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VISTART Joint Action Work package 4 Vigilance reporting for blood, tissues and cells

Working Group 3 - Guidelines on Horizon scanning for identifying new risks related with the donation of substances of human origin

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Abbreviations

AGES-MEA	-	Bundesamt fuer Sicherheit im Gesundheitswesen / Agentur für Gesundheit und Ernährungssicherheit (Department of Blood, Tissue and Vigilance)
ABM	-	Agence de la biomédecine
ART	-	Assisted Reproductive Technologies
BDA		Bulgarian Drug Agency: BDA
BE	-	Blood Establishment
BTC	-	Blood, blood components, tissues, reproductive and non-reproductive cells
CNPMA	-	Conselho Nacional de Procriação Medicamente Assistida
CNT	-	Italian National Transplant Centre
EATB	-	EATB - European Association of Tissue Banks
EC	-	European Commission
ECDC	-	European Center for Disease Control
EMA	-	European Medicines Agency
ESHRE	-	European Society of Human Reproduction and Embryology
EU	-	European Union
HFEA	-	Human Fertilisation and Embryology Authority
HTA	-	Human Tissue Authority
HZTM	-	Hrvatski zavod za transfuzijsku medicinu (Croatia)
IHTM	-	Institute of Hematology and Transfusion Medicine
IMB	-	Institute of Medical Biology
IPST		Instituto Português do Sangue e da Transplantação
JA	-	Joint Action
MOH	-	Ministery of Health
MS	-	Member States
NBC	-	National Blood Centre (Poland)
NCA	-	National Competent Authorities
ProMED	-	Program for monitoring Emerging Diseases
RAB	-	Rapid Alert for Blood
RATC	-	Rapid Alert For Cells and Tissues
RNDVCSH	-	Registrul national al donatorilor voluntari de celule stem hematopoietice (Romanina National Registry of HSC Voluntary Donors)
SKAE		Coordinating Haemovigilanve Centre (SKAE)
SoHO	-	Substances of Human Origin
T&C	-	Tissues and Cells
TE	-	Tissue Establishment
TRIPNET	-	Transfusion and Transplantation Reactions in Patients
VISTART	-	Vigilance and Inspection for the safety of transfusion, assisted reproduction and transplantation
WHO	-	World Health Organization

Working Group 3 - Guidelines on Horizon scanning for identifying new risks related with the donation of substances of human origin

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- Lithuania (LT)
- Greece (GR)
- The Netherlands (NL)
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Background

VISTART (Vigilance and Inspection for the safety of transfusion, assisted reproduction and transplantation) Joint Action (JA) is meant to support European Union (EU) Member States (MS) in developing and strengthening their capacity for monitoring and control in the field of blood, reproductive and non-reproductive tissues and cells transplantation (BTC).

The Work Package 4 aims to explore commonalities between blood, tissue and cells vigilance, identifying opportunities for sharing of information and procedures to improve safety and quality by harmonising work in the areas of annual serious adverse reactions and events reporting, rapid alert procedures and horizon scanning for identifying new risks.

To achieve these objectives three working groups have been established. The aims of Working Group 3, Horizon scanning for identifying new risks related with the donation of substances of human origin that may be of relevance to patient safety or BTC availability, are:

- To examine the existing risk response procedures at national and international levels and the notification tools used by MS, in order to assess their strengths and weaknesses.
- To develop Guidelines on horizon scanning activities to identify new risks from pathogens with recommendations for how appropriate preventive measures should be developed and communicated at EU and national level.

In order to examine the existing risk response procedures at EU level, how these procedures can be improved, and in order to document the key good practice principles to be incorporated in the decision making and communication procedures, a survey has been developed and their inputs analyzed (Deliverable 4.4.) to produce evidence that could support the guidelines.

A horizon scanning system for serious health threats that may be of relevance to patient safety or BTC availability should include: the early warning of new risks (risk identification and monitoring), management of the epidemiological situation (risk management) and communication procedures (risk communication). The risk management integrates risk assessment (risk analysis and risk evaluation) and risk control, the definition of preventive measures and their effectiveness, as well their impact on BTC supply.

These keys elements, (risk identification and monitoring, risk management and risk communication), are the backbone of the survey and of these guidelines.

1. Materials and Methods

Definitions for horizon scanning, risk identification, risk management, risk assessment, risk analysis, risk evaluation, risk control and risk communication have been elaborated after discussion and improvement of the proposal provided by the representative of ECDC, in the meeting that took place in Lisbon on the 4th May 2018.

The guidelines have been elaborated for each horizon scanning step using the evidence found on the survey, and taking in account the EU preparedness plans for Zika and West Nile Virus.

2. Definitions

1. **Horizon scanning,** is a systematic examination of information to identify potential threats, risks, emerging issues and opportunities.
   In this document, means an organized activity to collect, analyse, assess and communicate events that may pose a potential threat to the safety of substances of human origin (SoHO)
2. **Risk –** (Epidemiology) the chance or likelihood that an undesirable event or effect will occur, as a result of use or non-use, incidence, or influence of a chemical, physical, or biologic agent, especially during a stated period; the probability of developing a given disease over a specified time period (Mcgraw-Hill Concise Dictionary of Modern Medicine)
3. **Risk identification** - involves the identification of the potential health hazard, recognition that sources of risk (e.g., a specific pathogen) can cause a specific adverse health outcome, formulation of the problem in order to characterize the scope and level of detail required to produce information needed by decision-makers.
4. **Risk management** - integrates risk assessment (risk analysis and risk evaluation) and risk control.

   4.1. Risk Assessment - is a systematic process for estimating the level of risk that considers both the consequences of exposure to a hazard and the probability or frequency of their occurrence.

   4.1.1. Risk analysis - assesses the nature of risk by the systematic collection of event information, the extraction of evidence from literature and appraisal of the evidence. Several techniques for risk analysis are available including the analysis of uncertainties. The risk is expressed
   - By using a risk matrix to plot the likelihood of occurrence and consequences, or
   - Quantified by computing real data or exploiting mathematical models.

   4.1.2. Risk evaluation - evaluates the results of risk analysis and defines if the risk is acceptable and whether intervention is recommended.

5. **Risk control -** is a systematic approach to set the best course of action to prevent or minimize a risk.
6. **Risk communication -** is an exchange of information about risk among interested parties.
7. **Serious risk to public health** has been defined as a situation where there is a significant probability that a serious hazard resulting from a human medicinal product, in the context of its proposed use, will affect public health. ‘

   Serious in this context means a hazard that could:
   - result in death,
   - be life-threatening,
   - result in patient hospitalization or prolongation of existing hospitalisation,
   - result in persistent or significant disability or incapacity, or
   - be a congenital anomaly/birth defect or permanent or prolonged signs in exposed humans.
   - result in a serious effect on the availability of SOHO in a given county or region”
8. **Trigger event** - occurrence that initiates a set of actions or procedures.

3. Guidelines

In order to timely respond to risks posed by new pathogens to the safety of SoHO, following activities are foreseen:

Horizon scanning

1. Every emerging infectious threat which is relevant for the safety of substances of human origin (SoHO) should be detected, analyzed, assessed and communicated as soon as possible.
2. Infectious threats to SoHO are detected within the existing communicable diseases horizon scanning activities of the European Union (EU) Member State (MS).
3. National Competent Authorities (NCA) of each EU MS should collect detected infectious threats to SoHO, and assure that these threats are analyzed and assessed by pertinent experts and communicated to relevant stakeholders.
4. In order to efficiently collect infectious SoHO threats, NCA should establish communication with threat detecting and monitoring bodies, with the national public health institutions and European Centre for Disease Prevention and Control. NCA should also have direct access to alert EU platforms such as the Early Warning and Response System (EWRS) and Rapid Alert Systems for blood (RAB), tissues and cells (RATC). Other sources of information are national and international haemovigilance and biovigilance networks, SoHO establishments and other infectious disease sentinels.

5. NCA should ensure that detected threat is analyzed and assessed for its relevance and transmissibility through SoHO by the experts in the infectious diseases and safety of SoHO. Each potential threat should be analyzed from local, national and international perspectives.
6. NCA should communicate an assessed threat to
    - The other NCAs through Rapid Alert Blood (RAB) and Rapid Alert Tissues and Cells (RATC) platforms (only alerts requiring immediate/ urgent consideration or follow up measures in two or more MS should be recorded)
    - National public health institutions;
    - National blood and tissue and organ procurement establishments,
    - Other vigilance/alert healthcare sectors as well as pharmaceutical and medical devices sectors. (It should be avoided that there is a double reporting)

7. Risk identification, risk assessment, risk control and response interventions
   NCA should establish a group of experts or nominate a national or regional responsible body which identifies risk, prepares a risk assessment and proposes possible response interventions.

8. Risks management
   NCA should ensure that every infectious risk resulting from an assessed threat to the SoHO safety is analyzed and assessed, and response interventions are defined and implemented. NCA should also timely communicate all SoHO risks and interventions to all stakeholders in the country and EU.

The issues that have to be considered:

Risk identification

a. Risk identification requires a strong filter and validation capacities to ensure the accuracy of the information and the significance of data for SoHO
b. The known, the potential or theoretical risk of infectious diseases transmission through SoHO is present if an asymptomatic donor may donate infectious SoHO and if pathogen may survive in a donated product which if applied may cause a disease in the recipient.

Risk Assessment

c. Once a risk is identified the information about etiologic agent should be gathered by consulting the scientific evidence in the literature, individual expert opinions and comparison with experiences from previous outbreaks or other available sources.
d. Risk can be assessed qualitatively or estimated by using risk assessment tools such as EUFRAT (European Up-Front Risk Assessment Tool), Biggerstaff-Petersen model or other assessment tools/models.

e. A risk scale should be graded according to available recommendations and risk assessed in the setting of affected and non-affected areas within the country of an outbreak and other countries.

Risk Control

f. The preventive measures to control the risk should be defined according to the input from EU expert recommendations (ECDC Rapid Risk Assessment and EU preparedness plans), EDQM guides or WHO guidelines, other references, comparison with previous outbreaks and also the input from expert bodies in other countries.

g. Options, activities and resources for the management of infectious risk in the BTC setting are:

   i. Temporary interruption of donations in affected area
   ii. Supply of products from non-affected areas
   iii. Donor information and self-deferral
   iv. Deferral of potential donors at risk to be infected
      1. Geographical deferral of travelers returning from affected areas
      2. Temporary or permanent deferral of donors after clinical disease
      3. Temporary or permanent deferral of donors residing in affected areas
      4. Temporary or permanent deferral of donors with acute clinical symptoms
   v. Confidential donation self-exclusion
   vi. Leukocyte-reduction of donated blood components
   vii. Screening of donations/ donors for the presence of the involved pathogen
   viii. Quarantine of the donations
   ix. Reinforcement of post-donation information
   x. Tracing of recipients of potentially infectious BTC (look back / review)
   xi. Pathogen inactivation of donations
   xii. Balance the risk of disease transmission against the risk of not transplanting the organs especially if a treatment of infection involved is available.

Evaluation of risk and implementation of response interventions

Once risk is assessed and interventions proposed, NCA should:

h. Evaluate the acceptability/tolerability of assessed risk and the proportionality and adequacy of proposed interventions.

i. Prepare and coordinate the implementation of interventions in cooperation with BTC establishments to ensure sufficient and sustainable product supply during an outbreak. In some instances the coordination has to be performed with other EU

countries, with the EU Commission or with other sectors (Medicines, Advanced Therapies, Medical Devices if they are prepared with SOHO material)

j. Define geographical areas where interventions need to be implemented and declare initiation and/or discontinuation of interventions.
k. Collect and evaluate the BTC establishment feedback on applied interventions. Feedbacks about donor deferrals and screening test results are mandatory.
l. Analyse the cost-effectiveness and impact of safety interventions on BTC supply.
m. The effectiveness of the measures should also be performed regarding the transmission through transfusion/ transplantation, the morbidity and mortality in the affected population.

Risk Communication

In order to ensure an efficient communication of assessed risk and implemented interventions, NCAs should:

n. Inform stakeholders about risk assessment, and the implementation and/or discontinuation of preventive interventions as soon as possible.
o. Develop or cooperate in developing an information material for donors, clinicians and patients related to current the risk and interventions in place.
p. Communicate any subsequent change in existing national/local guidelines to all stakeholders.
q. Regularly inform the ministry of health about the implemented interventions and communicate to the other authorities at national level, including public health authorities, veterinary institutions, drug safety authorities and scientific bodies.
r. Inform other EU MS about assessed risk and implemented interventions though the RAB and RATC EU platforms.
s. Depending on the extent of the risk exchange information with international organizations and keeping the public health sector and the wider population informed.

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VISTART Joint Action Work package 4 Vigilance reporting for blood, tissues and cells

Working Group 3 - Survey on Horizon scanning for identifying new risks related with the donation of substances of human origin

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Abbreviations

ART	-	Assisted Reproductive Technologies
BE	-	Blood Establishment
BTC	-	Blood, blood components, tissues, reproductive and non-reproductive cells
CA	-	Competent Authority
EC	-	European Commission
ECDC	-	European Center for Disease Control
EU	-	European Union
JA	-	Joint Action
MoH	-	Minister of Health
MS	-	Member States
Q&S	-	Quality and Safety
SOHO	-	Substances of Human Origin
T&C	-	Tissues and Cells
TE	-	Tissue Establishment
RAB	-	Rapid Alert for Blood
RATC	-	Rapid Alert For Cells and Tissues
VISTART	-	Vigilance and Inspection for the safety of transfusion, assisted reproduction and transplantation

Background

VISTART (Vigilance and Inspection for the safety of transfusion, assisted reproduction and transplantation) Joint Action (JA) is meant to support European Union (EU) Member States (MS) in developing and strengthening their capacity for monitoring and control in the field of blood, reproductive and non-reproductive tissues and cells transplantation (BTC).

The Portuguese Blood and Transplantation Institute is the leader of Work Package 4 which aims to explore commonalities between blood, tissue and cells vigilance, identifying opportunities for sharing of information and procedures to improve safety and quality by harmonising work in the areas of annual serious adverse reactions and events reporting, rapid alert procedures and horizon scanning for identifying new risks.

To achieve these objectives three working groups have been established. The aims of Working Group 3, Horizon scanning for identifying new risks related with the donation of substances of human origin that may be of relevance to patient safety or BTC availability, are:

- To examine the existing risk response procedures at national and international levels and the notification tools used by MS, in order to assess their strengths and weaknesses.
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In order to examine the existing risk response procedures at EU level, how these procedures can be improved, and in order to document the key good practice principles to be incorporated in the decision making and communication procedures, a survey has been developed and their inputs analyzed.

A horizon scanning system for serious health threats that may be of relevance to patient safety or BTC availability should include: the early warning of new risks (risk identification and monitoring), management of the epidemiological situation (risk management) and communication procedures (risk communication). The risk management integrates risk assessment (risk analysis and risk evaluation) and risk control - the definition of preventive measures and their effectiveness as well their impact on BTC supply.

These keys elements are the backbone of this survey.

1. Materials and Methods

Only the 28 EU Competent Authorities for blood, tissues, cells and ART as well as Norway, Iceland and Lichtenstein have been invited to contribute to the survey available online from 10th January to 15th March 2018, no other entity has been invited.

The questionnaire was divided into 3 sections:

A. Identification
    A.1. Country
    A.2. Information provided by
B. Risk response procedures at national and international level
    B.1. Horizon scanning system/ epidemic intelligence activities
    B. 2. Sources of information used for scanning
    B.3.Triggers
    B.4. Risk assessment
    B.5. Risk management - Implementation of preventive measures
    B.6. Communication of preventive measures
    B.7. Establishment of the extent to which epidemiological alerts reach stakeholders
    B.8. Public health implications to other countries
C. Preparedness plans and activities

For the purposes of this survey, only risk response procedures to serious health threats related to epidemiological situations (e.g. disease outbreaks) have been evaluated. *Serious risk to public health* has been defined as a situation where there is a significant probability that a serious hazard resulting from a human medicinal product, in the context of its proposed use, will affect public health. '*Serious*' in this context means a hazard that could:

- result in death,
- be life-threatening,
- result in patient hospitalization or prolongation of existing hospitalisation,
- result in persistent or significant disability or incapacity, or
- be a congenital anomaly/birth defect or permanent or prolonged signs in exposed humans.

*Trigge*r event has been defined as the occurrence that initiates a set of actions or procedures.

2. Results

A. Country Identification

30 answers were received from 22 MS CA with an answer rate of 70,96%,; 21 answers from blood CA; 19 from T&C CA and 19 from ART CA . (Figure 1 and Table 1)

Figure 1- Answers by country

	Blood	T&C	ART
Austria	X	X	X
Belgium	X	X	X
Bulgaria	X	X	X
Cyprus	X	X	X
Czech Republic	X	X	X
Denmark	X	X	X
Estonia	X	X	X
Finland	X	X	X
France	X	X	X
Germany	X	X	X
Greece	X		X

	Blood	T&C	ART
Ireland	X	X	X
Italy	X	X	X
Lithuania	X	X	X
Malta	X	X	X
Norway	X	X	X
Poland	X		
Portugal	X	X	X
Romania	X		
Spain		X	
Sweden	X	X	X
United Kingdom	X	X	X

Table 1 - Answers by BTC area

B. Risk response procedures at national and international level

B.1. Horizon scanning system / epidemic intelligence activities

16 countries for blood, 13 for T&C and 12 for ART have in place a formal horizon scanning system/epidemic intelligence activities for the early warning of new risks, emerging infection news that may be of relevance to patient safety or BTC availability. (Figure 2)

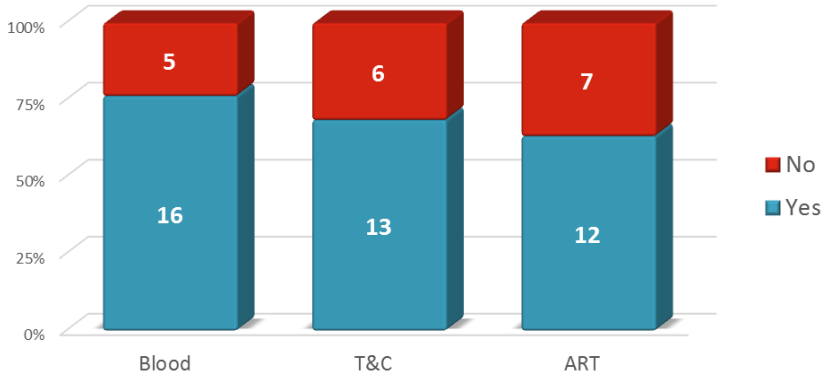

Figure 2 - Formal horizon scanning system/epidemic intelligence activities

100% of the respondents have in in place a system to exchange information between CA, Tissue establishments (TEs)/ Blood Establishments (BEs) and organizations for human application of BTC, urgently, in case of serious health threats related to epidemiological situations.

According to Figure 3 the organizations involved in the national horizon scanning systems are the National/ Regional CA, National/ Regional Haemovigilance Biovigilance Offices, BE and TE, the ministry of Health and other organizations. Other organizations have been identified, by country, in table 2.

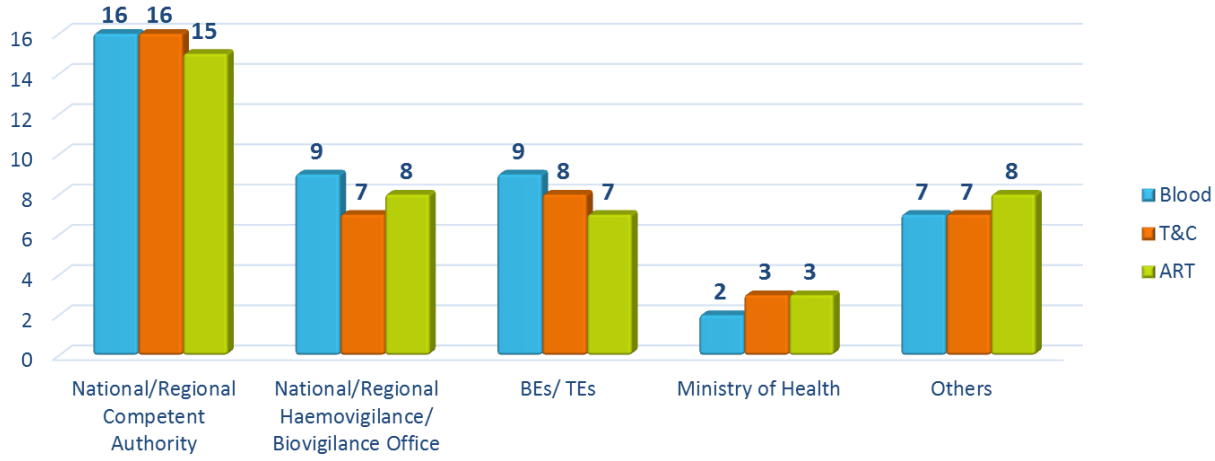

Figure 3 - Organizations involved in the national horizon scanning systems

Austria	AGES MED, national epidemiological monitoring system (EMS)
Bulgaria	National Centre for Infectious and Parasitic Diseases (NCIPD), National Coordinating Council for the Management of the National Program for Prevention and Control of Vector Transmitted Infections in people in the Republic of Bulgaria, 2014-2018, National Centre of Transfusion Haematology
Estonia	Estonian Health Board
France	SPF = National Agency for public health, MoH, French Advisory group (FAG), NCAs (ANSM for blood, ABM for organs, tissues and cells), EFS = national blood service, National Reference CentREs (NRC), scientific experts..
Greece	Coordinating Haemovigilanve Centre (SKAE) is part of the Hellenic Center Control and Prevention (KEELPNO)
Ireland	Health Protection Surveillance Centre (HPSC), is the International Health Regulator (IHR) and ECDC National Focal Point for infectious disease surveillance.
Italy	National Haemovigilance Office is part of the National Competent Authority. Dept. of Infectious Diseases - Superior Institute of Health (ISS)
Romania	National centre for disease control
Sweden	Public Health Agency of Sweden
United Kingdom	Public Health England, The National Health Service Blood & Transfusion, Department of Health

Table 2 – Other organizations involved in the national horizon scanning systems others

Once a risk is identified, 100% of the countries, for blood and T&C, and all but one for ART, inform other national vigilance healthcare sectors (Figure 4) identified in Figure 5.

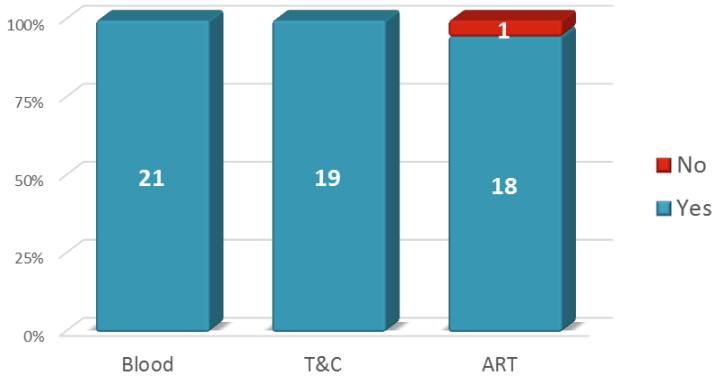

Figure 4 – information to other national vigilance healthcare sectors

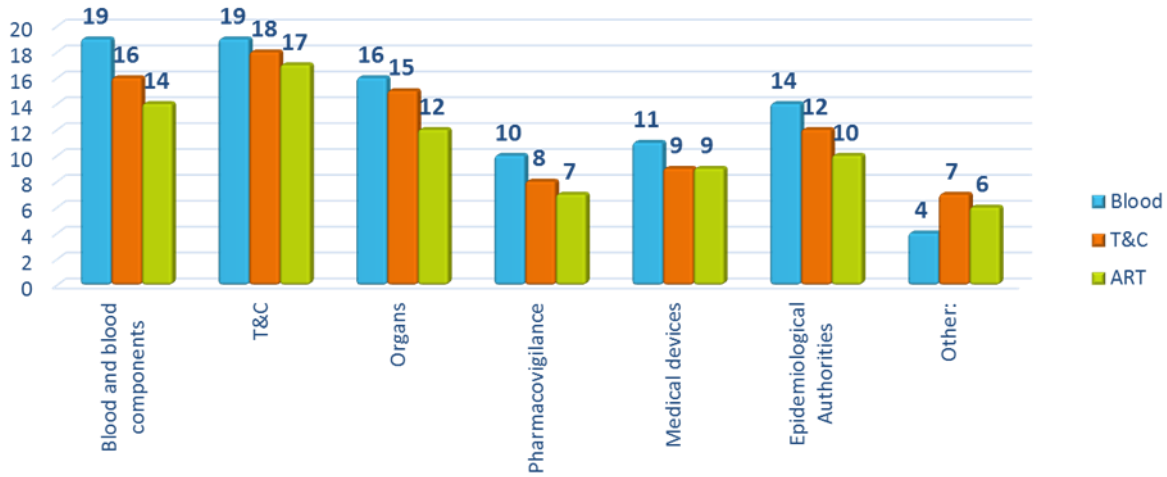

Figure 5 – Informed national vigilance healthcare sectors

B.2. Sources of information used for scanning/ Threats detection

About 66% of the systems for blood; 52,6% for T&C and 47,36% for ART monitor maps / websites lists of relevant vector distribution or affected areas and countries. (Figures 6 and 7)

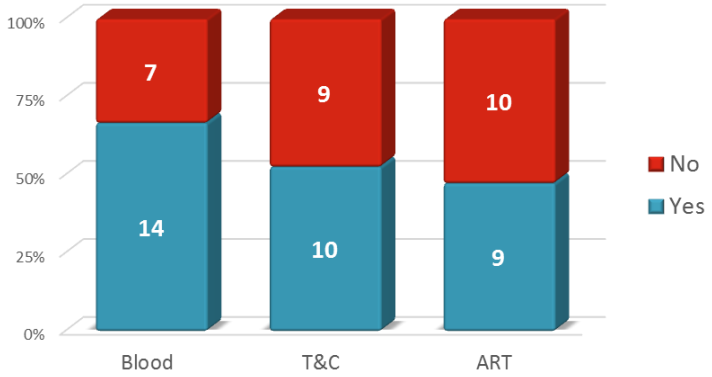

Figure 6 – Existence of monitorization of maps / websites lists of relevant vector distribution or affected areas and countries

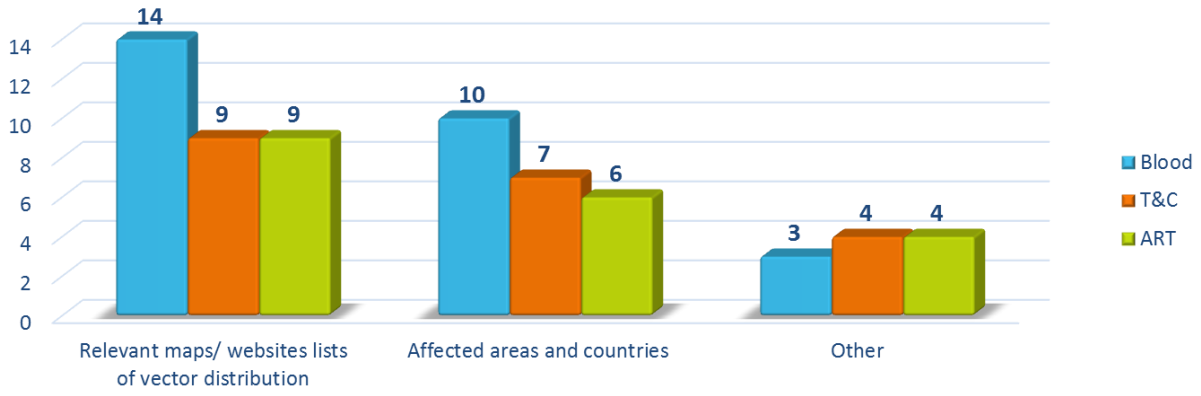

Figure 7 - Monitorization of maps / websites lists of relevant vector distribution or affected areas and countries

The organizations responsible for that monitoring are identified in Figure 8 and Table 3.

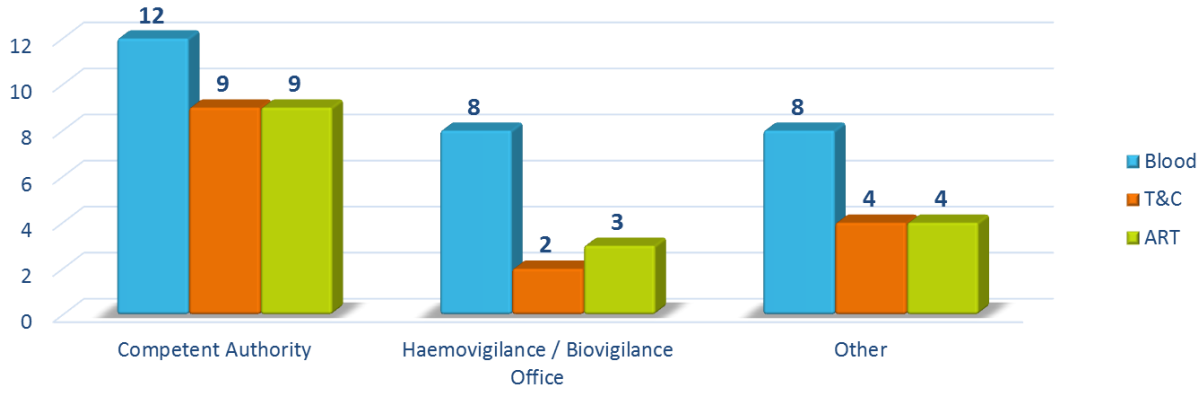

Figure 8 – Responsible organizations for monitoration of maps / websites lists of relevant vector distribution or affected areas and countries

Austria	Ministry of Health, AGES MED
Bulgaria	The National Centre for Infectious and Parasitic Diseases (NCIPD), National Centre of Transfusion Haematology
France	Epidemiological CA (SPF)
Greece	Hellenic Center for Disease Control and Prevention (KEELPNO)
Romania	BEs
Sweden	Public Health Agency of Sweden
UK	UK Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI)

Table 3 – Other responsible organizations for monitorization of maps / websites lists of relevant vector distribution or affected areas and countries

For the respondents, as national competent authorities, the EU RATC/RAB platforms, the ECDC and the National Communicable Diseases agencies information are the usual sources of information (Figure 9). The other sources of information are identified in Table 4.

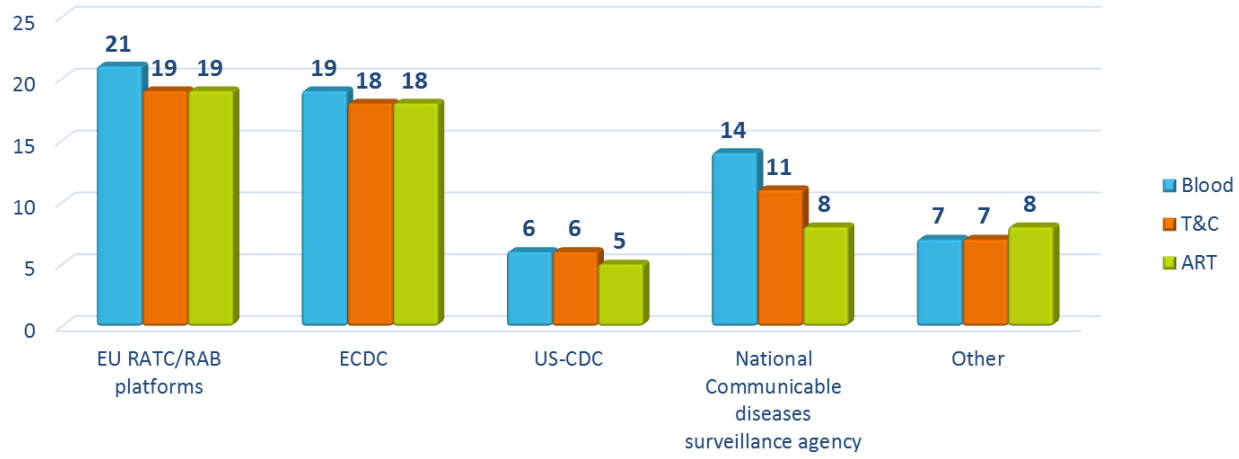

Figure 9 - Usual sources of information

Austria	National epidemiological monitoring system (EMS)
Bulgaria	Directorate "Health Control" - Ministry of Health
France	SPF and MoH for communicable diseases surveillance. Information provided also by the Italian Centro Nazionale Sangue Istituto Superiore di Sanita
Germany	WHO, EMA
Greece	KEELPNO
Ireland	Other national infectious disease surveillance agencies and WHO
Italy	WHO and its Regional Offices.
Sweden	Noise detection from sources such as ProMed-mail
UK	Joint Professional Advisory Committee (JPAC)
United Kingdom	Public Health England

Table 4 – Other usual sources of information

B.3. Triggers incident

Regarding the trigger incident, in the majority of the cases, the trigger incident is the first human case (Figure 10 and Table 5) occurring in the country or in one or more EU countries (Figure 11) with a known or potential risk to the quality and safety of BTC that may impact patients or a known or potential risk to donors (Figure 12)

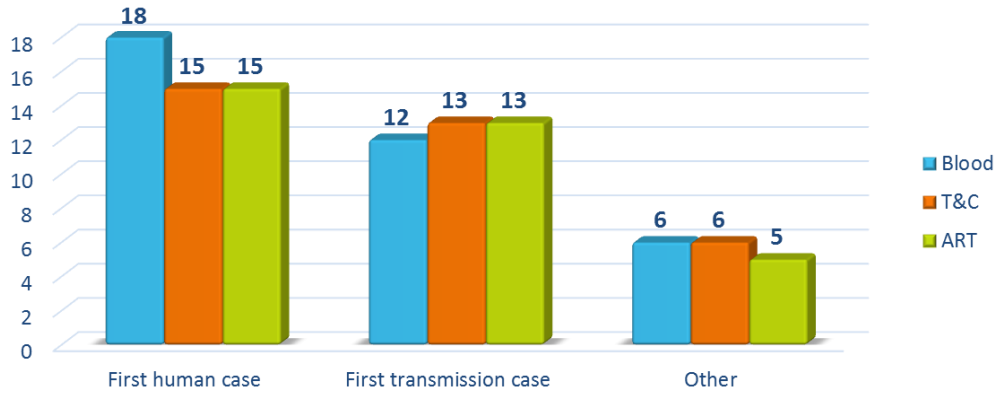

Figure 10 - trigger incident

Czech Republic	Information concerning potential risk (any source)
Finland	Whatever is considered relevant by ECDC or RAB/RATC alert
France	It depends on the characteristics of communicable diseases defined together via FAG
Greece	A preparedness plan for the protection of blood safety against WNV include trigger criteria for the implementation of WNV-RNA in affected areas and deferral of donors travelling to endemic regions as well as entomological and veterinary surveillance is in place. All WNV cases with or without neuro-invasive WNV infections are notified in the Hellenic Center for Disease Control and Prevention. Haemovigilance measures including post donation information and post transfusion information as well as monitoring of epidemiological surveillance of blood donors are applied
Italy	Considering that some Italian Regions are endemic for WNV, the trigger criteria for the implementation of WNV NAT testing from June to October are the following: a) Notification of WNV circulation through entomological (vector mosquitoes) and veterinary (wild birds) surveillance in the Regions where the integrated surveillance plan is in place; b) Notification of cases of neuro-invasive and non-neuro-invasive human WNV infections.
	Depending on the infection/disease
Sweden	Scheduled surveillance activities (e.g. West Nile Virus)
UK	Cases within a country, vector presence, need to ensure accuracy of information

Table 5 –- Other trigger incident

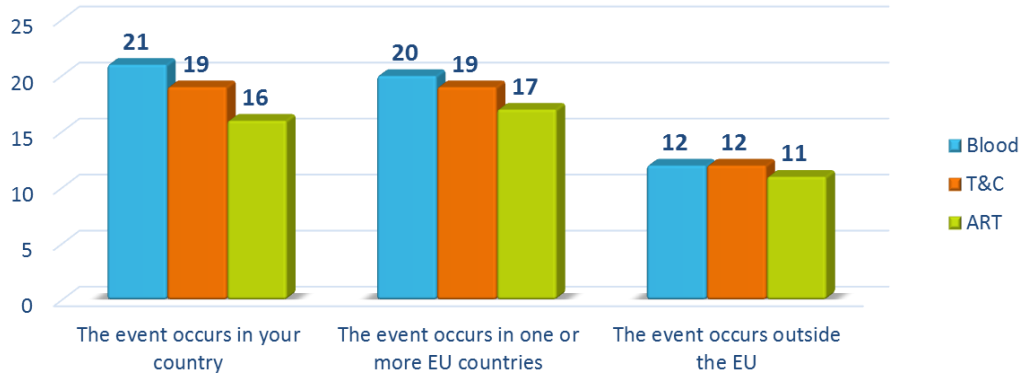

Figure 11 – Geographical expense of trigger incident

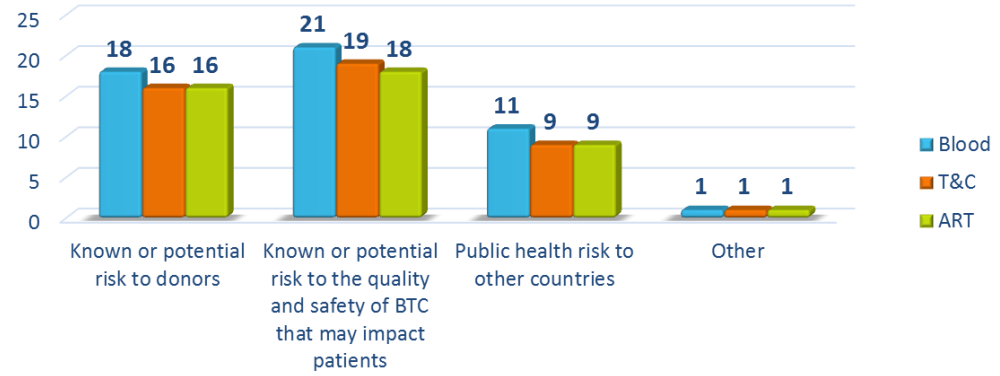

Figure 12 - Trigger incident regarding risk?

B.4. Risk assessment

Once a risk is identified the evidence about etiologic agent information is gather consulting bibliography, individual experts and comparison with available information concerning previous outbreaks according to Figure 13.

The other sources used are listed in table 6.

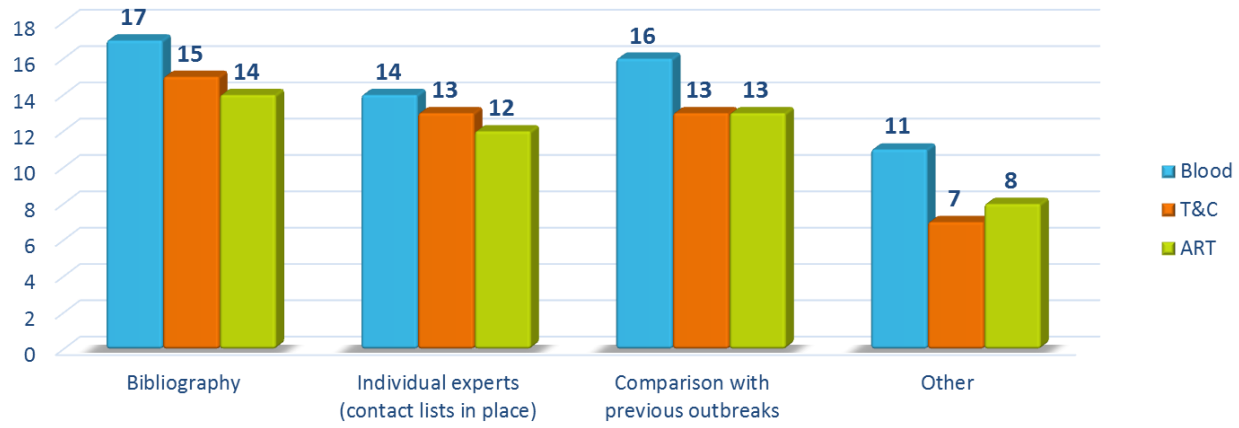

Figure 13 - etiologic agent information

Czech Republic	information from other CA of MS
Denmark	Liaise with National Epidemiological Authority (SSI) and ECDC.
Estonia	Estonian Health Board
Finland	ECDC or RAB/RATC
France	SPF's tools and National Reference Centers
Greece	Hellenic Center for Disease Control and Prevention (KEELPNO), Haemovigilance Centre and National Blood Centre
	Multisectoral Committee of Experts in SoHO, Epidemiology, Veterinary Entomology, Reference Labs
Ireland	Based on expert advice from other sources
Italy	Other EU or extra-EU Competent Authorities experienced the same risk.
Poland	Conferences, websites
Romania	specialised services
Sweden	International reports

Table 6 - Etiologic agent information

The Competent Authorities are the organization responsible to perform risk assessment (Figure 14) for the vast majority of the respondents. The other organizations responsible to perform risk assessment are identified, by country, in table 7.

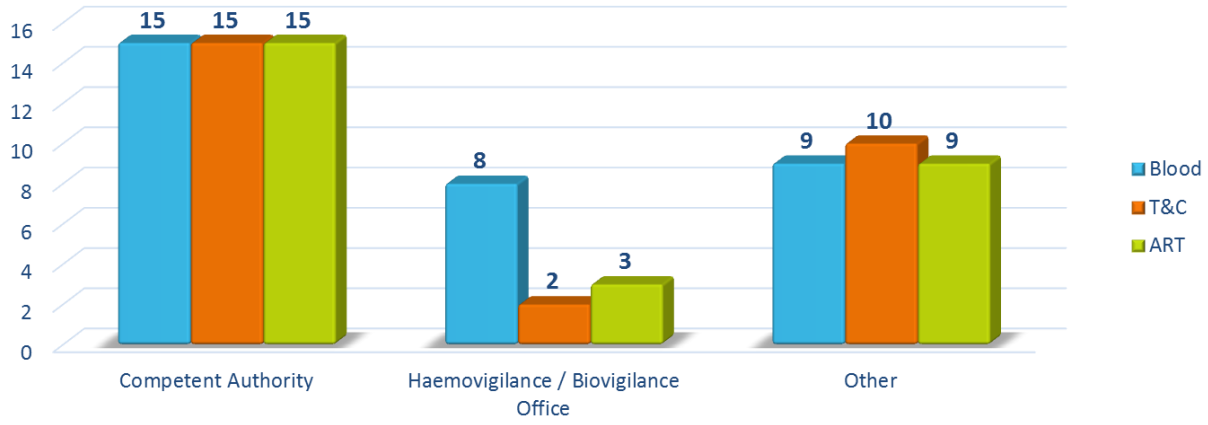

Figure 14 – Responsible organizations to perform risk assessment

Austria	AGES MED
Bulgaria	National Centre of Transfusion Haematology, The National Centre for Infectious and Parasitic Diseases (NCIPD)
Czech Republic	Ministry of Health
Estonia	Estonian Health Board
Finland	BE,TE
France	Haemo/Biovigilance Office, The assessment of SoHO is performed by the FAG a multidisciplinary expert group (composed with NCAs representatives, MoH representatives, and scientific experts notably virologists) in charge of the assessment of scientific data, epidemiological data, risk based approach for patients
Greece	Hellenic Center for Disease Control and Prevention (KEELPNO)
Ireland	Based on expert advice from other sources
Romania	National Institute of Public Health- centre for disease control
UK	JPAC
United Kingdom	Public Health England and the Department of Health

Table 7 – Other responsible organizations to perform risk assessment

About 38% of the MS for blood, 57;9% for T&C and 52;6% for ART don´t use healthcare assessment tools to estimate the risk (Figure 15) and about 30% of the countries use other healthcare assessment tools (Table 8).

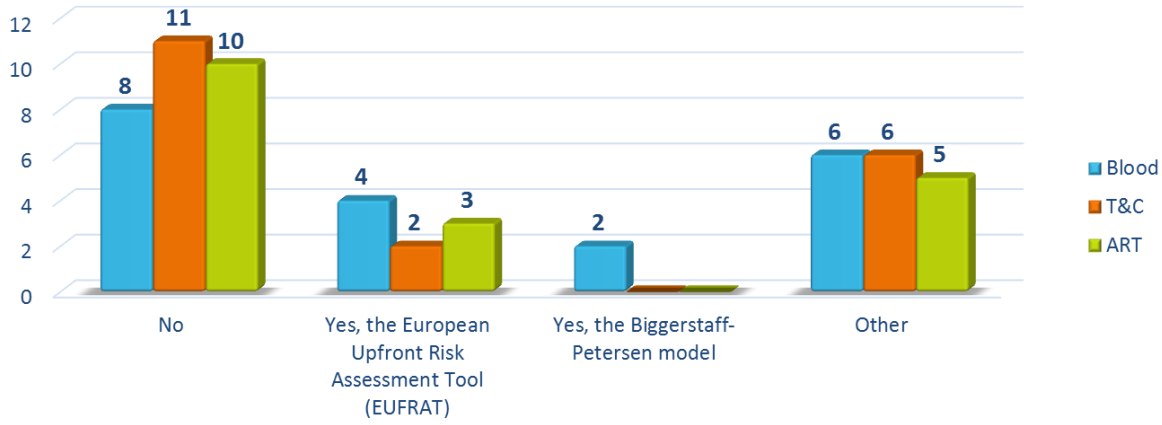

Figure 15 - Use of healthcare assessment tools to estimate the risk

United-Kingdom	ABO Risk-Based Decision Framework (RBDF)
Denmark	NEA (SSI) and ECDC.
Sweden	Rapid Risk Assessment Tool (ECDC) and national
Germany	Risk modelling
France	SPF tools for blood donation assessment

Table 8 – Other use of healthcare assessment tools to estimate the risk

B.5. Implementation of preventive measures

For the majority of the respondents the National Competent Authorities are responsible to define geographical areas where preventive measures need to be considered (Figure 16).The other organizations responsible to define geographical areas where preventive measures need to be considered are listed in table 9.

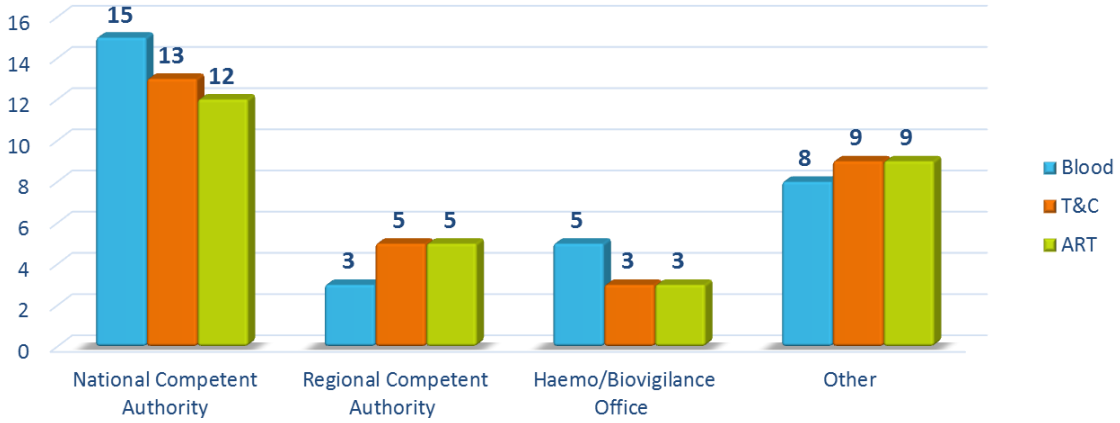

Figure 16 – Responsible organizations to define geographical areas where preventive measures are implemented

Austria	AGES MED
Bulgaria	Ministry of Health
Bulgaria	The National Centre for Infectious and Parasitic Diseases (NCIPD)
Czech Republic	Ministry of Health
Estonia	Estonian Health Board
Finland	BE,TE
France	SPF (or sometimes ECDC). It depends on pathogen agent and other countries/affected areas concerned.
Greece	Hellenic Center for Disease Control and Prevention (KEELPNO), Multisectoral Committee of Experts in SoHO, Haemovigilance, Public Health, Epidemiology, National Blood Centre , Veterinary Entomology, Reference Labs
Ireland	Relevant public health authorities
Portugal	The competent authority responsible for epidemiological vigilance
Spain	Transplantation Commission in the Inter-territorial Council of the National Health System.
United Kingdom	JPAC

Table 9 – Other responsible organizations to define geographical areas where preventive measures are implemented

In the majority of the cases the responsible authority doesn´t define a risk scale, from very low to high potential threat, for the implementation of measures (Figure 17).

The risk scales adopted by country are presented in table 10.

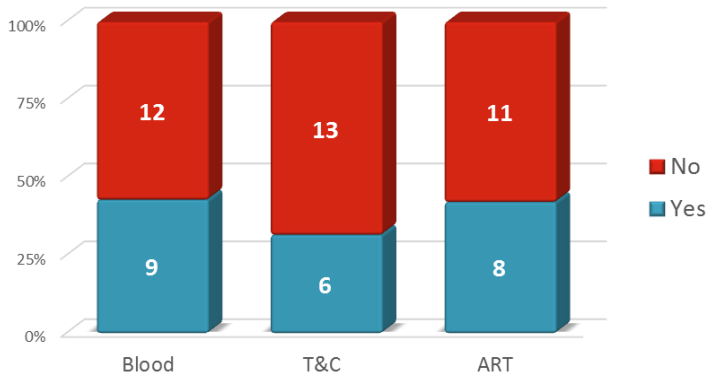

Figure 17 – Implementation of a risk scale

Estonia	Decided by the Estonian Health Board
France	It is defined for some pathogen agents like arboviruses
Italy	Taking into account the indications provided by other organisations/stakeholders (e.g. ECDC), the CA adjusted the risk scale according to the local risk assessment: 1. West Nile 2. Chikungunya virus 3. Malaria 4. Chagas disease 5. Leishmaniosis 6. Zika virus 7. Tick-borne diseases 8. Usutu virus 9. Dengue 10. Yellow fever 11. Others
Portugal	Affected areas, non-affected areas, affected areas in other countries
Sweden	Very low risk; Low risk; Moderate risk; High risk; Very high risk
Greece	The risk scale is defined, according to the etiologic agent, by National Authorities For WNV, the lowest administrative unit (Municipality) with a record of at least one locally acquired human WNF case is defined as affected. In the affected area, response activities are implemented, including blood safety measures. Reference used for risk scale are the ECDC Technical report, WNV risk assessment tool and the EU WNV blood safety introduction to a preparedness plan in Europe. In areas with a record of at least one infected equid or mosquito pool, response activities are also implemented including enhanced surveillance by raising awareness of the local clinicians, enhanced communication activities for the public and enhanced vector surveillance and control activities. For locally acquired malaria (P.Vivax) an affected area is within a radius of 6km around the probable place of exposure. Risk assessment for the re-emergence of malaria: all areas (Regions, Municipalities) are assigned a Risk Level from 0-3, taking into consideration the malaria cases reported since 2009, and other local risk factors (entomological, environmental and demographic data). In general, the Risk Levels are as follows: Risk level 0: regions without any transmission risk factors Risk level 1: regions with local transmission risk factors Risk level 2: regions with a record of at least one (even sporadic) locally acquired case.

Table 10 – Risk scale adopted by country

In MS that adopt a risk scale, (see figure 17) different type of measures are implemented: for Blood in 7 countries, for ART in 6 and for T&C in 5 countries (Figure 18) These measures are specified in Table 11.

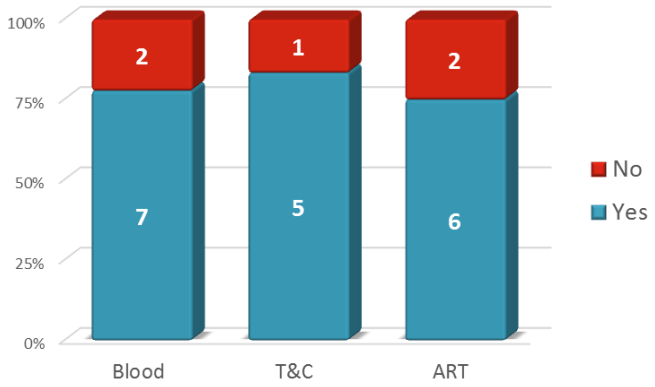

Figure 18 - Measures implemented In the MS that adopt a risk scale

Cyprus	Mode of transmission
Estonia	Decided by the Estonian Health Board
France	For some virus notably emergent ones, different steps for action are defined: 1. surveillance of the virus vectors when it is known (birds, horses…) 2. surveillance of the epidemiological situation 3. definition of an alert threshold 4. definition of a postponed period, for donation/collection of SoHO or identification of biological testing required before donation/collection These measures are regularly updated taken into account epidemiological situation.
Greece	For instance, to define an area as affected, at least one locally acquired human WNF case should be recorded. In the affected area, response activities are implemented, including blood safety measures. Reference used to define risk scale are the ECDC Technical report, WNV risk assessment tool and the EU WNV and blood safety introduction to a preparedness plan in Europe. In areas with a record of at least one infected equid or mosquito pool, response activities are also implemented including enhanced surveillance by raising awareness of the local clinicians, enhanced communication activities for the public and enhanced vector surveillance and control activities. For locally acquired malaria (P.Vivax) an affected area is defined within a radius of 6km around the probable place of exposure. Risk assessment for the re-emergence of malaria: all areas (Regions, Municipalities) are assigned a Risk Level from 0-3, taking into consideration the malaria cases reported since 2009, and other local risk factors (entomological, environmental and demographic data)
Italy	1. Application of specific deferral period; 2. Implementation of testing, if specific screening test is available; 3. Strengthening the pre-donation interview and physical examination of donors 4. Strengthening post-donation information; 5. Implementation of ad hoc haemovigilance procedures.
Portugal	Affected areas, non-affected areas, affected areas in other countries. The initial communication procedures are the same, but the measures taken depends on the probability of risk to donors, patients and offspring.
Spain	The scope of the measures is always adapted to the risk for the target population.
Sweden	Continue routine surveillance; closely monitor; seek further information; repeat risk assessment; preparedness measures; etc.

Table 11 – Specification of different Mmeasures implemented In the MS that adopt a risk scale

The preventive measures to manage risk are defined according to the input from EU expert bodies (ECDC), bibliography, comparison with previous outbreaks and also the input from expert bodies in other countries (Figure 19)

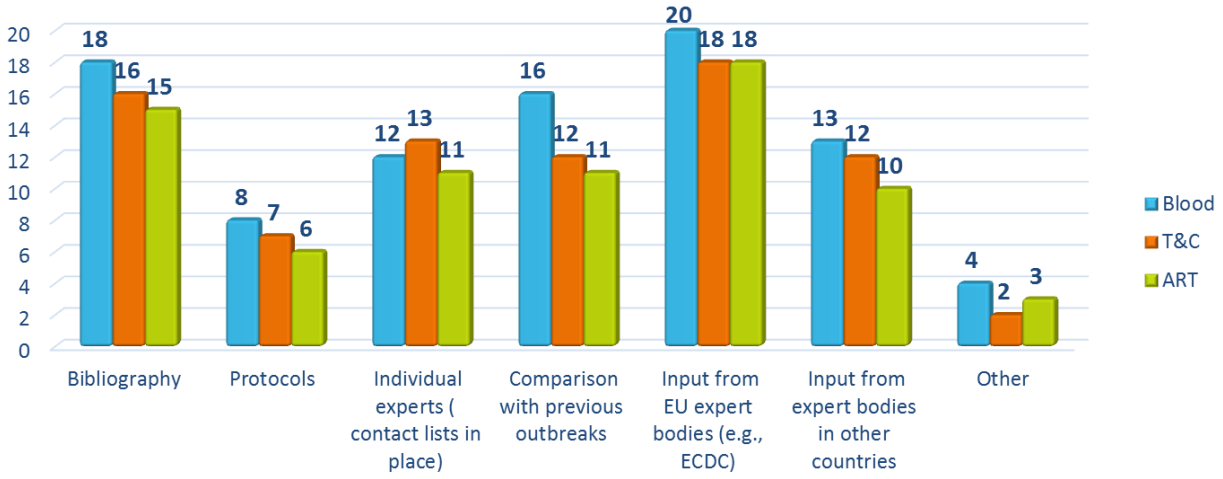

Figure 19 – Sources of d definition of preventive measures

The reference documents used to define preventive measures are ECDC guidelines for all the MS CA but also EU preparedness plans and WHO guidelines according to figure 20.

The other documents used are National guidelines or preparedness plans according to Table 11.

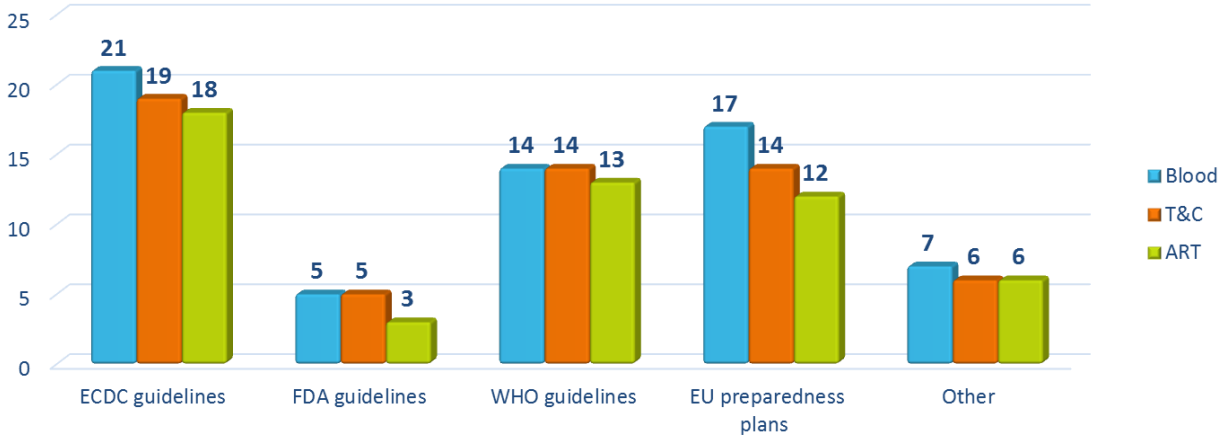

Figure 20 - Reference documents used to define preventive measures

Austria	National preparedness plans
Bulgaria	National preparedness plans
Estonia	Documents issued by Estonian Health Board
France	National guidelines
France	National guidelines
Greece	National guidelines
Italy	CDC guidelines
Italy	U.S CDC Guidelines
Poland	Scientific papers
Portugal	Depends on the type of risk and may differ from CA to CA
Spain	Documents of the Asociación Española de Bancos de Tejidos (AEBT), Guide of the Council of Europe for Tissues and Cells, other international standards from other professional associations.
Sweden	National legislation

Table 12 – Other reference documents used to define preventive measures

In the majority of the MS the Competent Authority is responsible to initiate and discontinue the preventive measures (Figure 21). The other organizations with this responsibility are identified, by country in Table 12.

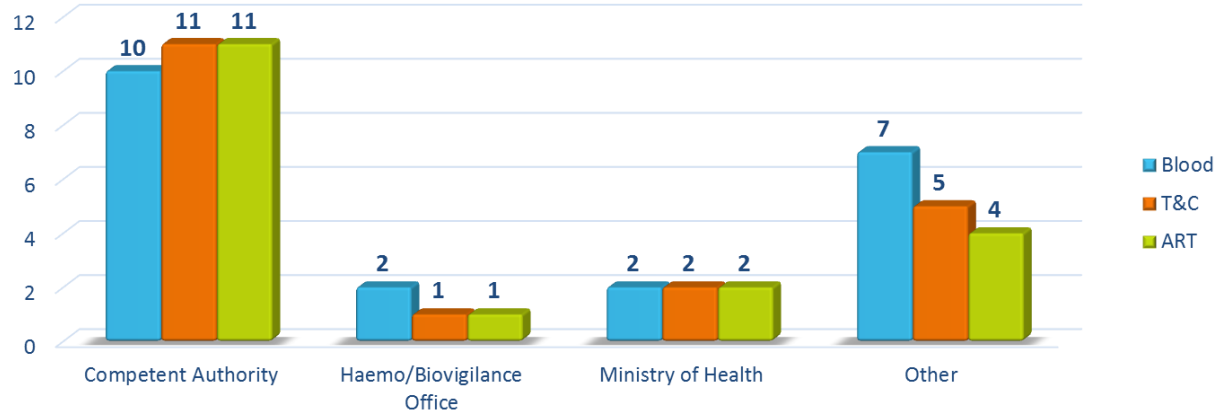

Figure 21 – Responsible organization to initiate and discontinue the preventive measures

Bulgaria	National Centre of Transfusion Haematology
Estonia	Estonian Health Board
Finland	Blood Establishment, Tissue Establishments
France	MoH based on the opinion of the same multidisciplinary expert group (FAG)
Greece	Multisectoral Committee for designation of affected areas - KEELPNO
Romania	Centre for disease control
Spain	Any bodies in the chain of donation and transplantation are accountable to start any preventive measure at their level, when needed.
UK	JPAC

Table 13 – Other Responsible organization to initiate and discontinue the preventive measures

13 respondent MS for blood and 9 For T&C and ART analyse the effectiveness of the measures taken (Figure 22). The responsible organizations for that analysis are identified, by country, in table 14.

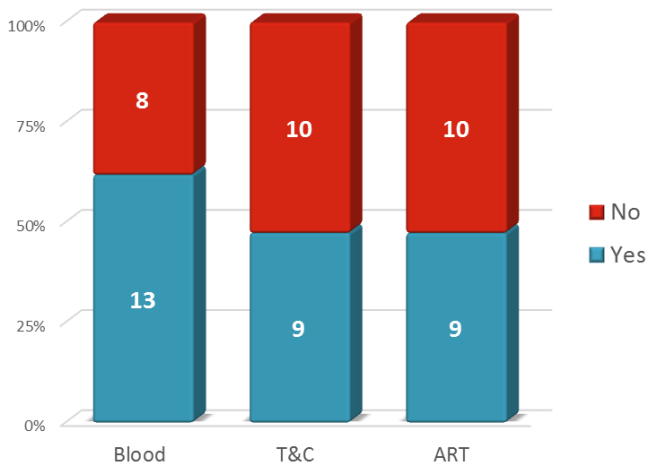

Figure 22 – Responsible organizations for analysis the effectiveness of the measures taken

Bulgaria	National Center of Infectious and Parasitic Diseases
Bulgaria	National Centre of Transfusion Haematology
Estonia	State Agency of Medicines, Health Board
Finland	BE and TEs, and CA
France	For blood and blood components, ANSM = Blood NCA
France	For SoHO other than blood products, Agence de la BIomédecine (ABM)
Germany	National Competent Authority
Greece	The Ministry of Health National Committee for the Prevention and Management of Tropical diseases
Italy	Competent authority
Italy	The National Haemovigilance Office under the aegis of Ministry of Health
Lithuania	Competent authorities
Poland	Competent authorities
	CA and ART Centre
	National Haemovigilance office
Romania	CA
Spain	The organization that implements the measure.
Sweden	National Board of Health and Welfare and Health and Social Care Inspectorate
UK	Haemovigilance systems

Table 14 – Other Responsible organizations for analisis the effectiveness of the measures taken

The analysis of the effectiveness of the measures taken is performed regarding the transmission through transfusion/ transplantation, the morbidity and mortality in the affected population (Figure 23 and Table 15).

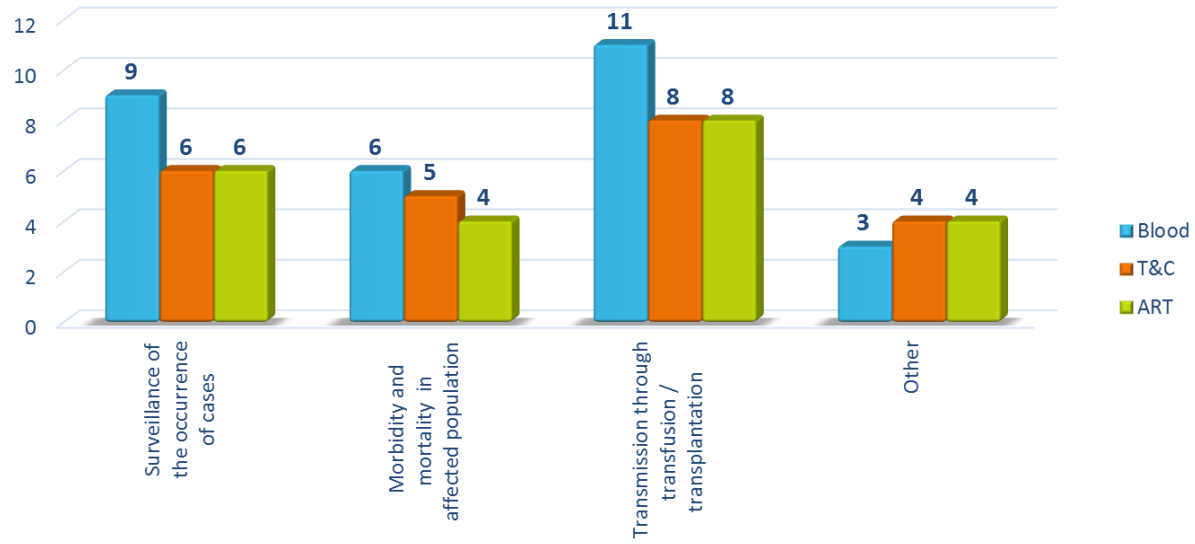

Figure 23 – Methods for analysis of the effectiveness of the measures taken

Finland	Case by case
France	We assess the consequences of the FAG proposals (e.g. number of loss of donations due to the testing positive infectious markers, when the FAG recommendations were a mandatory testing of blood donors and a deferral of the positive donors)
Germany	Reporting rates before/after implementation of measures
Greece	Case by case, follow up of donors and recipients
Portugal	Follow-up of donors, recipients and offspring
Romania	I do not have information
Spain	Disposal of tissues and cells.

Table 15 – Other methods for analysis of the effectiveness of the measures taken

B.6. Communication of appropriate preventive measures

MS use an electronic reporting template (email) or the electronic reporting through a website to circulate the information about preventive measures, in the majority of the cases (Figure 24). The other means used are identified in table 16).

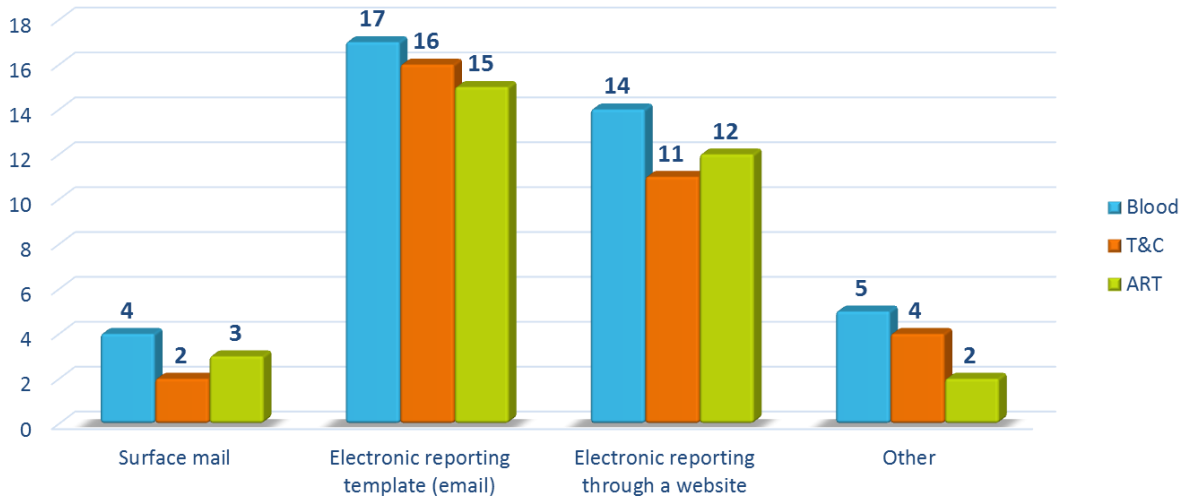

Figure 24 – Means used to circulate the information about preventive measures

Finland	E-mail, phone
Bulgaria	letter of formal notice, Health Minister's order
UK	meetings as appropriate e.g. JPAC
Czech Republic	RSS

Table 16 – Means used to circulate the information about preventive measures

The Competent Authority is responsible to communicate this information to the relevant stakeholders, in about 57% of the respondents for blood, 68% for T&C and 63% for ART (Figure 25) . The other responsible organizations are identified in Table 17.

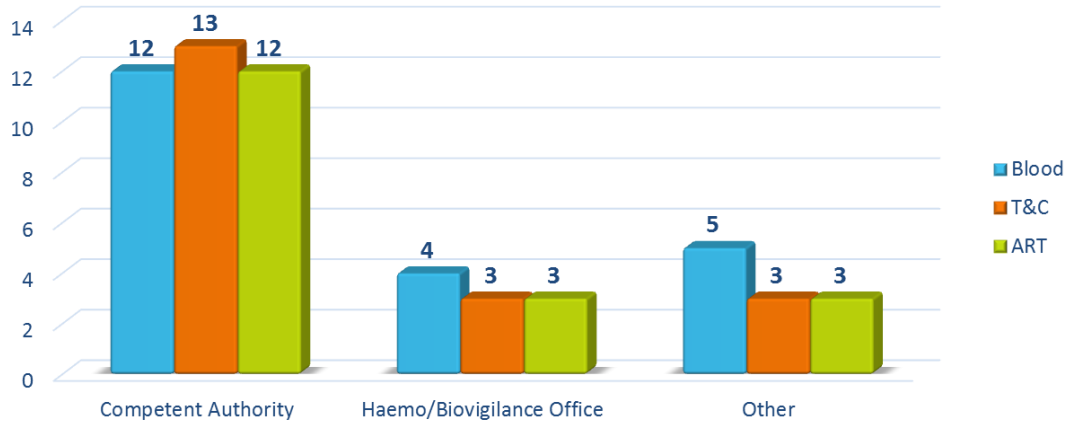

Figure 25 - responsible organizations to communicate this information

Bulgaria	National Centre of Transfusion Haematology
Estonia	Estonian Health Board
Greece	Hellenic Center for Disease Control and Prevention (KEELPNO)
Ireland	Competent Authority and Health Protection Surveillance Centre
UK	JPAC

Table 17 – Other responsible organizations to communicate this information

According to Figure 26, 71% of the respondents for blood, 68% for T&C and 63% for ART have in place a system to effectively inform the relevant stakeholders about the discontinued measures.

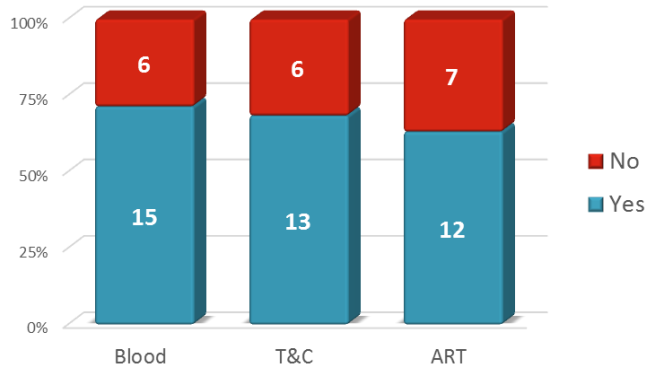

Figure 26 – Implemented systems to effectively inform the relevant stakeholders

33% of the respondent MS for blood and 36,8% for T&C and ART don't perform the evaluation of the impact of implemented measures on BTC supply. In 38% of the cases for blood, 42,1% for T&C and 36,8% for ART the Competent Authorities are the responsible organization for that evaluation. (Figure 27 and Table 18)

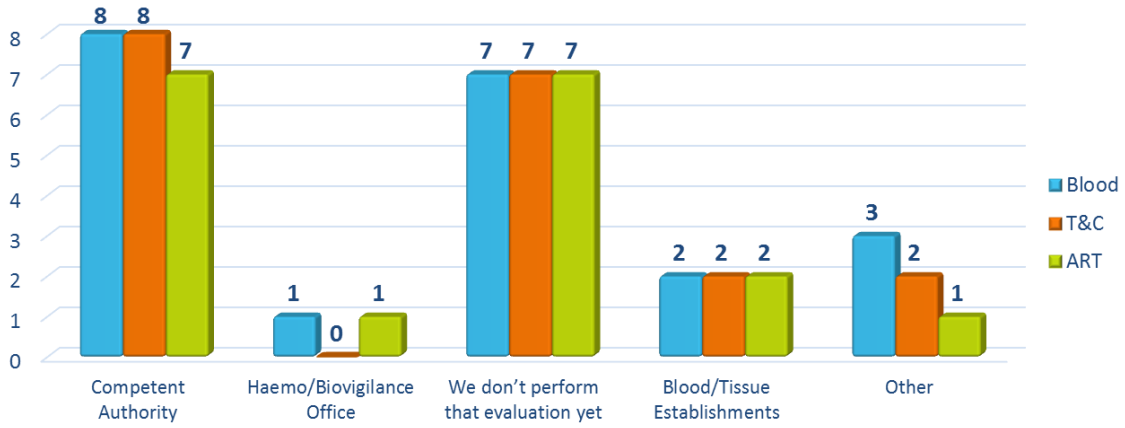

Figure 27 - Evaluation of the impact of implemented measures on BTC supply.

Bulgaria	National Center of Infectious and Parasitic Diseases
Bulgaria	National Centre of Transfusion Haematology
Romania	Centre for disease control- National Institute of Public Health
UK	UK blood services / JPAC

Table 18 – Other organizations responsible for the e valuation of the impact of implemented measures on BTC supply

B.7. Establishment of the extent to which epidemiological alerts reach stakeholders

In 57,1% for blood, 47,3% for T&C and 52,6% for ART a notification from stakeholders is requested once the preventive measures are implemented. (Figure 28)

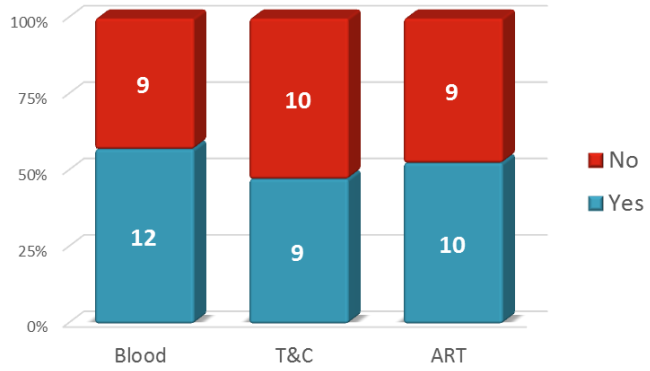

Figure 28 - notification requested from stakeholders

The extent to which the epidemiological alerts reach stakeholders is established in the majority of the cases by inspections/ audits (71,4 % for blood, 57,9 T&C and 56,2 % for ART. In 42,8 % for blood, 42,1% for T&C e 47,4 % for ART, mandatory feed-back information is required (figure 29).

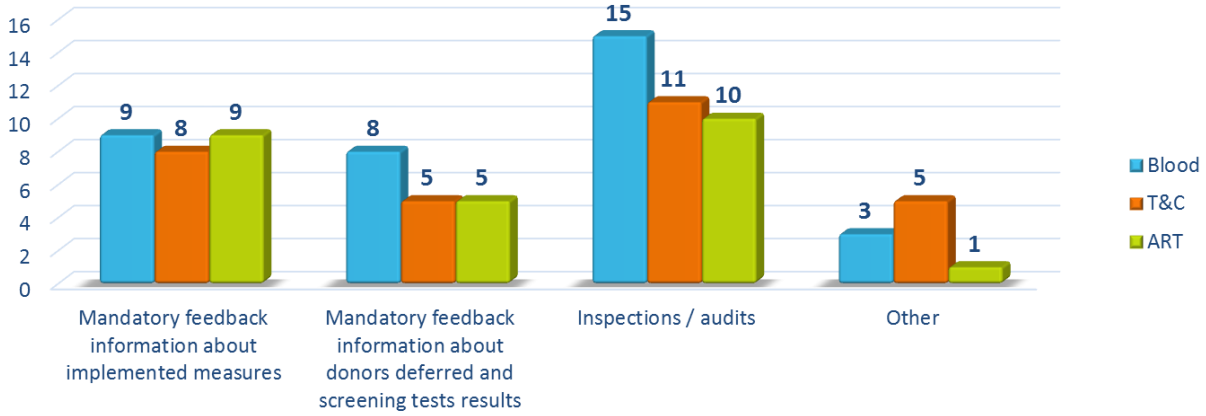

Figure 29 – Methods of establishments of the extend that epidemiological alerts reach stakeholders

B.8. Public health implications to other countries

There are 4 countries for blood, 2 for T&C, and 2 for ART that don't inform other EU countries through the RAB and RATC EU platforms (Figure 30)

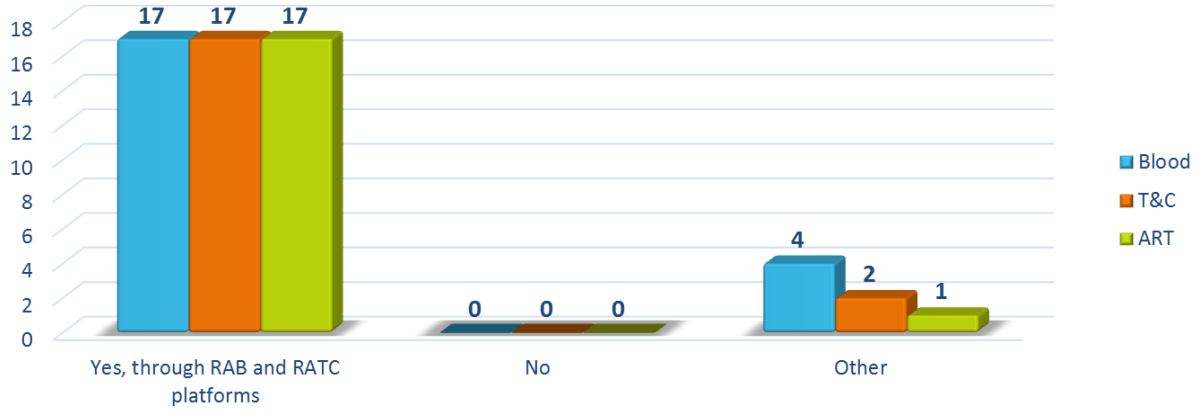

Figure 30 – Information of other EU countries when urgent / remedial or precautionary, actions is need

The organization responsible for sharing this information is in the majority of the cases the CA (Figure 31 and table 19)

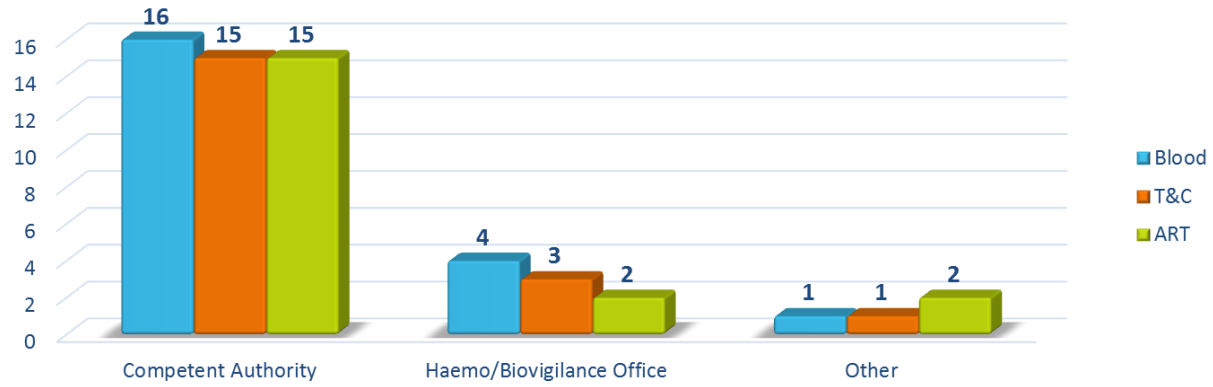

Figure 31 - Rresponsible organization for sharing the information within EU

Sweden	In some case also Public Health Agency via EWRS and IHR
United Kingdom	Public Health England, National Health Service Blood and Transfusion, Department of Health

Table 19 – Other organizations responsible for the e valuation of the impact of implemented measures on BTC supply

Almost all respondents (but one for blood; but 2 for T&C; but 3 for ART), think that RAB and RATC platforms have been effective as a means to rapidly communicate in cases of urgent need (Figure 32)

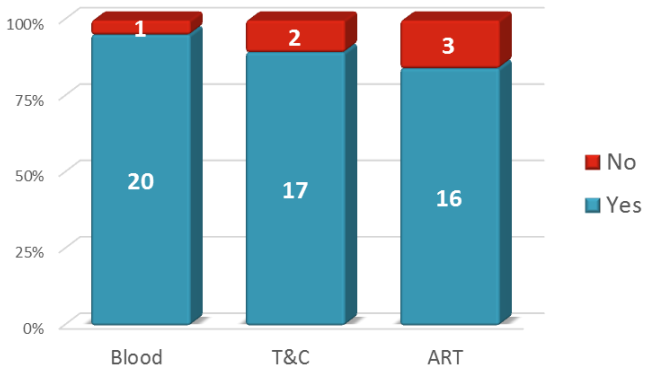

Figure 32 – Effectiveness of use of RAB and RATC platforms

Regarding the specification of the previous answer about RAB and RATC platforms, the argument pro are:

- Effective and quick information
- Rapid anticipation possible
- Rapid Feedback/Information from other countries
- Rapid implementation of preventive measures
- Once the alert is published, it is immediately received.
- All relevant CAs receive information instantly and can take actions accordingly.
- RATC platforms were currently effective to communicate alerts on emerging agents (ie. Zika virus) or on quality defects (ie. HIV-1 NAT quality defect).
- Reply given from experience of alerts placed by other CAs
- Communication network function well.

Argument cons are:

- Need a better interface. They are ok in use but should be even more intuitive. Easy to get lost for new users.
- There have been some cases that have been reported with delay.
- Effective to communicate risks, not suitable to discuss measures
- Recent outbreaks like West Niles Virus, Chikungunya have not been reported by RAB/RATC
- Dependent on the quality and timeliness of communication.
- A shorter time lapse from the events and the related notification would be desirable.

Regarding ***the need*** for legally binding requirements at the EU level to ensure that the relevant authorities / bodies effectively mitigate risks, responses are divide between those who agree and those who disagree (figure 33)

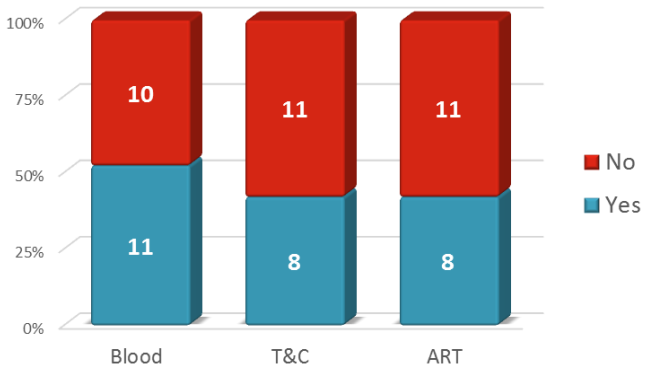

Figure 33 - Need for legally binding requirements at the EU level to ensure that the relevant authorities/bodies effectively mitigate risks

The arguments presented by those ***respondents who agree are:***

- Ensure that risks are mitigated
- All the countries should be reporting according to common rules to ensure effective exchange of information.
- It would be useful to have a structured framework to facilitate timely and appropriate information to mitigate risk
- It is not clear how well all authorities are effectively mitigating risks. There is different practice. If there is a legal binding framework, the practice will be more harmonized
- To be sure that preventive measures are really in place and patient safety is increased
- Such measures would increase mutual trust among the EU Member States, of course after a wide-open debate.
- Preparation of relevant guidelines and increasing surveillance and intervention activities
- Relevant guidelines and increasing surveillance and intervention activities are applied
- CA must work in cooperation with National and European Communicable disease surveillance agencies and use their healthcare assessment tools, their risk management approach and expertise in epidemiological area. However not all CA may have the possibility to meet all the requirements and when legislation will be changed this must be kept in mind.
- Public consultations and other consultation activities on the update of EU Directives highlighted however the need:
    - To provide a better definition of the term “epidemiological emergency”;
    - To define a common approach on emerging and re-emerging pathogens;
    - To standardise the time of the notification in the RAB and RATC platforms

- CA shall use existing Communicable disease surveillance structures at National and European level.
- This will be important in particular because the increasing movement of populations and the future possibilities of exchanges of therapeutic blood components (import/export) between EU member states and with other countries (third countries).

The arguments presented by those ***respondents who disagree are:***

- RATC/RAB Systems seem to be effective.
- Competence of ECDC.
- The structure of the national systems is different, so the responsibility and organisation of these systems are a Member State function.
- It should be common sense to mitigate risks and share information.
- It is the responsibility of the CA to advocate any measure aimed at avoiding or minimizing the transmission of infectious diseases, in particular by taking into account the existing provisions of Directives, national recommendations, recommendations of ECDC and WHO.
- Guidelines are preferable.
- The role of ECDC is very important and can be strengthened in particular by
    1) Published risk assessment reports on transfusion-transmissible pathogens.
    2) Published maps with country-specific viral/microbiological risks.
- Evaluation of risk minimisation could be sufficiently monitored at national level
- Different MS take different measures based on geographic location, previous history and statistic of diseases, specific features of country, different national legislations.
- It is a matter of competence of the MS. Those should be accountable to ensure the measures implemented effectively mitigate risks
- Each MS should adapt an effective mechanism to mitigate risks
- Satisfactory measures in place

Regarding the existence of any preparedness plans on specific emerging infections concerning the safety of BTC, the proportion between those who have and those who don't have is similar for blood, T&C and ART (Figure 34)

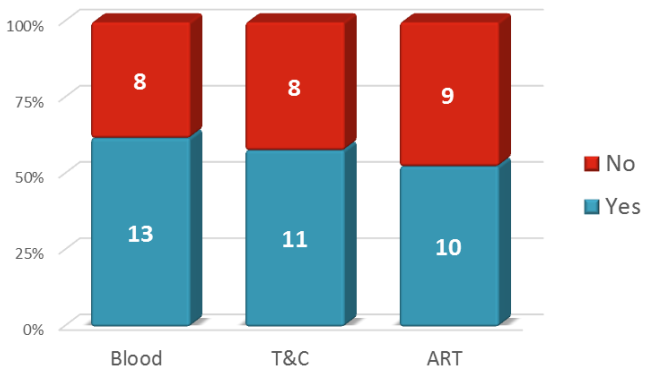

Figure 34 - Existence of preparedness plans on specific emerging infections

In figure 35 we can find that the preparedness plans in place by agent. The most prevalent preparedness plans are for West Nile Virus and Zika.

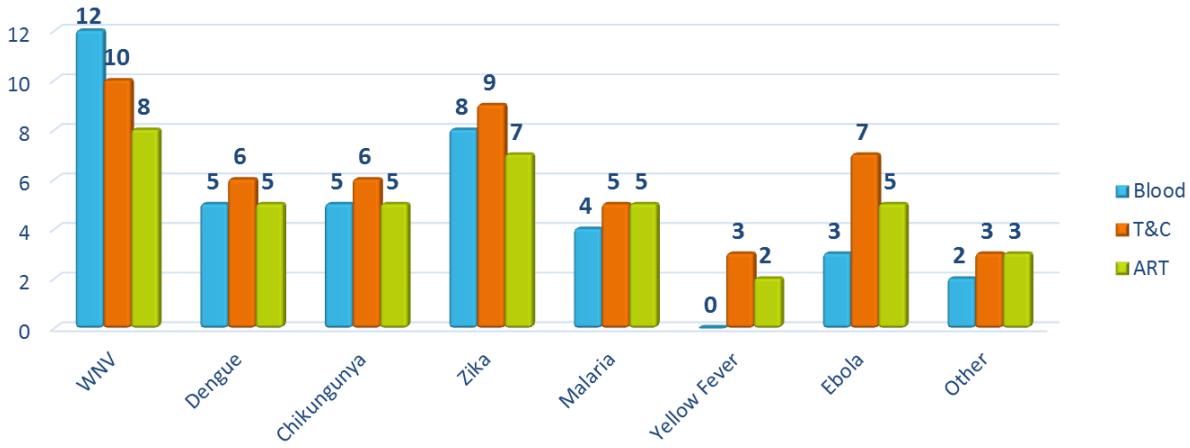

Figure 35 - Preparedness plans in place by agent

3. Bibliography

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Annex 1

Survey on Horizon scanning for identifying new risks

VISTART Joint Action Work package 4 Vigilance reporting for blood, tissues and cells

*Required

Identification

1. **Country** *

Information provided by:

2. **Name** *

3. **Institution** *

4. **Position** *

5. **Email address** *

6. **In which area of BTC are you involved** *
   Tick all that apply.
   - [ ] Blood and blood components
   - [ ] Non reproductive tissues and cells
   - [ ] Reproductive tissues and cells

Risk response procedures at national and international level

Horizon scanning system / epidemic intelligence activities

For the purposes of this survey, only risk response procedures to serious health threats related to epidemiological situations (e.g. disease outbreaks) will be evaluated.

7. **Does your country have in place a formal horizon scanning system/epidemic intelligence activities for the early warning of new risks, emerging infection news that may be of relevance to patient safety or BTC availability?** *
   Mark only one oval.
   - ◯ Yes
   - ◯ No

8. **Does your country have in in place a system to exchange information between a CA, TEs/BEs and organizations for human application of BTC, urgently, in case of serious health threats related to epidemiological situations (e.g. disease outbreaks)?** *
Mark only one oval.

- ◯ Yes
- ◯ No

9. **Please identify who is involved in your national horizon scanning system** *
Tick all that apply.

- ☐ National/Regional Competent Authority
- ☐ National/Regional Haemovigilance/ Biovigilance Office
- ☐ BEs/ TEs
- ☐ Other: _____

10. **Once a risk is identified do you inform other national vigilance/alert healthcare sectors?** *
Mark only one oval.

- ◯ Yes *Skip to question 11.*
- ◯ No *Skip to question 12.*

Risk response procedures at national and international level
Horizon scanning system / epidemic intelligence activities

11. **Once a risk is identified which national vigilance/alert healthcare sectors do you inform?** *
Tick all that apply.

- ☐ Blood and blood components
- ☐ T&C
- ☐ Organs
- ☐ Pharmacovigilance
- ☐ Medical devices
- ☐ Epidemiological Authorities
- ☐ Other: _____

Risk response procedures at national and international level
Sources of information used for scanning/ Threats detection

12. **Does your system monitor maps / websites lists of relevant vector distribution or affected areas and countries?** *
Mark only one oval.

- ◯ Yes
- ◯ No *Skip to question 15.*

Risk response procedures at national and international level
Sources of information used for scanning/ Threats detection

13. **Which sources of information does your system monitor?** *
Tick all that apply.

- [ ] Relevant maps/ websites lists of vector distribution
- [ ] Affected areas and countries
- [ ] Other: _____

14. **Who is responsible for that monitoring?** *
Tick all that apply.

- [ ] Competent Authority
- [ ] Haemovigilance / Biovigilance Office
- [ ] N/A
- [ ] Other: _____

Risk response procedures at national and international level
Sources of information used for scanning/ Threats detection

15. **For you as national authority, what are your usual sources of information?** *
Tick all that apply.

- [ ] EU RATC/RAB platforms
- [ ] ECDC
- [ ] US-CDC
- [ ] National Communicable diseases surveillance agency
- [ ] Other: _____

Risk response procedures at national and international level
Triggers incident

16. **What is your trigger incident?** *
Tick all that apply.

- [ ] First human case
- [ ] First transmission case
- [ ] Other: _____

17. **What is the geographical extent of your trigger incident?** *
Tick all that apply.

- [ ] The event occurs in your country
- [ ] The event occurs in one or more EU countries
- [ ] The event occurs outside the EU
- [ ] Other: _____

18. **What is your trigger incident regarding risk?** *
Tick all that apply.

- [ ] Known or potential risk to donors
- [ ] Known or potential risk to the quality and safety of BTC that may impact patients
- [ ] Public health risk to other countries
- [ ] Other: _____

Risk response procedures at national and international level
Risk assessment

19. **Once a risk is identified how do you gather evidence about etiologic agent information?** *
Tick all that apply.

- [ ] Bibliography
- [ ] Individual experts (contact lists in place)
- [ ] Comparison with previous outbreaks
- [ ] Other: _____

20. **In your country which is the responsible organization to perform risk assessment?** *
Tick all that apply.

- [ ] Competent Authority
- [ ] Haemo/Biovigilance Office
- [ ] Other: _____

21. **Do you use healthcare assessment healthcare tools to estimate the risk?** *
Mark only one oval.

- ◯ No
- ◯ Yes, the European Upfront Risk Assessment Tool (EUFRAT)
- ◯ Yes, the Biggerstaff-Petersen model
- ◯ Other: _____

Risk response procedures at national and international level
Implementation of preventive measures

22. **Who is responsible to define geographical areas where preventive measures need to be considered?** *
Tick all that apply.

- [ ] National Competent Authority
- [ ] Regional Competent Authority
- [ ] Haemo/Biovigilance Office
- [ ] Other: _____

23. **Does the responsible authority define a risk scale, ie from very low to high potential threat?** *

Mark only one oval.

- ◯ Yes
- ◯ No *Skip to question 26.*

Risk response procedures at national and international level

Implementation of preventive measures

24. **Please describe your risk scale**

_____

_____

_____

_____

_____

25. **Do you implement different type of measures according to a risk scale?** *

Mark only one oval.

- ◯ Yes
- ◯ No

Risk response procedures at national and international level

Implementation of preventive measures

26. **How do you define preventive measures to manage risk?** *

Tick all that apply.

- ☐ Bibliography
- ☐ Protocols
- ☐ Individual experts (contact lists in place)
- ☐ Comparison with previous outbreaks
- ☐ Input from EU expert bodies (e.g., ECDC)
- ☐ Input from expert bodies in other countries
- ☐ Other: _____

27. **What are the reference documents used in your country to define appropriate preventive measures?** *

Tick all that apply.

- ☐ ECDC guidelines
- ☐ FDA guidelines
- ☐ WHO guidelines
- ☐ EU preparedness plans
- ☐ Other: _____

28. **Who is responsible to initiate and discontinue the preventive measures?** *
Mark only one oval.

- ◯ Competent Authority
- ◯ Haemo/Biovigilance Office
- ◯ Other: _____

29. **Do you analyze the effectiveness of the measures taken?** *
Mark only one oval.

- ◯ Yes
- ◯ No *Skip to question 31.*

Risk response procedures at national and international level
Implementation of preventive measures

30. **How do you analyze the effectiveness of the measures taken?** *
Tick all that apply.

- ☐ Surveillance of the occurrence of cases
- ☐ Morbidity and mortality in affected population
- ☐ Transmission through transfusion/transplantation
- ☐ Other: _____

Risk response procedures at national and international level
Communication of appropriate preventive measures

31. **What are the means used to circulate the information about preventive measures?** *
Tick all that apply.

- ☐ Surface mail
- ☐ Electronic reporting template (email)
- ☐ Electronic reporting through a website
- ☐ Other: _____

32. **At national level who is responsible to communicate this information to the relevant stakeholders including ministry of health and other authorities about the implemented measures?** *
Mark only one oval.

- ◯ Competent Authority
- ◯ Haemo/Biovigilance Office
- ◯ Other: _____

33. **Is there a system in place to effectively inform the relevant stakeholders about the discontinued measures?** *
Mark only one oval.

- ◯ Yes
- ◯ No

34. **Who is responsible for the evaluation of the impact of implemented measures on BTC supply?** *

Mark only one oval.

- ◯ Competent Authority
- ◯ Haemo/Biovigilance Office
- ◯ We don't perform that evaluation yet
- ◯ Other: _____

Risk response procedures at national and international level

Establishment of the extent to which epidemiological alerts reach stakeholders

35. **Is there a notification requested from stakeholders once the preventive measures are implemented?** *

Mark only one oval.

- ◯ Yes
- ◯ No

36. **How do you establish the extent to which epidemiological alerts reach stakeholders?** *

Tick all that apply.

- ☐ Mandatory feedback information about implemented measures
- ☐ Mandatory feedback information about donors deferred and screening tests results
- ☐ Inspections / audits
- ☐ Other: _____

Risk response procedures at national and international level

Sharing information within the EU

37. **Does your country inform the other EU countries when urgent remedial or precautionary action is needed due to a serious public health threat to other countries?** *

Mark only one oval.

- ◯ Yes, through RAB and RATC platforms
- ◯ No
- ◯ Other: _____

38. **Which organization in your country is responsible for sharing this information?** *

Mark only one oval.

- ◯ Competent Authority
- ◯ Haemo/Biovigilance Office
- ◯ Other: _____

39. **On RAB and RATC platforms, have these systems been effective as a means to rapidly communicate in cases of urgent need?** *

Mark only one oval.

- ◯ Yes
- ◯ No

34. **Who is responsible for the evaluation of the impact of implemented measures on BTC supply?** *

Mark only one oval.

- ◯ Competent Authority
- ◯ Haemo/Biovigilance Office
- ◯ We don't perform that evaluation yet
- ◯ Other: _____

Risk response procedures at national and international level

Establishment of the extent to which epidemiological alerts reach stakeholders

35. **Is there a notification requested from stakeholders once the preventive measures are implemented?** *

Mark only one oval.

- ◯ Yes
- ◯ No

36. **How do you establish the extent to which epidemiological alerts reach stakeholders?** *

Tick all that apply.

- ☐ Mandatory feedback information about implemented measures
- ☐ Mandatory feedback information about donors deferred and screening tests results
- ☐ Inspections / audits
- ☐ Other: _____

Risk response procedures at national and international level

Sharing information within the EU

37. **Does your country inform the other EU countries when urgent remedial or precautionary action is needed due to a serious public health threat to other countries?** *

Mark only one oval.

- ◯ Yes, through RAB and RATC platforms
- ◯ No
- ◯ Other: _____

38. **Which organization in your country is responsible for sharing this information?** *

Mark only one oval.

- ◯ Competent Authority
- ◯ Haemo/Biovigilance Office
- ◯ Other: _____

39. **On RAB and RATC platforms, have these systems been effective as a means to rapidly communicate in cases of urgent need?** *

Mark only one oval.

- ◯ Yes
- ◯ No

40. Please specify the previous answer *

41. Is there a need for legally binding requirements at the EU level to ensure that the relevant authorities/bodies effectively mitigate risks? *
Mark only one oval.

- Yes
- No

42. Please specify the previous answer *

Risk response procedures at national and international level
Preparedness plans and activities

43. Does your country have in place any preparedness plan on specific emerging infections concerning the safety of BTC? *
Mark only one oval.

- Yes
- No *Skip to question 45.*

Risk response procedures at national and international level
Preparedness plans and activities

44. For which infections concerning the safety of BTC does your country have in place any preparedness plan?
Tick all that apply.

- [ ] WNV
- [ ] Dengue
- [ ] Chikungunya
- [ ] Zika
- [ ] Malaria
- [ ] Yellow fever
- [ ] Ebola
- [ ] Other:

45. Any additional information you want to provide?

	National Level				International Level			
	NCA	PH	VS	Others	ECDC	EWRS	EU Com	Others
Detection / Identification								
Indicator based surveillance System		x						
Event based monitorization (Monitoration of maps / websites lists of relevant vector distribution or affected areas and countries)	x	x	x	Ministry of Health, Centre for Infectious and Parasitic Diseases, Centre of Transfusion Haematology; Center for Disease Control and Prevention; BEs;Standing Advisory Committee on Transfusion Transmitted Infection;Professional Advisory Committee	x		x	WHO;EMA; ProMed
Assessment								
Risk Analysis (Bibliography, individual experts; comparation with previous outbreaks) Risk Evaluation	x		x	SPF, CDC; Multisectoral Committee of Experts	x		x	Others CA, National Centre of Transfusion Haematology, l Centre for Infectious and Parasitic Diseases,Ministry of Health, Blood Establishment, Tissue Establishments, Center for Disease Control and Prevention (KEELPNO), JPAC
Communication								
	x	x	x	National Centre of Transfusion Haematology Center for Disease Control and Prevention JPAC			x	EWRS
Management								
Prevention	x	x	x	Ministry of Health, Centre for Infectious and Parasitic Diseases, Blood Establishment, Tissue Establishments, SPF , Multisectoral Committee of Experts, Epidemiology, Veterinary Entomology, Reference Labs. Center for disease control JPAC	x		x	FDA, WHO, CDC
Evaluation	x			BE/TE , Center of Infectious and Parasitic Diseases, Centre of Transfusion Haematology,Centre for disease control , JPAC				
Effectiveness	x		x	National Center of Infectious and Parasitic Diseases; Centre of Transfusion Haematology; BE ,TEs, ABM , Ministry of Health , Board of Health and Welfare, Health and Social Care Inspectorate,				

Responsibilities by horizon scanning step at national and international level