

Institution Name: Directorate General of Specialized Medical Care, MOH

Document Title: Policy and Procedure of Emergency issue of untested blood components

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Acronyms:

HBsAg	Hepatitis B surface antigen
Anti-HBc	Antibody to Hepatitis B Core
Anti-HCV	Antibody to Hepatitis C
HIV 1/2	Human Immunodeficiency Virus 1/2
HTLV-I/II	Human T-Cell Lymphotropic Virus I/II
NAT	Nucleic acid testing
RNA	Ribonucleic acid
HCV	Hepatitis C virus
HBV	Hepatitis B virus
DNA	Deoxynucleic acid
МОН	Ministry of Health
DBBS	Department of Blood Banks Services

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Policy and Procedure of Emergency issue of untested blood components

1. Introduction

Blood components are tested routinely for infectious markers and compatibility prior to issuing to patients. Rare circumstances may arise when issuing of incompletely tested blood components is necessary to save lives during an emergency. The following tests are performed routinely on blood components in Oman; Hepatitis B surface antigen (HBsAg), Hepatitis B Core (anti-HBc) antibody, Hepatitis C (anti-HCV) antibody, Human Immunodeficiency Virus 1/2 (HIV 1/2) antigen, Human Immunodeficiency Virus 1/2 antibodies, Syphilis, Human T-Cell Lymphotropic Virus (HTLV-I/II) antibody and NAT test (HIV RNA, HCV RNA, HBV DNA).

2. Scope

This document applies to all MOH blood banks.

3. Purpose

Regulate and control the release of incompletely tested blood components during emergencies.

4. Definitions

- 4.1 Incompletely tested blood component: Any unit on which one or more test is not performed prior to issue.
- 4.2 Physician: The health care worker in-charge of the care of the patient who is at a level of Senior specialist or Senior consultant.
- 4.3 Hospital Transfusion Committee: Internal committee within the health institution who is responsible for auditing and monitoring of transfusion practices.



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5. Policy

- 5.1 Blood banks maintain an adequate inventory of all blood components which are tested for emergency issuing.
- 5.2 Release of incompletely tested blood components due to failure of maintaining an emergency stock of tested components are not acceptable and shall trigger an incident investigation within the blood bank.
- 5.3 Release of incompletely tested blood components is only for emergency cases where it is life-saving as per the physician opinion, time frame does not allow issuing of tested blood components and any of the following:
 - 5.3.1 Demand surge (mass casualty, Trauma.) where the blood bank inventory consumption exceeds the collection within 24 hours.
 - 5.3.2 Test is not available (reagent or instrument availability problem)
 - 5.3.3 Natural disaster affecting transportation of samples or blood units (e.g. absence of air transport)

6. Procedure

- 6.1 Once the blood bank receives a blood component request for emergency transfusion and incompletely tested unit is only available the following initial steps are necessary:
 - 6.1.1 Inform the technical supervisor of the blood bank
 - 6.1.2 Assess the time frame needed to complete the testing
 - 6.1.3 Assess the potential of getting a tested unit from a nearby blood bank and timeframe to do so
 - 6.1.4 The technical supervisor contacts the Haematologist/Pathologist in-charge and inform him/her about the situation and above information.
- 6.2 The Haematologist/Pathologist in-charge contact the physician to:
 - 6.2.1 discuss the urgency (time frame during which the unit is needed and how many units are needed)
 - 6.2.2 Available options and time frame for each option
 - 6.2.3 Likely risks associated with transfusing the available incompletely tested unit.
- 6.3 If Physician accept the incompletely tested unit, then the unit can be issued as follows:



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- 6.4 Issue the unit manually using the Emergence Blood Component Release Form. Issue one unit a time if possible.
- 6.5 Complete legibly the blood bank section.
- 6.6 Write the physician's name and staff number who is approving the release. The physician should counter sign the form and return it to the blood bank.
- 6.7 Save the donor blood sample and unit segment for retrospective testing
- 6.8 Ensure that the Emergency Blood Component Release Form (Appendix 1) is returned to the blood bank.
- 6.9 Complete retrospectively the tests on the issued unit.
- 6.10 Quarantine other components related to this donation.
- 6.11 Once the test results are available, enter them in the Hospital information system and issue the unit electronically.
- 6.12 If test results are normal, then quarantine units can be issued for patients use.
- 6.13 Inform the physician about the results of tests.
- 6.14 A copy of the emergency Blood Component Release Form must be faxed to DBBS
- 6.15 If test of the unit is abnormal, then trace the fate of the unit and perform lookback investigation.
- 6.16 The Emergency Blood Component Release Form must be saved permanently in the patient's medical record
- 6.17 Notify the Hospital Transfusion Committee about this event.



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7. Responsibilities

7.1 Physician:

- 7.1.1 Ensure that the benefit outweigh the risk when accepting incompletely tested blood component
- 7.1.2 Sign the Emergency Blood Component Release Form and return it back to the blood bank

7.2 Blood Bank Supervisor:

- 7.2.1 Ensure the standard operating procedure and policy are followed strictly throughout the process
- 7.2.2 Inform the Haematologist/Pathologist in-charge about the incident.
- 7.2.3 Follow the incident until testing is complete and its investigation is closed.

7.3 Haematologist/ Pathologist in-charge:

- 7.3.1 Communicate with the physician
- 7.3.2 Follow the incident and related investigations until it is closed.
- 7.3.3 Ensure that DBBS has been notified and copy of Emergency Blood Component Release Form faxed to DBBS
- 7.3.4 Notify the Hospital Transfusion Committee

7.4 Hospital Transfusion Committee:

- 7.4.1 Audit all incidents of emergency release of incompletely tested blood component
- 7.4.2 Implement corrective actions to minimize such incidents in the future
- 7.4.3 Communicate with DBBS to ensure that such incidents are thoroughly investigated.

7.5 Department of Blood Bank Services (DBBS):

- 7.5.1 Follow all incidents of emergency release of incompletely tested blood components
- 7.5.2 Ensure all incidents are investigated and closed
- 7.5.3 Provide mitigation strategies where possible to minimize such incidents in the future.

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8. Document History and Version Control

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9. Related Documents:

Ministerial decree (114/2020) related to National Blood program and document published on 16/08/2020

10. References:

There are no references for this policy and procedure



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11. Appendix 1: Emergency Blood Component Release Form:

Emergency Blood Component Release
The following blood component/s has been released fromblood bank on an EMERGANCY REQUEST.
Donation Number:ABO/Rh
Type of component:
Date and Time of issue:
Patient Name and hospital Record Number
Physician Name and staff number
If this component is not used by the intended patient, return to the BLOOD BANK for relabeling or quarantine.
Testing for the following has <u>NOT</u> been completed:
Hepatitis B surface antigen (HBsAg)
Antibody to Hepatitis B Core (anti-HBc)
Antibody to Hepatitis C (anti-HCV)
Human Immunodeficiency Virus 1/2 (HIV 1/2) antigen
Human Immunodeficiency Virus 1/2 antibodies
Syphilis
Antibody to Human T-Cell Lymphotropic Virus (HTLV-I/II)



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NAT test for HIV RNA, HCV RNA, HBV DNA
Others (Please specify):

Declaration from the Physician

As the physician making this request for release of blood, I represent that emergency or exceptional circumstances exist which require the blood component referred to herein be released for immediate transfusion before all testing has been completed or under exceptional conditions.

I have fully explained all of the risks involved in transfusing the emergency or exceptional blood to the patient or the patient's next of kin.

I have also obtained his/her consent to proceed with the transfusion even though the blood component has not been fully tested or is otherwise an exception to standard policy.

In complying with this request, the Blood Bank and its staff are released from any liability arising by reason of the transfusion of this blood component.

THIS IS AN EMERGENCY REQUEST. Requesting physician must sign release form.

Signature of PHYSICIAN/ staff number:

RETURN COMPLETED FORM TO BLOOD BANK PROMPTLY.