Position Statement

March 2026

The contents of this document are believed to be current. Please continue to refer to the website for in-date versions.

Surveillance: Preparedness for emerging infectious agents

Summary

Policy

Surveillance is performed to ensure that the UK Blood Services identify new and re-emerging infectious agents which may threaten the safety of materials derived from donated blood, tissues and cells, 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

Monthly EIRS are received and reviewed by the SACTTI EIR Review Group. SACTTI is responsible for preparation of Risk Assessments and/or Position Statements for emerging infectious agents as required and for conveying any recommendations and/or actions that arise from the EIR to JPAC and/or relevant SACs. JPAC and/or relevant SACs to ensure they take cognisance of any actions required following SACTTI review of the EIR.

Definitions

EBA EID	European Blood Alliance Emerging infectious Disease	**SaBTO**	Advisory Committee on the Safety of Blood. Tissues and Organs
EIR	Emerging Infection Report	**SAC**	Standing Advisory Committee
EpiIntel	UKHSA Epidemiological Intelligence	**SACCSD**	SAC on Care and Selection of Donors
JPAC	Joint UKBTS Professional Advisory Committee	**SACTTI**	SAC on Transfusion Transmitted Infection
GDRI	Geographical Disease Risk Index	**UKBTS**	UK Blood Transfusion Services
OTDT	Organ and Tissue Donation and Transplantation	**UKHSA**	UK Health Security Agency

Applicable documents

Appendix 1 – Infectious agent risk assessment tool (page 4)

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 document 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/UKHSA Epidemiology Unit compiles a monthly EIR 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 or routes at any time. Any such information must be passed to the Epidemiology Unit immediately, to be fed into the process, either being added to the monthly EIR and analysed at the time of the next EIR analysis or, if more urgent, analysed at the time of receipt, through email circulation to the SACTTI EIR Review Group.

The information in the EIR is analysed in the first instance by the SACTTI EIR Review Group, which includes the SACTTI Chair, OTDT representation and additional SACTTI members. The information is assessed to determine any possible risk to the safety of donated products. Any risks identified are graded to determine if action is required and the urgency of any action (Table 1). Documentation of the initial assessment is made on the EIR, including any minor changes, and any specific action required is identified and recorded (with a target date). The infectious agent risk assessment tool (Appendix 1) can be used to assess a new emerging risk, which is then retained as a record. The monthly EIR and analysis outcomes are a standing agenda item for SACTTI; highlights are verbally shared for awareness. If the review indicated need for discussion by SACTTI, this is done at the next committee meeting. If more urgent action is required, this can be done through electronic correspondence or an ad hoc meeting if deemed necessary.

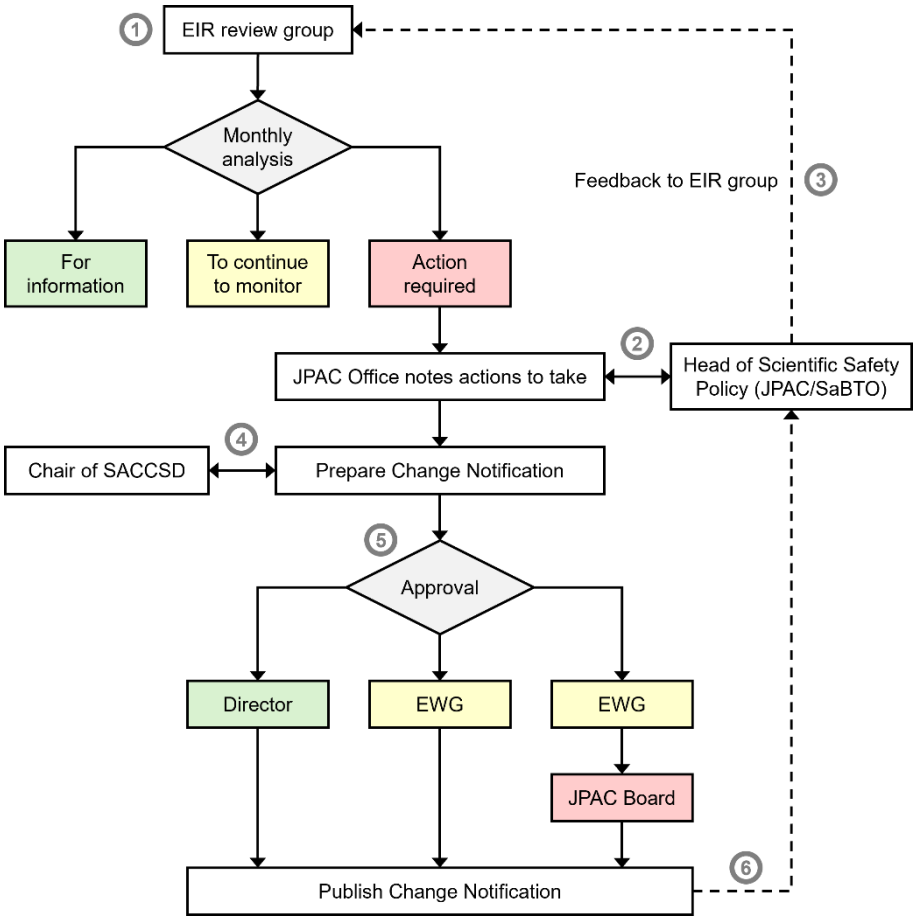
The completed EIR analyses are retained as formal SACTTI papers as well as a formal log of analyses, outcomes and actions being maintained by the JPAC Office. These reports may be circulated to appropriate in organisations outwith the UK Blood Services on request; such requests must be made to the JPAC Office and discussed with the Chair of SACTTI.

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

Where EIR analysis recommends an update is required to the GDRI, this will be coordinated by the JPAC Office according to the process shown in Figure 1.

An annual report is produced for JPAC, which includes highlights of specific topics of interest that have required action or should continue to be monitored given the potential significance for the safety of substances of human origin (SoHO).

Figure 1. Process for completing actions arising from EIR analysis (see numbered notes below)



1. The EIR review group prepares a monthly analysis, which includes its recommendations for updates to the GDRI and clearly indicates where specific action is required by the JPAC Office.

2. The analysis is sent to the JPAC Office, which notes its actions and liaises with the Head of Scientific Safety Policy, who attends the monthly EIR meetings, where further information is required.

3. The Head of Scientific Safety Policy provides a link between the JPAC Office and the EIR review group and will inform the group that JPAC Office actions have been noted and are in progress.

4. The JPAC Office coordinates with the Chair of SACCSD (and other relevant members of JPAC) to prepare any Change Notifications required to address the noted actions.

5. The appropriate approval route is identified by the JPAC Office, following the established governance procedure. Approval may be obtained from the Professional Director of JPAC, the Executive Working Group (EWG) or the JPAC Board, as appropriate.

6. Upon publication of the approved Change Notification(s), the JPAC Office informs the EIR review group, via the Head of Scientific Safety Policy, that the noted actions are complete.

Table 1. Outcome of the EIR analysis

Risk assessment	Colour coding		Decision / action	Timescale
Very low	White		No further action. No further action required at this time beyond the formal recording of the analysis.	None
Likely very low and/or insufficient information at this time	Grey		Minor changes to GDRI. OR If new infectious agent, maintain awareness and gather additional information before taking any action.	2 months to update GDRI
Low	Green		No specific additional action at this time. Maintain awareness.	None
Potential risk	Amber		Potential risk present. Although a potential risk, the reports are currently either ad hoc cases or increasing spread of known risk. Keep a close watching brief for changes in incidence and spread of infectious agent. Ongoing review of the situation which may be dealt with in the first instance by the Professional Director of JPAC and Chairs of relevant SACs, but which may subsequently require action from SACTTI.	4 months, to allow one full meeting cycle (subject to no escalation to red status)
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 the Professional Director and Chairs of relevant SACs.	2 weeks to review risk assessment 1 week to meet and agree action plan
N/A	Blue		For Organ Donation information.	Communicate within one week

Dr Ines Ushiro-Lumb
Chair of Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI)

Dr Stephen Thomas
Professional Director of JPAC

Appendix 1 – Infectious agent risk assessment tool

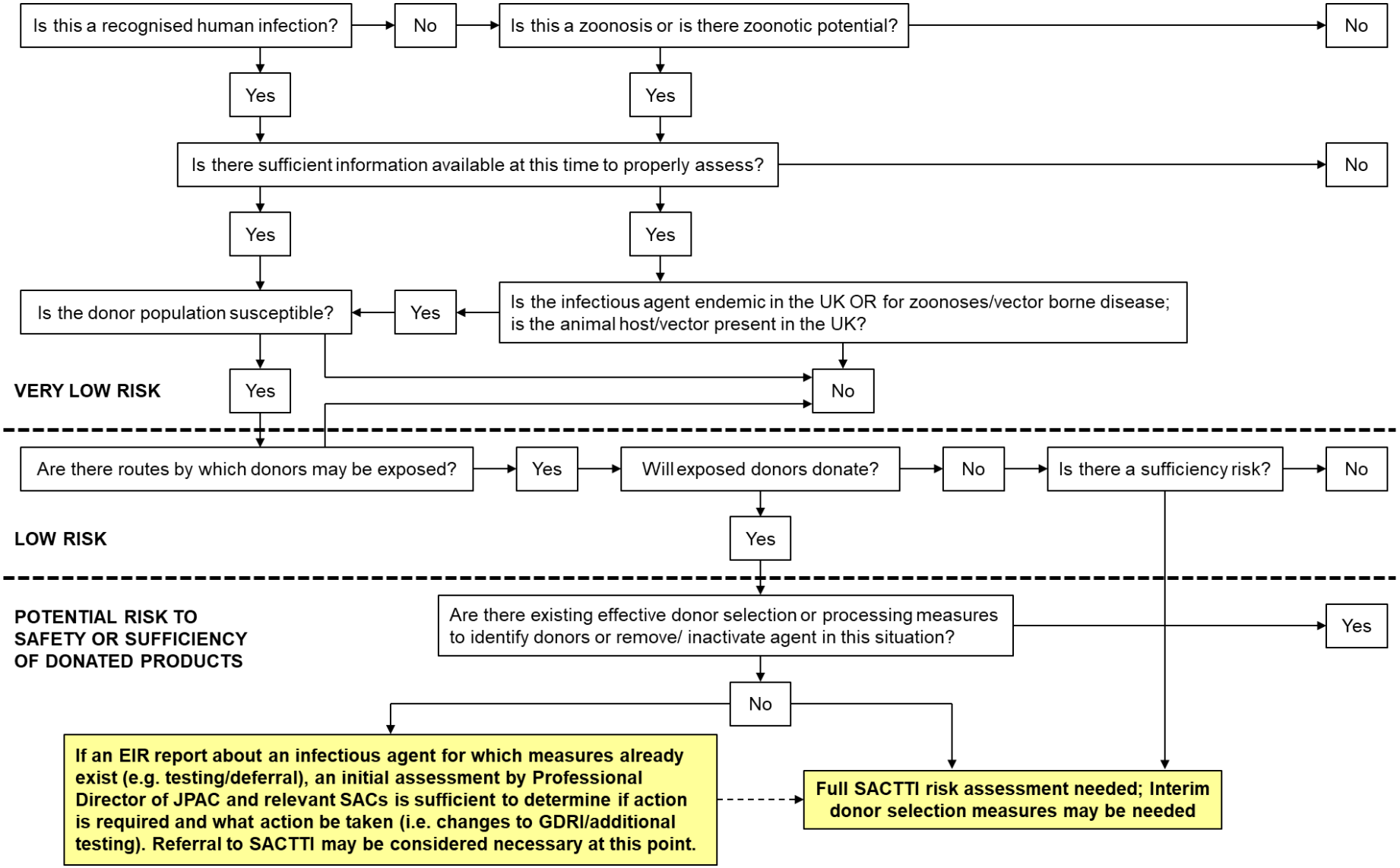
Assessment of the probability of the exposure of the UK donor population to an infectious agent which may pose a threat to product safety

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 the 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


Is this a recognised human infection?
No
Is this a zoonosis or is there zoonotic potential?
No
Yes
Yes
Is there sufficient information available at this time to properly assess?
No
Yes
Yes
Is the donor population susceptible?
Yes
Is the infectious agent endemic in the UK OR for zoonoses/vector borne disease; is the animal host/vector present in the UK?
VERY LOW RISK
Yes
No
Are there routes by which donors may be exposed?
Yes
Will exposed donors donate?
No
Is there a sufficiency risk?
No
LOW RISK
Yes
POTENTIAL RISK TO SAFETY OR SUFFICIENCY OF DONATED PRODUCTS
Are there existing effective donor selection or processing measures to identify donors or remove/ inactivate agent in this situation?
Yes
No
If an EIR report about an infectious agent for which measures already exist (e.g. testing/deferral), an initial assessment by Professional Director of JPAC and relevant SACs is sufficient to determine if action is required and what action be taken (i.e. changes to GDRI/additional testing). Referral to SACTTI may be considered necessary at this point.
Full SACTTI risk assessment needed; Interim donor selection measures may be needed