inactivated*
- **Donor Complications:** *events related to whole blood and also to apheresis donations*
- **Errors-incorrect blood component transfused (IBCT):**
ABO incompatible - sampling errors - wrong label
- **Adverse transfusion reactions by component, imputability and severity**



Results

ULUSLARARASI
KAN
GÜVENLİĞİ
VE HEMOVİJİLANS

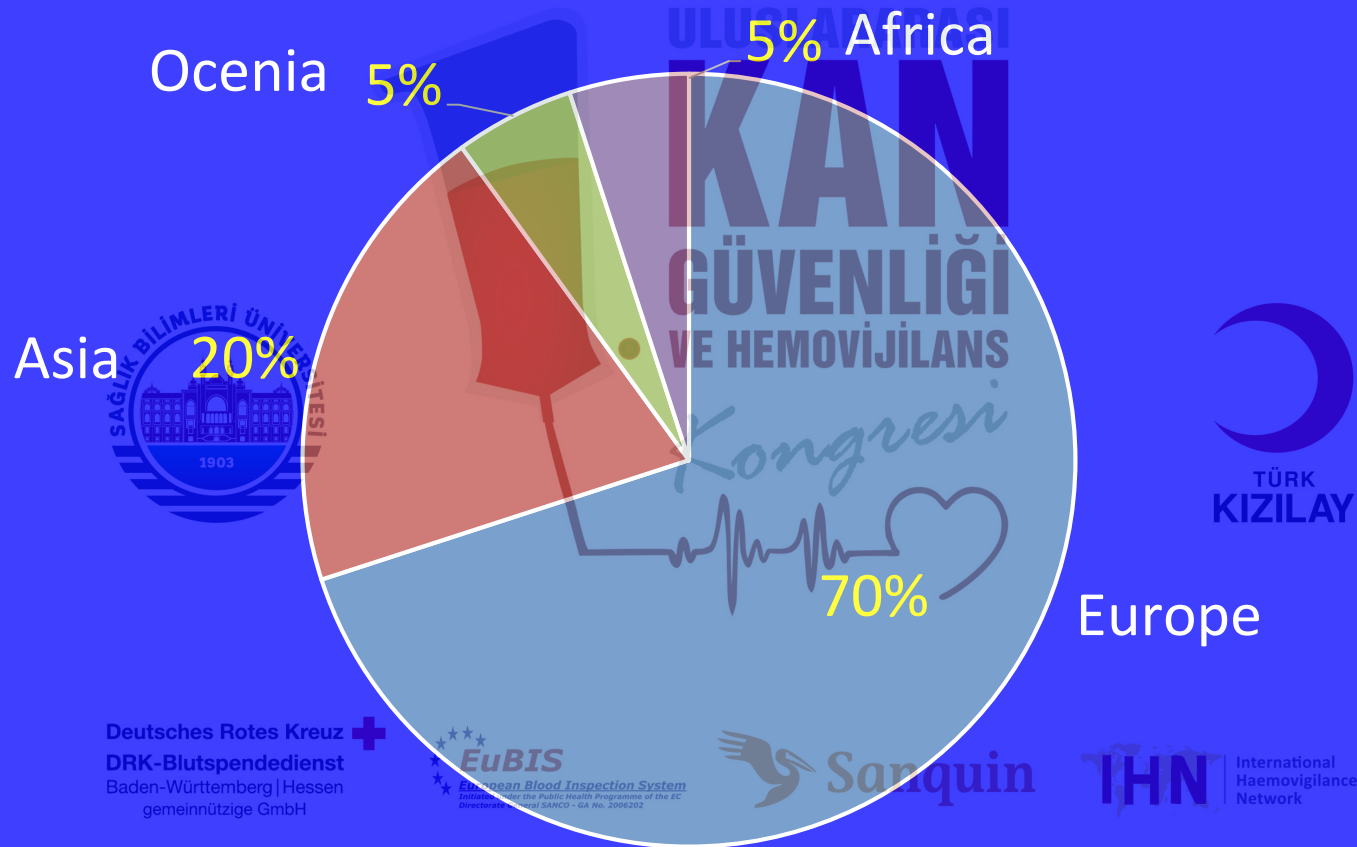
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Participating Countries 2016 (n=21)



ISTARE update 2016

Reporting

General denominators donations	95%
Specific denominators	90%
Donors complications	60%
Adverse reactions by component	80%
Adverse reactions on severity and imputability	80% /90%
IBCT (Incorrect Blood Component Transfused)	80%

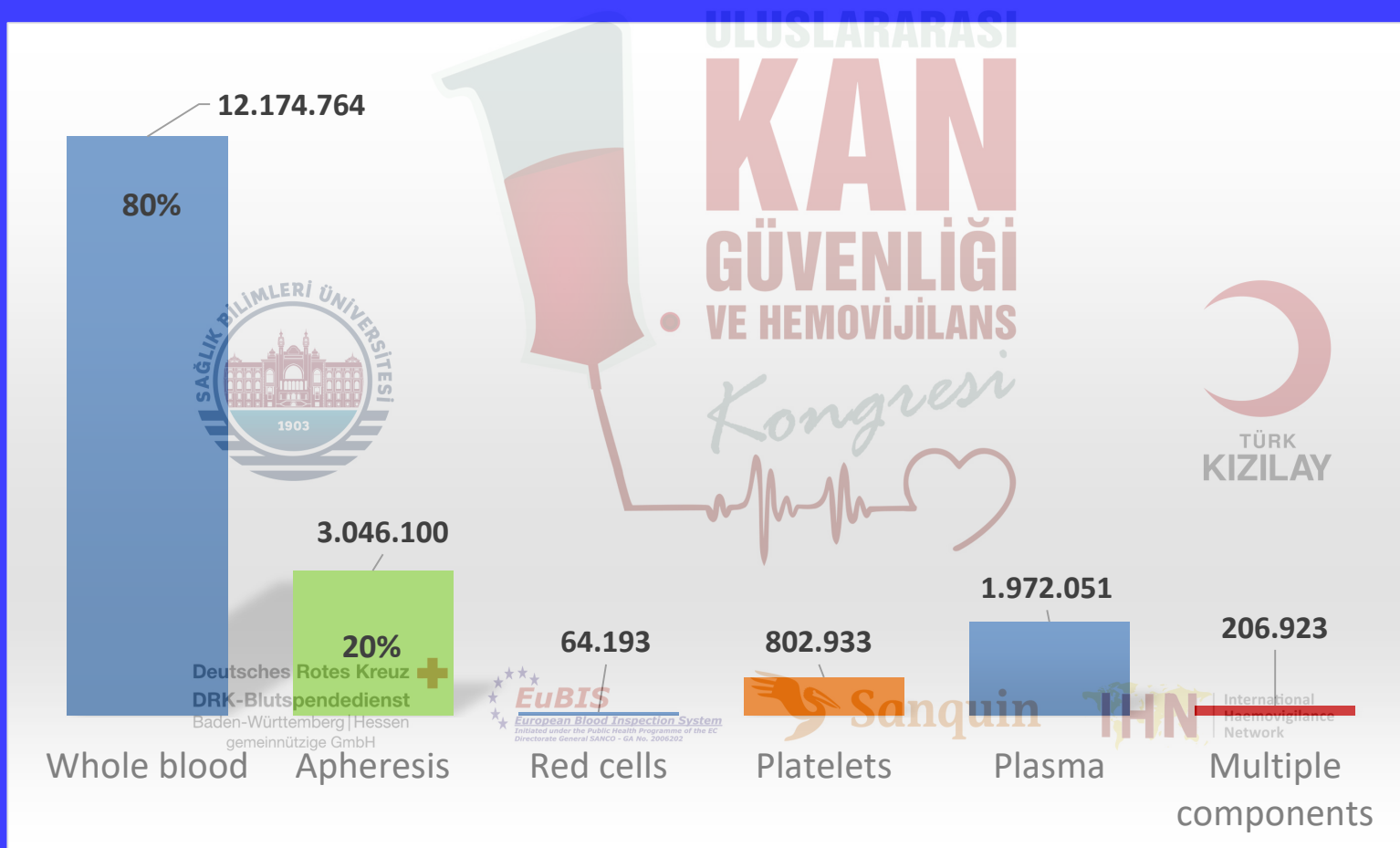
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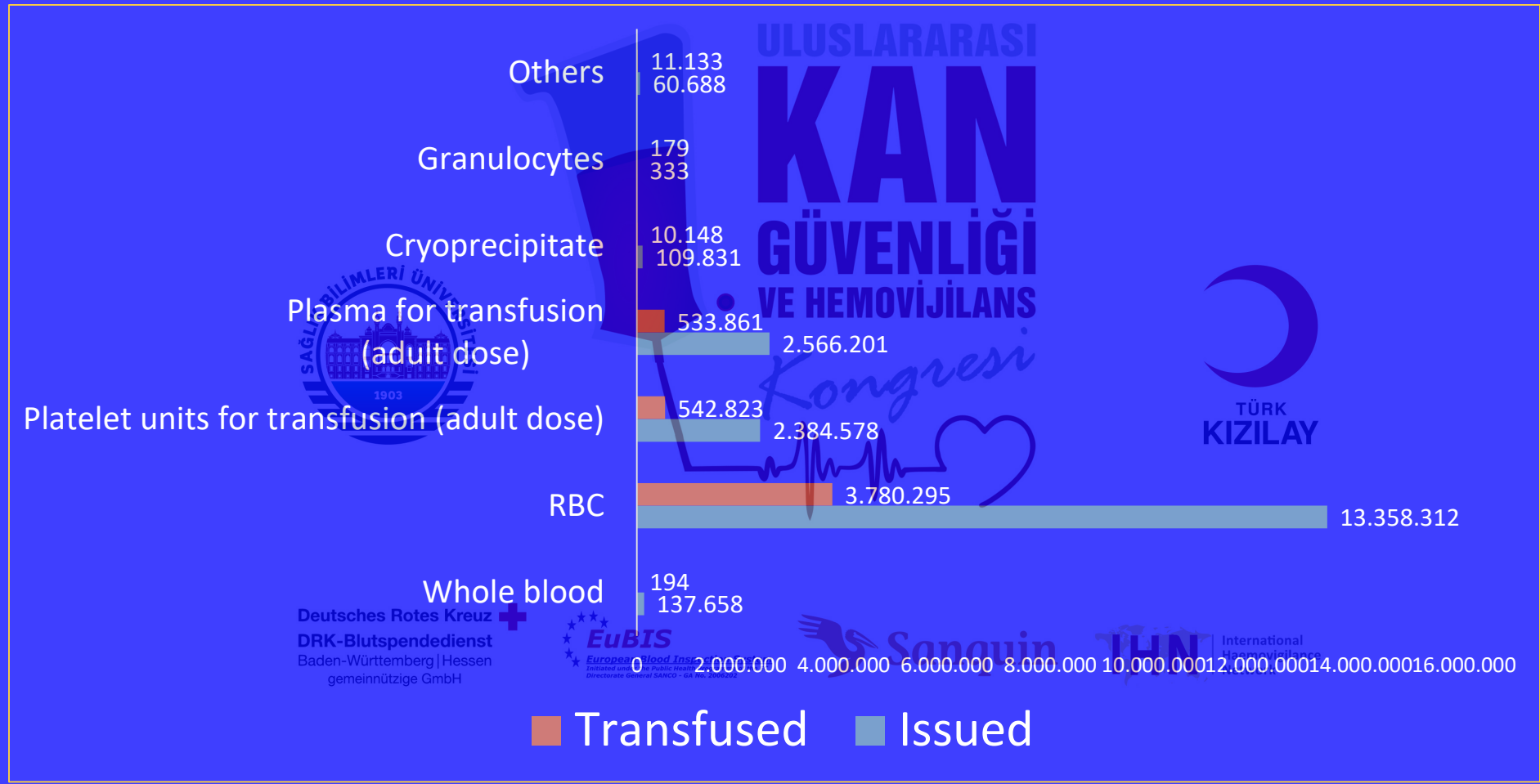
 **IHN** International Haemovigilance Network

Donations 2016 (n= 15.220.864)

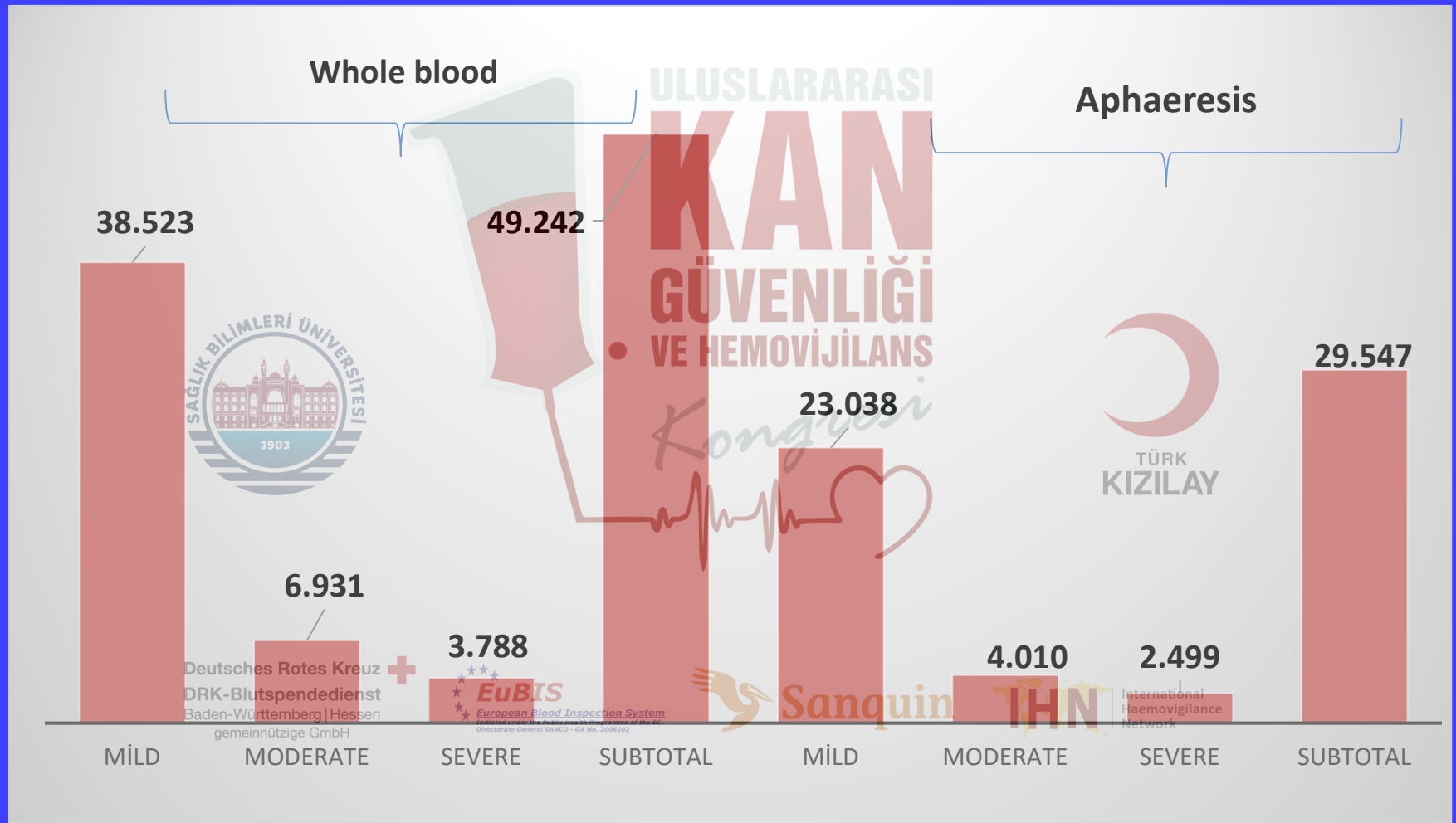


Blood components 2016

(ratio issued/transfused)



78,789 Donors Adverse Reactions associated with 14,498,234 donations (2016)

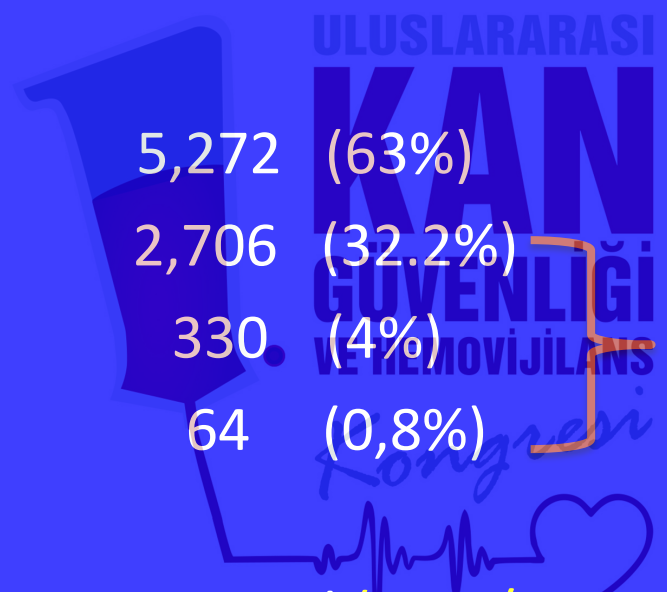


Rates 1 : 184 donations

543/100,000

Total ARs in recipients 2016 in 16,948,683 issued blood components (n=8,372)

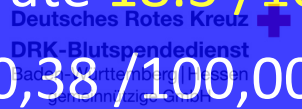
- Non severe 5,272 (63%)
- Severe 2,706 (32.2%)
- Life-threatening 330 (4%)
- Death 64 (0,8%)



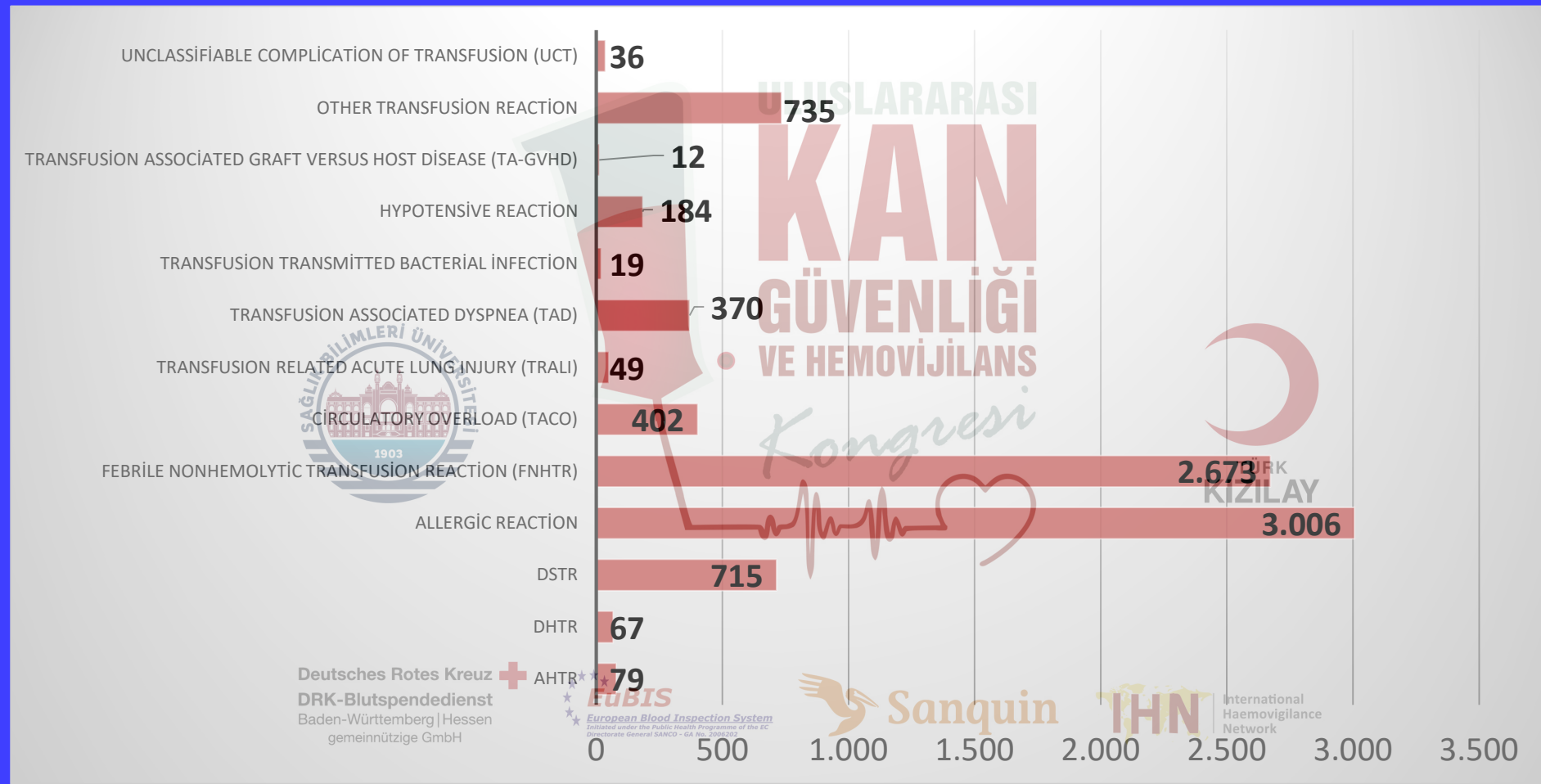
Total ARs, rate 49.4 /100,000 issued (1 AR/2,024 BC issued)

Serious ARs rate 18.3 /100,000 issued

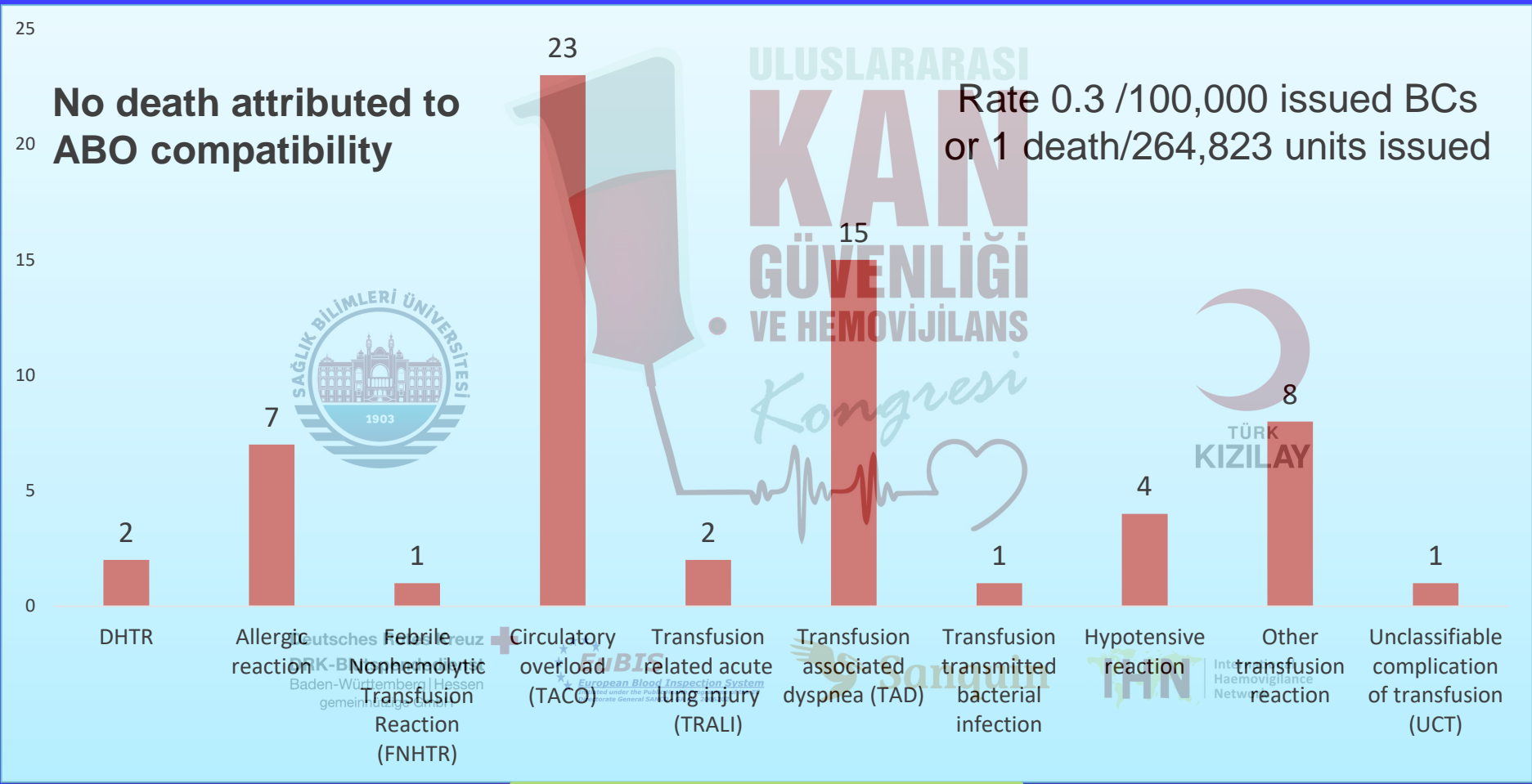
Deaths rate 0,38 /100,000 issued



Total ARs by severity (2016)



Fatalities n= 64 (2016)



TACO +TAD+TRALI 62.5%

Transfusion Transmitted Infections - TTIs

Definition

- The recipient had evidence of infection post transfusion with blood component and,
 - there was no evidence of infection prior to transfusion and,
 - no evidence of an alternative source of infection
- and, either:*
- At least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection

or

- at least one component received by the infected recipient was shown to contain the agent of infection



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ISBT-Basel 2019
SHOT, 2018

The Infectious risk of transfusion in the recipient (I)

2013-2016

- 89 sets of annual aggregated data from 25 countries with HVS
- 85,521,393 Blood Components (BCs) issued
- All Adverse Reactions (ARs) were 76,907 (90/100,000 units of BCs issued)
- Infectious ARs amounted to 285 (0.4%) overall incidence 0.33/100,000 units of BCs issued

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The Infectious risk of transfusion in the recipient (II)

2013-2016

- Bacterial infections (66%) viral (29.5%) parasitic (4.5%)
- Serious were 46% and there were 11 fatalities (3.9%, incidence 0.013/100,000) Nine deaths were attributed to sepsis and another two were associated with parasitic and fungal pathogens respectively.
- One of the fatal cases reported as free text communication was attributed to *Geotrichum clavatum* fungal infection associated with apheresis platelets. The imputability in this case was not assessable.
- The other fatal parasitic infection was associated with Trypanosoma Cruzi. This case was reported in 2014 in the course of a look back procedure and the imputability grade was possible.

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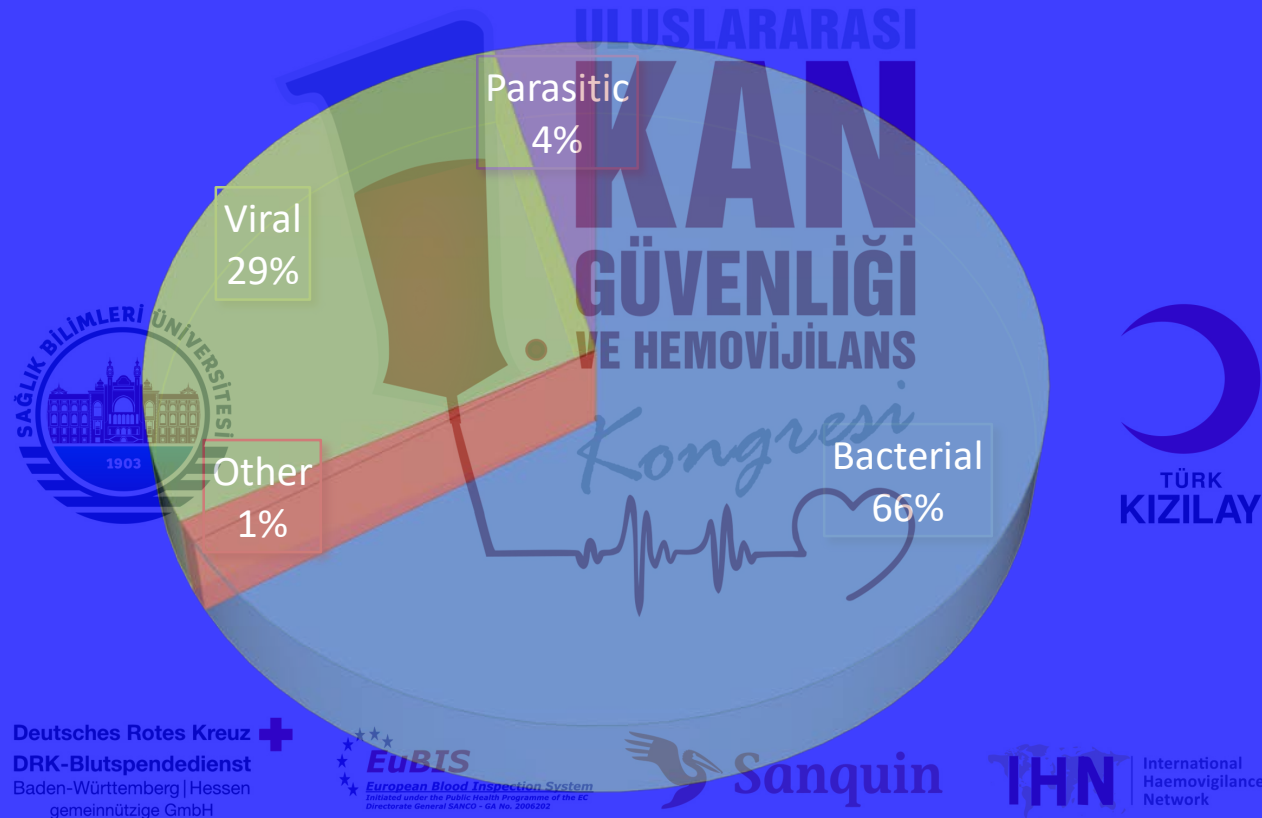
European Blood Inspection System
Certified under the Public Health Programme of the EC
Reference: 01/01/2006/2012

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The infectious risk of transfusion in the recipient

ISTARE DATA 2013-2016

TYPES OF INFECTIOUS ARS

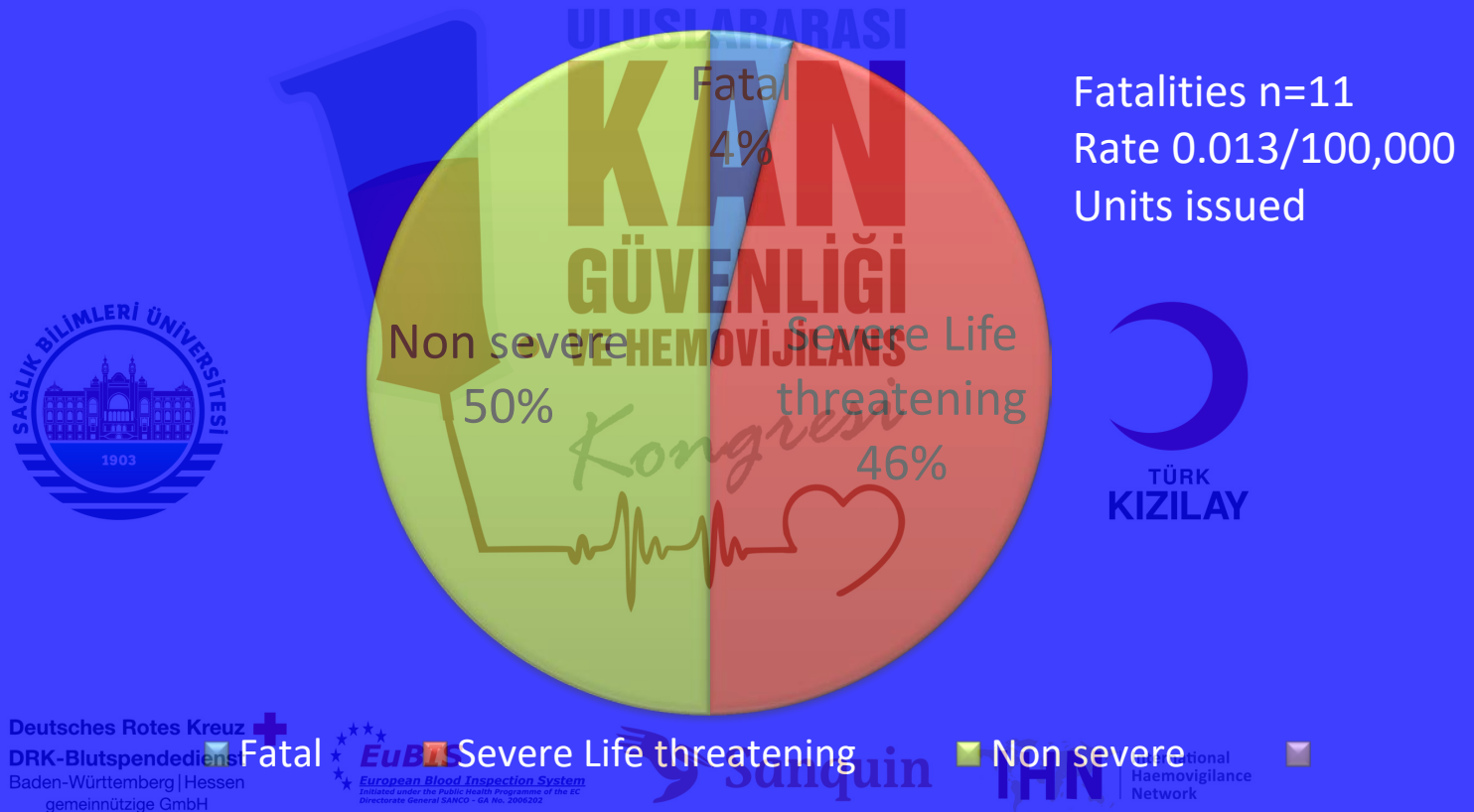


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The infectious risk of transfusion in the recipient

ISTARE DATA 2013-2016

Infectious ARs by severity grade

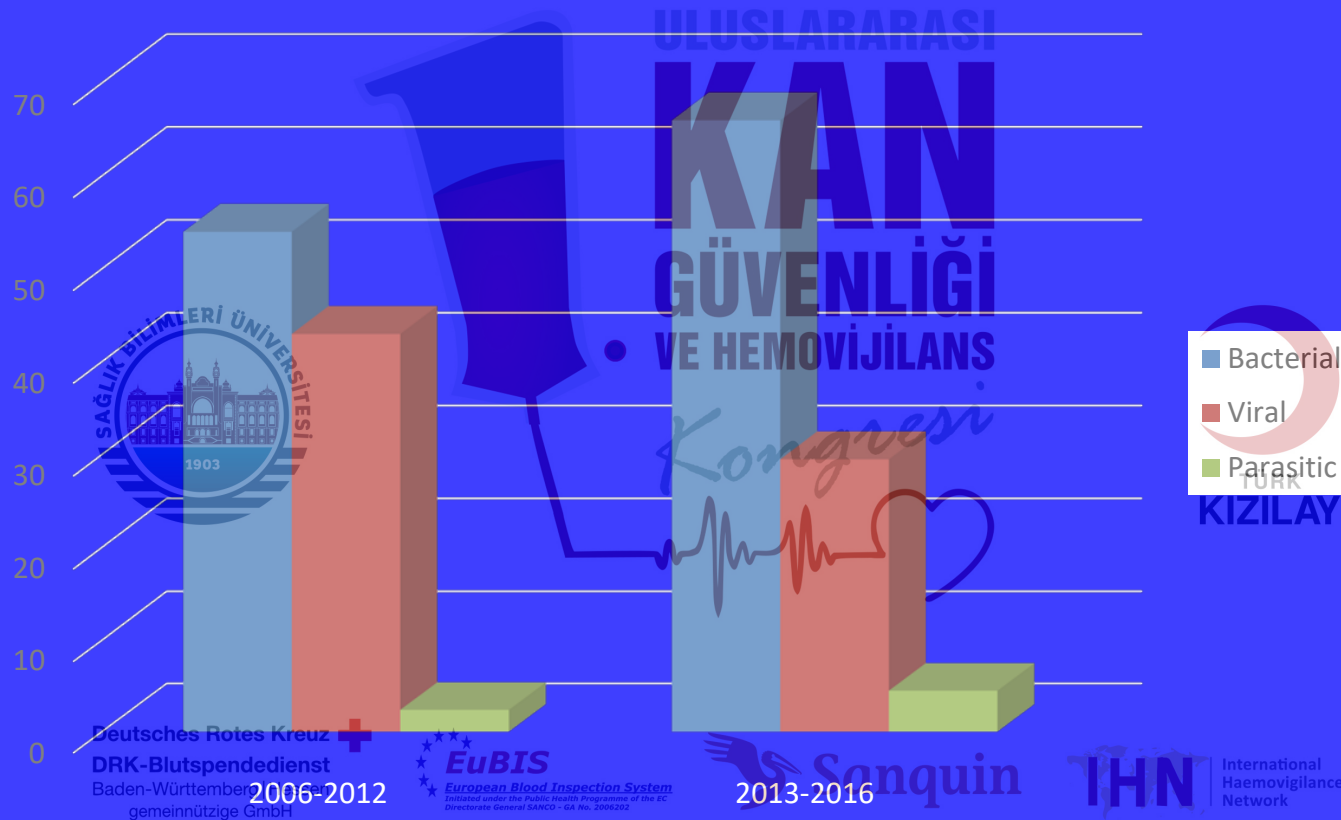


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The infectious risk of transfusion in the recipient

ISTARE DATA

The Incidence of TTIs in the two time periods

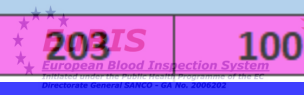
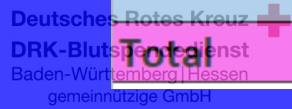
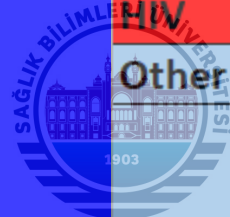


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The infectious risk of transfusion in the recipient

ISTARE DATA

Viral TTIs				
	2006-2012		2013-2016	
	n	%	n	%
HBV	160	79	17	20
HCV	6	3	10	12
HIV	4	2	2	2,5
Other	33	16	55	65,5
24 HEV 1 ParvB19 1 CMV 1 EBV 18 not specified				
Total	203	100	84	100



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Conclusions

- Most frequent Ars are Febrile, Allergic and Other
- The most serious ARs are TACO+TRALI+TAD
- The infectious risk of transfusion overall remains very low.

The rate of bacterial cases has increased and among other viral TTIs the frequency of HEV is increasing. The mortality of transfusion due to sTTIs is lower than in the previous period of surveillance

New Steps

- Further improvements to the **software**
- Adaptation of the **donor complications** spreadsheet with the update ISBT definitions
- Preparation of the aforementioned **quality survey**,
- More **radical change in the data collecting tool**
 - a granular approach to numerators and denominators,
 - critical assessment for improving current ISTARE functionality
 - **other strategies and tasks in line with IHN's instructions and guidance for future work**

Thank you

Any questions about ISTARE ?



Next IHS 2020

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