UK Blood and Tissue Services' Pandemic Preparation

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1. Glossary

ABO	Alliance of Blood Operators
BC	Business Continuity
BSBMTCT	British Society of Blood and Marrow Transplantation and Cellular Therapy
BSH	British Society of Haematology
BRTU-GEMS	Blood and Transplant Research Unit on Genomics to Enhance Microbial Screening
CD-P-TO	European Committee on Organ Transplantation
CD-P-TS	European Committee on Blood Transfusion
COVID-19	Coronavirus disease caused by the SARS-CoV-2 virus
CVP	Convalescent plasma
DATER	Detection / Assessment / Treatment / Escalation / Recovery categorisation
DHSC	Department of Health and Social Care
DIPC	Director of Infection Prevention and Control
EBA	European Blood Alliance
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate on the Quality of Medicines
FFP	Fresh frozen plasma
HTA	Human Tissue Authority
MHRA	Medicines and Healthcare products Regulatory Agency
NHSBT	NHS Blood and Transplant
OTDT	NHSBT Organ and Tissue Donation and Transplantation
PFM	Plasma for fractionation
PPE	Personal protective equipment
PR(T)	Pathogen reduction (technology)
RACI	Responsible / Accountable / Consulted / Informed (responsibility assignment matrix)
RCC	Red cell concentrate
SaBTO	Advisory Committee on the Safety and Blood, Tissues and Organs
SACCSD	Standing Advisory Committee on Care and Selection of Donors
SACCTP	Standing Advisory Committee on Cellular Therapy Products
SACBC	Standing Advisory Committee on Blood Components
SACIH	Standing Advisory Committee on Immunohaematology
SACIT	Standing Advisory Committee on Information Technology
SACT	Standing Advisory Committee on Tissues
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection
SHOT	Serious Hazards of Transfusion
SoHO	Substances of human origin
UKBTS	UK Blood Transfusion and Tissue Transplantation Services
UKHSA	UK Health Security Agency
WHO	World Health Organization
WMDA	World Marrow Donor Association

2. Background

JPAC received the following commission from UK Forum:

"In the event of the virus being widely transmitted via Substances of Human Origin (SoHO) there would have been widespread pressure on both the donation and supply of blood, stem cells and organs to hospitals with immediate effect. Whilst this would immediately trigger our blood shortage plans, we do not feel that we have sufficiently considered what we would do in this circumstance. JPAC should be asked to consider/write a pandemic plan for this scenario with regard to blood, tissues and stem cells in the first instance."

3. Aim

The purpose of this paper is to set out how UK Blood Transfusion and Tissue Transplantation Services (UKBTS) should respond in the event that an emergent pathogen has the capacity to cause a pandemic and is considered likely to be transmittable via blood, tissues, and haematopoietic stem cells.

Part or all of this document may be adapted to provide a response checklist and/or a RACI framework for the various key actions to be carried out (see **14. Appendices**).

Assumptions

- All UKBTS have business continuity plans in place for a flu pandemic
- Social distancing, mask-wearing, personal protective equipment (PPE) requirements, venue assessments and donor communications are out of scope, as they will be covered by UKBTS pandemic plans
- This paper does not cover organs which are outside JPAC's remit – NHSBT Organ and Tissue Donation and Transplantation (OTDT) has its own separate plans

4. **Urgent actions** (JPAC Office)

JPAC has surveillance systems and networks in place, so should respond rapidly and not await a trigger from central response teams within external organisations (e.g. UKBTS, DHSC, UKHSA; see **14. Appendices**).

The precautionary principle should be followed, and initial actions by the JPAC Office should include:

a. Informing the UK Forum (Chief Executives and Medical Directors of UKBTS), who may wish to consider convening an emergency JPAC Board meeting and/or commissioning the JPAC Board to act as an emergency team

b. Informing the JPAC Board, including any actions arising from point **a**

c. Placing a holding message on the JPAC website to communicate awareness of the situation and to assure that action is being taken

d. Expediting the publication of Risk Assessment(s)

e. Publishing Position Statement(s), updating them as frequently as required, including when a vaccine becomes available

f. Ensure that the Blood and Transplant Research Unit on Genomics to Enhance Microbial Screening (BTRU-GEMS) is aware and engaged

g. Ensure the JPAC website is updated, and Change Notifications are issued as appropriate (immediately and ongoing)

h. Confirming the JPAC Business Continuity plan is in place and remains valid

i. Considering any current safety measures that could be paused or relaxed to release capacity to respond

j. Reviewing and developing any existing provisional or contingency specifications for rapid approval

k. Ensuring any negative SoHO (e.g. stored plasma components) are ‘quarantined’ immediately, to potentially serve as negative control material

5. **Communications** (JPAC Office)

The JPAC Office should ensure that effective communication channels are in place between JPAC and/or each UKBTS, the following groups and any others that may be relevant:

a. Emerging Infectious Diseases Monitor group of the European Blood Alliance (EID-Monitor, EBA), which also provides a link to the European Centre for Disease Prevention and Control (ECDC, an EU agency)

b. UK Health Security Agency (UKHSA) and other UK Public Health Agencies

c. Infection Prevention and Control channels:

i. Director of Infection Prevention and Control (DIPC) and committees in each service
ii. Infection Prevention Society

d. Regulators:

i. Medicines and Healthcare Products Regulatory Agency (MHRA)
ii. Human Tissue Authority (HTA)

e. International colleagues:

i. Alliance of Blood Operators (ABO)
ii. European Blood Alliance (EBA)
iii. European Directorate on the Quality of Medicines (EDQM, and the CD-P-TS & CD-P-TO committees)
iv. Anthony Nolan Trust
v. DKMS
vi. World Marrow Donor Association (WMDA)
vii. World Health Organization (WHO)

f. Department of Health and Social Care (DHSC), Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)

g. National Blood Transfusion Committees in the four nations

h. Serious Hazards of Transfusion (SHOT) and other vigilance groups

i. Guideline writing groups and societies:

i. British Society for Haematology (BSH)
ii. British Society of Blood and Marrow Transplantation and Cellular Therapy (BSBMTCT)
iii. Royal Colleges, as appropriate

6. **Transmission** (SACTTI)

a. Assess likelihood of blood-borne transmission, taking advice from other sources as appropriate. Consider whether tissues can transmit (see **10a**). SACTTI to lead, with early publication of a Position Statement.

b. Take the precautionary principle into account when deciding measures

c. Consider if there is additional impact on any specific group of recipients (e.g. as with Zika Virus and pregnant women). This may require specific guidance.

d. If the risk of transmission via components and products is thought to require mitigation, UKBTS should consider implementing blood/tissue shortage plans proactively (see **8c**). This should be coordinated between services via an emergency team (UK Forum, JPAC Board, or other).

e. Consider if any other mitigation measures should be required, e.g. donation testing (see **12**) or pathogen reduction of blood components (see **8e**). Remain in close communication with other SACs, SaBTO, UKHSA diagnostic cell and BTRU GEMS.

f. Vigilance and reporting of any new adverse event/reaction to relevant bodies (e.g. MHRA, HTA, SHOT) and feedback loops to share insights

7. **Deferrals** (SACCSD)

a. Donor Selection Guidelines will need to be reviewed for each SoHO. SACCSD to lead for blood, in collaboration with SACTTI. See **10** for tissues and **11** for haematopoietic stem cells.

b. For travel:

i. Assess whether the main source of infection is acquisition within or outwith the UK and implement appropriate travel deferrals. It is likely that the risk will change as the outbreak evolves.

ii. If ongoing person-to-person transmission is taking place in the UK, consider if travel deferrals are still required and implement appropriate deferrals for management of those with symptoms, exposure or vaccination

iii. Is there a trigger point where testing might replace deferral? Are there suitable tests for donor screening?

c. Consider the length of deferral in each circumstance and the need for any testing

d. Consider when deferrals can be removed, and what evidence will be needed

e. Assess whether any other deferrals required

f. Assess any post-donation information required for donors, look back procedures and discard principles

8. **Blood** (UKBTS)

a. Local guidelines will need to be reviewed and updated in accordance with the risk assessments and JPAC Change Notifications to the Donor Selection Guidelines

b. Demand for blood components:

i. Assess the impact on the healthcare system using data from central sources (e.g. numbers of cases, severity) and consider whether this will increase or reduce the demand for blood components

ii. Hospital practices may change leading to a change in demand patterns (e.g. for O RhD negative red cells and A RhD negative platelets). Ensure data and communications channels with hospitals are adequate.

iii. Consider separately for red cells, FFP, cryoprecipitate, platelets and granulocytes

iv. Clinical indications and recipient categories

v. Affected patients may need blood components. Note, demand was low during the COVID-19 pandemic but could be high in a future pandemic depending on the resulting disease.

vi. Clinical risks from pathogen to specific patient groups (e.g. immunocompetent versus immunosuppressed, fetal risk as with Zika Virus)

c. Consider whether blood shortage plans need to be implemented (e.g. amber or red alert, or equivalent). UKBTS should be mindful that the demand for O RhD negative blood is unlikely to materially reduce in absolute numbers.

d. Alignment across UKBTS:

i. Decide how UKBTS will discuss and align – establish the coordinating group

ii. Communication routes and messages should be coordinated, established and clear, both with hospitals and the public

iii. Ensure governance frameworks are in place, and are clear and aligned for each service

iv. UKBTS should have plans to cope with a surge in demand

e. Treatment options may exist for blood, to reduce the risk of transmission from asymptomatic donors. For example, implementation of Pathogen Reduction Technology (PRT) should be considered. (JPAC and SaBTO to lead).

i. Consider potential effectiveness versus the relevant or likely pathogen(s)

ii. Would patients be protected by PR-plasma and/or PR-platelets but exposed anyway through red cells? Note that NHSBT ‘where does blood go’ audit data indicated that 65% of patients receiving platelets also received red cells or FFP.

iii. What donor deferral criteria could be lifted and for which components? (e.g. exposure rather than illness)

iv. Consider whether to prepare/validate in advance – explore assumptions on capacity to implement before or during a pandemic

f. Component manufacturing may be affected if, for example, staffing or consumable supply chains are impacted by the pandemic. Consider the following:

i. Can alternative (low tech and/or highly automated) options be used?

ii. Should these be validated in advance?

g. Contingency components in the Red Book:

i. Ensure relevant component specifications are in place and valid

ii. UKBTS validations should be considered in advance

h. Provision of guidance for any new components or products

i. Consideration that there may be recovered/immune donors and recipients

9. **Plasma** (Emergency Team)

Consider whether the collection and supply of plasma for fractionation (PFM) could or should be paused and/or collection started for convalescent plasma (CVP) or a hyperimmune product. Each service may have a different view, to be discussed by the emergency team, as above.

This should include consideration of:

a. Whole blood versus plasma demands:

i. Consider continuing or pausing plasma operations

ii. Is the decision-making process for this in place?

b. Potential for redeployment of staff and infrastructure for whole blood collection, plans to be prepared in advance

c. Convalescent plasma may be required:

i. What would be needed to make the decision to pivot PFM collection to collect CVP? Consider whether to be proactive or await a request from UKHSA.

ii. Would pathogen reduction be needed for CVP and how would this be determined? (See below)

iii. The specification for CVP will be added to the Red Book annex on contingency components

10. **Tissues** (SACT)

SACT should consider whether UKBTS need to alter the collection and supply of tissues. This should include:

a. Assessing the risk of transmission by different tissue products (e.g. vascular versus avascular), with input from SACTTI

b. The effect of routine processing and decontamination processes on the pathogen and consideration of additional measures

c. Donor Selection Guidelines for living and deceased donors, which will need frequent review and updating

d. Any changes in demand for tissues – most tissue grafts are used in elective surgeries, so there may be reduced demand due to postponing of operations; note, that this may result in increased post-pandemic demand and result in shortages and waiting lists. Consider the availability of potential alternatives. The need for serum eye drops is likely to remain unchanged.

e. Whether collection of some tissues should be paused to allow redeployment of resources (in the wider NHS as well as in UKBTS), considering the inertia of restarting

f. Consider potential risks to staff retrieving and processing tissues from deceased donors; the nature of the processes lead to risk of needlestick and cut injuries, and the generation of aerosols through the use of powered saws and dermatomes

11. **Haemopoietic stem cells** (SACCTP)

SACCTP should consider whether UKBTS need to alter the collection/supply of haematopoietic stem cells. This should include:

a. The risk of transmission of a blood-borne pathogen versus the risk that could arise from delaying the transplant

b. Different types of transplant:

i. Allogeneic transplants potentially could be collected and cryopreserved in advance of the start of the recipient's transplant conditioning

ii. Autologous collections would likely need clinical risk assessment e.g. if the donor tested positive close to or at the time of planned collection

c. Consideration of any changes to donor characterisation

d. Continue to review evidence and update the risk assessment

e. Establish in advance the criteria for amending testing requirements

f. Liaise with national and international stakeholders (e.g. WMDA)

12. **Testing** (UKBTS)

The UKBTS should assess the potential provision of testing of donor samples for a new pathogen will be an urgent priority.

The following should be considered:

a. The specific impacts on screening and reference laboratories should be carefully considered given that mandatory resting will need to continue

b. Decision points for discontinuation of discretionary testing should be explored in advance

c. If confirmatory testing is required, how this will be provided (internal or external) and how positive or indeterminate results will be managed

d. Validation of new tests will be required, and validation protocols should be ready to use as soon as the test is available. The BTRU-GEMS PRECEPT project aims to have a ready-to-go system for development and approval of tests for emerging pathogens within weeks.

e. Some assay development may be needed, and consideration should be given to sample collection and handling requirements (e.g. consumables, PPE, staff safety, capacity, safety cabinets)

f. See **14. Mutual aid** regarding testing of non-donor samples

13. **Supply chains** (UKBTS)

Each UKBTS will have Business Continuity (BC) plans in place to assure a resilient supply of consumables. However, these plans should be reviewed in the context of a pandemic scenario as follows:

a. Consider all services (e.g. blood, tissues, stem cells, pathology services)

b. Consumables, machines, and engineers who may have travel restrictions and/or be in high demand

c. Some BC plans will reference alternative treatments should the preferred treatment be unavailable, but a third option might be required if the second is not available (e.g. a restricted supply of anti-D when no fetal RhD screening kits are available)

14. Mutual aid (Emergency Team)

The Emergency Team should consider support for other blood and tissue services, including the following:

a. Protocols should be in place to enable cross-border supply of SoHO within GB, UK, Europe and the rest of the world. There is ongoing discussion within various agencies and alliances around the need to assure interoperability (e.g. to EDQM and/or WHO standards) but no solid action to date.

b. Standardised specifications for donor selection, donation, manufacturing, testing, and labelling, as well as IT requirements for data transfer, should be established

The Emergency Team should consider support for the wider NHS response should be considered, including the following:

a. Testing provision for non-donors (e.g. staff, the public):

i. It should be noted that the only analyte that UKBTS are able to test is blood/plasma/serum – consideration should be given in advance as to whether any other analytes could be considered (e.g. respiratory samples, which may need containment facilities)

ii. There may be suitable facilities available within UKBTS (e.g. a Category 3 containment lab at Filton) but a plan should be in place to commission and staff these facilities should they be needed

iii. The need for sufficient IT support to enable transmission of sample requests and receipt of results

b. Supply of resources such as analysers, consumables, and people to other agencies and the impact on UKBTS capacity

c. Quarantine of all definitively negative units of FFP for use in laboratory standards

d. Liaison with MHRA Science Campus (formerly NIBSC) regarding supply of materials such as pre-exposure frozen plasma components and post-exposure therapeutic apheresis output, for use as laboratory standards and in quality assurance exercises

e. Setting up a biobank

f. Liaison with UKHSA on the supply of samples for any serosurveillance programmes

15. Stand down

Once the pandemic response has been stood down, a review should be undertaken to examine how effectively the plans worked and to identify areas for further improvement.

16. Appendices

Stakeholders

- UKHSA, SaBTO, DHSC (see list of Scientific Advisory Committees, May 2025)
- Health bodies in devolved administrations (Scottish Government, Welsh Government, Northern Ireland Executive)
- Other blood services (e.g. via UK Forum, EBA, ABO)
- Other agencies (e.g. WHO, Council of Europe/EDQM, EU/ECDC)
- SACTTI, SACCSD, SACT and SACCTP to ensure collaboration
    - SACBC, SACIH and SACIT are likely to be self-contained
    - National Blood Transfusion Committees

External triggers and escalations

- DHSC – established the Detection / Assessment / Treatment / Escalation / Recovery (DATER) categorisation, but did not use it during COVID-19
- WHO – Phases: Inter-pandemic (1, 2), Pandemic Alert (3, 4, 5), Pandemic (6)

JPAC response checklist

4. Urgent actions (JPAC Office)

Item / Task	Comments	Date	Sign
Inform the UK Forum (Chief Executives & Medical Directors of UKBTS)			
Inform the JPAC Board, including actions from the UK Forum			
Place a holding message on the JPAC website			
Expedite publication of Risk Assessment(s)			
Publish Position Statement(s) and update as required			
Ensure BTRU-GEMS is aware and engaged			
Update JPAC website & issue Change Notifications (immediate & ongoing)			
Confirm JPAC Business Continuity Plan remains valid			
Consider pausing/relaxing safety measures to release capacity			
Review/develop provisional or contingency specifications for rapid approval			
Quarantine negative SoHO (e.g., stored plasma components)			

5. Communications (JPAC Office)

Item / Task	Comments	Date	Sign
EID Monitor group of EBA (link to ECDC)			
UKHSA & other UK Public Health Agencies			
Infection Prevention & Control: DIPC & committees			
Infection Prevention Society			
MHRA			
HTA			
Alliance of Blood Operators (ABO)			
European Blood Alliance (EBA)			
EDQM (CD-P-TS & CD-P-TO committees)			
Anthony Nolan Trust			
DKMS			
World Marrow Donor Association (WMDA)			
World Health Organization (WHO)			
DHSC / SaBTO			
National Blood Transfusion Committees			
SHOT & other vigilance groups			
British Society for Haematology (BSH)			
BSBMTCT			
Relevant Royal Colleges			

RACI matrix

	JPAC Office	JPAC Board	Emergency Team	UKBTS	SACTTI	SACCSD	SACT	SACCTP	UK Forum
Immediate actions	R	A	C	I	C	C	I	I	C
Comms	R	A	C	I	I	I	I	I	C
Transmission	C	A	I	C	R/A	I	I	I	I
Deferrals	C	A	I	C	C	R/A	I	I	I
Blood	C	A	C	R/A	C	C	I	I	I
Plasma	C	A	R/A	R	C	C	I	I	C
Tissues	C	A	I	C	I	I	R/A	C	I
HSC	C	A	I	C	I	I	C	R/A	I
Testing	C	A	C	R/A	C	I	I	I	I
Supply chains	C	A	C	R/A	I	I	I	I	C
Mutual aid	C	A	R/A	R	I	I	I	I	C

Key

Responsible
Accountable
Consulted
Informed