Management Process Description

Preparedness for emerging infectious agents

January 2021

Prepared by: SAC on Transfusion Transmitted Infections

Policy

Horizon scanning is performed to ensure that the UK Blood Services identify new and reemerging infectious agents which may threaten the safety of donated products, and that appropriate actions are taken to mitigate any risk.

Purpose

To outline the processes in place to support UK Blood Services to ensure preparedness in the handling of emerging infections.

Responsibilities

Chair and Secretary of SACTTI to ensure monthly Emerging Infectious Agents Report received and teleconference held. JPAC and its SACs to ensure they take cognisance of any actions required following SACTTI review of the Emerging Infectious Agents Report.

Definitions

EBA EID - European Blood Alliance	PHE - Public Health England		
Emerging Infectious Diseases EIAR - Emerging Infectious Agents Report	SaBTO - Advisory Committee on the Safety of Blood, Tissues and Organs		
EpiIntel – PHE Epidemiological Intelligence	SAC - Standing Advisory Committee		
EU Rapid Alert System - European Union Rapid Alert System	SACCSD - Standing Advisory Committee on Care and Selection of		
JPAC - Joint UKBTS Professional Advisory Committee	Donors SACTTI - Standing Advisory Committee		
GDRI - Geographical Disease Risk Index	for Transfusion Transmitted Infections		

Applicable Documents

Appendix 1 - Infectious agent risk assessment tool

 Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)

JPAC\General Documents\JPAC Management Processes June 2020

Management Process Description

Preparedness for emerging infectious agents

January 2021

Introduction

Emerging infectious agents are a continuing challenge to the safety of blood, tissues and organs. The routes for gathering information and decision making are complex with many interdependencies, involving both UK and international sources. This MPD outlines the process in place to support the UK Blood Services to ensure preparedness in the handling of new and re-emerging infectious agents.

The Process

The process is divided into the following areas: sources of information, analysis of data, risk rating, recommendations, decisions, and implementation of policy.

The initiating information sources are broad and the initial information gathering process seeks to gather relevant information on infectious threats to blood, tissue and organ donations from appropriate and relevant national and international sources.

The NHSBT/PHE Epidemiology Unit compiles a monthly Emerging Infectious Agents Report (EIAR) using the information provided by a range of national and international evidence sources. Information on new potential risks may also come from other sources, including EU Rapid Alert System, EBA EID Monitor group and EpiIntel. Information may also come from other sources at any time; Any such information feeds into the same process, either being added to the monthly EIAR and analysed at the time of the next EIAR analysis or, if more urgent, analysed at the time of receipt.

The information in the EIAR is analysed in the first instance by the Chair and Secretary of SACTTI and an ODT representative. The information is assessed to determine any possible risk to the safety of donated products and any risks identified are graded to determine if action is required and the urgency of any action.

Documentation of the initial assessment is made on the EIAR, including any minor changes, and any specific action required is identified and recorded through the infectious agent risk assessment tool (Appendix 1) which is then retained as a record. The monthly EIAR and analysis outcomes are reviewed by SACTTI, either at its next meeting or, if more urgent action is required, through electronic correspondence or an ad hoc meeting if deemed necessary.

The completed EIAR analyses are retained as formal SACTTI papers as well as a formal log of analyses and outcomes, being maintained by the JPAC Manager. The Consolidated SACTTI Master List will be updated and colour-coded whenever there is a change

In addition to new and emerging risks, the horizon scanning process identifies changes in the epidemiology of known infectious agents e.g. where autochthonous infections in humans are reported in a new area/country. The Chair of SACCSD is notified of these changes and a rapid

Management Process Description

Preparedness for emerging infectious agents

January 2021

change control may be required if the risk is not covered by the GDRI (i.e. where the risk is not already mitigated by alternative deferrals). The change could also be the removal of a risk.

The confidential monthly reviewed horizon scanning reports may be circulated to approved individuals in organisations out with the UK Blood Services on request. Any risk identified that results in a change to the GDRI/procedure will proceed through the JPAC change control process and will be published on the JPAC website.

This review process will be summarised in an annual report to JPAC, which includes details of any actions required.

Risk assessment	Colour coding	Decision / Action		
Very low	White	No further action		
		No further action required at this time beyond the formal recording of the analysis and any subsequent recommendations for further or on-going review.		
Likely very low	Grey	Minor changes to GDRI		
and/or insufficient information at this time		If new infectious agent maintain awareness and gather additional information before taking any other action.		
Low	Green	No specific additional action at this time.		
		Maintain awareness.		
Potential risk	Amber	Potential risk present		
		Although a potential risk, the reports are currently either ad-hoc cases OR increasing spread of known risk. Close watching brief for changes in incidence and spread of infectious agent. On-going review of the situation which may be dealt with in the first instance by Chair of JPAC and Chairs of relevant SACs, but which may subsequently require action from SACTTI.		
Potential risk	Red	Risk present		
		Risk present and a full SACTTI risk assessment is required together with possible immediate action. SaBTO involvement may be required.		
		If immediate action is required, this to be discussed initially between Chair of JPAC and Chairs of relevant SACs.		

Table 1 Outcomes of the EIAR analysis

Appendix 1

Assessment of the probability of the exposure of the UK donor population to an infectious agent which may pose a threat to product safety

Infectious agent: Date assessment performed: Assessors:

Question	Outcome (Yes/No/NK ¹)		Quality of evidence (Excellent/Good/Poor) ²
Is this a recognised human infection?			
Is this a zoonosis or is there zoonotic potential?			
Is this donor population susceptible?			
Is this infectious agent endemic in the UK OR, for zoonoses/vector borne disease, is the animal host/vector present in the UK?			
Are there routes by which donors may be exposed?			
Will exposed donors donate?			
Is there a risk to sufficiency rather than a risk of transmission			
Are there existing effective donor selection or processing measures in place to identify such donors or remove/inactivate the infectious agent?			

¹ NK = not known

² If current quality of evidence is poor, additional evidence must be sought before completing the assessment

