1.0 MEDICAL ROLES AND RESPONSIBILITIES

Policy	The Transfusion Medicine Service shall have a Medical Director who is a licensed physician and who will be responsible for the overall conduct of transfusion practice in a hospital or formally recognized group of hospitals.
Qualifications	The Medical Director shall be: • A Physician licensed to practice in Ontario, with established evidence of training and expertise in the practice of Transfusion Medicine • Be required to undertake and document completion of ongoing continuing education in Transfusion Medicine for maintenance of competence
General oversight	The Medical Director shall ensure that the Transfusion Medicine service policies and procedures meet all regulatory and accreditation requirements and are consonant with clinical practice obligations of the hospital(s).
Availability of medical consultation in Transfusion Medicine	The Medical Director or his/her delegate shall be available at all times to provide support and consultation in urgent matters of clinical, technical or administrative importance. Should circumstances dictate that immediate responsibilities are delegated to non-medical personnel, provision shall be made for access to medically qualified transfusion medicine advice.
Personnel	The Medical Director shall: • Supervise the practice of other physicians covering the Transfusion Medicine service in the hospital(s) for which he/she is responsible • Ensure that regular performance review of senior technical staff is completed • Participate in hiring and performance management of senior technical staff
Laboratory Supervision	The Medical Director shall: • Evaluate and determine the appropriate technical examination methods to be used to support the clinical practices of the hospital(s), including reagents, supplies and equipment • Continuously assess and evaluate evolving technologies with potential to provide scientifically improved and/or more cost-effective service • Ensure that policies, processes and procedures are clearly defined in writing, consistently applied and updated in a timely manner when changes are made • Ensure technical and medical staff compliance with defined policies, processes and procedures • Ensure that any external services provide reference laboratory testing on behalf of the blood transfusion service are utilizing validated techniques • Ensure staffing levels to meet the workload requirements to provide for optimal support of patient care • Ensure that laboratory reports are accurate, timely and delivered in clinically helpful terms • Be actively involved in, and sign off on, the regular review of Transfusion Medicine Laboratory Procedure Manual (SOPs) • Ensure that policies and processes for blood sample procurement, patient identification, sample identification and handling and sample processing meet required standards of accuracy and safety • Institute remedial action when examination processes deviate from internal or external quality assurance requirements

Role in clinical transfusion practices and product utilization:	The Medical Director shall: • Approve blood component and product inventory requirements to meet clinical program needs while minimizing component and product wastage • In collaboration with Transfusion Committee members, develop clinical practice guidelines to be referred for approval to the Medical Advisory Committee • Approve policies, processes and procedures for blood component and product ordering and distribution • Ensure that blood products received from other institutions (e.g. as part of a hospital redistribution program) have been stored and shipped according to necessary regulations and requirements • Ensure that protocols and guidelines for prescribing and administering transfusion of blood components and products are up to date and available where these are administered • Ensure that these protocols and guidelines are used to develop training programs for staff administering blood components and products • Provide input into the creation of procedures to ensure the appropriate use of blood components and manufactured products (e.g. IVIG) through prospective and retrospective reviews, consultation and audits • Participate in the activities of hospital transfusion committee(s), including contributing to the composition of appropriate terms of reference • Assist in the establishment of a Hospital Emergency Blood Management Committee (HEMBC) and collaborate with administration on the development of the hospital's contingency plan for the management of blood shortages • Work with clinical, administrative, nursing and other ancillary staff to ensure that transfusion related equipment (e.g. blood salvage and warming devices) and their use meet current regulatory requirements under the Institute for Quality Management in Healthcare (IQMH) and are in compliance with the current versions of the CSA and CSTM. Maintain awareness of regulatory requirements of Health Canada as they relate to the hospital transfusion service • Ensure that all blood product manufacturing processes undertaken by the hospital (including pre-operative autologous donation, intra-operative cell salvage, directed and walking donor programs) are performed according to applicable regulations and requirements • Ensure that all blood products issued for use outside the hospital (e.g. shipment to dispensary facilities, home transfusion programs, or directly to patients for home use) are handled and administered according to applicable regulations and requirements
Consultation and education	The Medical Director shall: • Provide consultation and professional advice to physicians prescribing or administering blood components and products, including, where appropriate, advice on clinical blood component or product usage • Provide continuing education in transfusion medicine standards and practices to physicians, nurses and technologists • Where applicable provide access to education in Transfusion Medicine to medical students and residents • Cooperate with medical, technical and nursing personnel to establish and maintain programs to ensure ongoing quality and competence in transfusion practice • Ensure that medical and non-medical staff members using transfusion related equipment (e.g. blood salvage devices, blood warmers, apheresis devices) are trained and competent to do so, that such training and competence is documented, and that ongoing preventative maintenance protocols for such equipment are in place

Quality Management	The Medical Director shall: • Supervise and participate in the management of quality systems to ensure that examinations performed in the Transfusion Medicine Service provide accurate, reliable and timely results required to support high quality patient care • Ensure implementation of established current Transfusion Medicine Standards as required under IQMH and defined by the CSA and CSTM. • Ensure compliance with all National and Provincial regulatory requirements, including participation in mandated external quality assurance schemes • Review external quality assurance examination results, and initiate and oversee remedial action when these results are unsatisfactory • Ensure mechanisms are in place for the recording of adverse events, of the results of review of quality assurance data (external and internal) and of any consequent remedial actions
External Reporting Relationships	The Medical Director shall ensure: • Compliance with reporting requirements of Health Canada (HC), Public Health Agency of Canada (PHAC), Canadian Blood Services (CBS) and IQMH • Timely participation in lookback and traceback investigations as required by CBS

1.1 Indications for Consultation with Transfusion Medicine medical staff

Policy	The Medical Director, Transfusion Medicine or delegate shall be available at all times for consultation on clinical, technical, administrative or quality issues.
Rationale	The reason for this policy is the requirement for medical input from a physician knowledgeable in transfusion medicine to: • Assess patient needs • Advise in the selection of appropriate blood products in unusual or specialized circumstances • Consult on the management of adverse transfusion reactions • Assist with patient blood management and appropriate blood conservation measures
Responsibility of the Medical Director, Transfusion Medicine	The Medical Director shall be responsible for providing a contact list to Transfusion Medicine Staff and for ensuring the availability of Medical Staff support at all times. The Medical Director shall define the indications for contacting the Medical Director or scheduled delegate, and the procedure to be followed if the Medical Director or delegate is non-responsive (including appropriate documentation).

Table 1.1 Indications for Immediate Consultation

Situation	When
Blood product shortage	• Reasonable possibility that medical or surgical blood products requests will not be met • Amber or red phase blood product shortage declared by Canadian Blood Services • The contingency plan for blood shortages requires it to be implemented • Screening of requests during critical shortages according to policies set by the Hospital Emergency Blood Management Committee, in accordance with the National Plan for the Management of Shortages of Labile Blood Components and the Ontario Contingency Plan for the Management of Blood Shortages
Errors	• Any error with the potential to result in adverse consequences to a recipient such as an incorrect or incompatible blood product has been issued • Clerical or other error has led to release of an incorrect or incompatible unit (even if not actually transfused) • Sampling error detected that may affect one or more patients

Transfusion reactions	• Symptoms suggestive of severe transfusion reaction notified by verbal contact from patient location (MD, RN) or by transfusion reaction report form • Post-transfusion work-up reveals features suggestive of incompatibility such as icteric or hemolysed sample or positive DAT post-transfusion, and further transfusion is medically indicated • Requests received for further blood product transfusion before transfusion reaction investigation is completed • At technologist's discretion
Massive transfusion	• Patient's blood volume is replaced over a short period (>10 units within 24 hours) and there is continuing blood loss • Initiation of Massive Hemorrhage Protocol (MHP) if applicable • Clinically significant antibodies are detected in a sample from a massive transfusion recipient • RhD-negative patient of child-bearing potential is switched from RhD-negative to RhD-positive red blood cells or platelets according to established policy
STAT/urgent/special red blood cell unit requests	• Blood issued "uncrossmatched" is found to be incompatible • Permission is required to issue crossmatched incompatible units, with the exception of patients with autoantibodies where complete investigation has excluded all clinically significant antibodies • Compatible or antigen negative units are not available (e.g. antibody to high incidence antigen; multiple antibodies present; warm reactive auto-antibody) • Request is received for blood for transfusion before an antibody investigation is completed • Release of a large number of O RhD-negative units threatens appropriate inventory levels or cannot be supported by CBS • Clinically significant antibody is found in a neonatal sample and the infant has biochemical evidence of hemolysis • Request for use or dose of blood component or product inappropriate to the institution's Transfusion Medicine guidelines, or where there will be delay in availability for transfusion • Need to transfuse untested or partially tested components or products from CBS
RhD-positive products to RhD-negative patient	• Any RhD-positive product is to be issued for an RhD-negative recipient of child-bearing potential, unless a pre-approved policy or specific instruction is in place • RhD-positive platelets are to be given to an RhD-negative recipient of child-bearing potential and RhIg is required, unless a pre-approved policy or specific instruction is in place

Other blood product requests requiring consultation with the Medical Director, Transfusion Medicine	• Urgent request for use or dose of any blood component or product outside the institution's Transfusion Medicine guidelines • A new request is received for irradiated and/or CMV sero-negative product does not meet established indications • A new request is received for: » Washed or plasma-depleted cellular component » HLA matched platelets » IVIG not meeting MOHLTC guidelines unless a pre-approved policy assigns this responsibility to other physicians at the facility » Coagulation factor products for new single factor patient » Rarely requested products (e.g. recombinant factor VIIa, C1 esterase inhibitor) » Exchange or intra-uterine transfusions • Platelets are requested for a patient with a diagnosis of ITP, TTP/HUS, heparin induced thrombocytopenia or undiagnosed thrombocytopenia • Urgent request for platelets for transfusion and no platelets are immediately available • Infusion of any component or product beyond its expiration time • Allogeneic unit is sought when autologous unit(s) is (are) available • Urgent request (e.g. from OR) for red blood cells for a patient with alloantibodies • Request for red blood cells in presence of high thermal amplitude cold agglutinin • Request for red blood cells for a patient with a sickle cell syndrome (see section 9.8) • Request for prothrombin complex concentrates for other indications than emergency warfarin reversal • Requests for therapeutic apheresis
Issues of product quality	• There is any doubt about component or product quality and clinical circumstances require urgent transfusion • Identification of a component or product of questionable quality leading to quarantine should be reported on the next working day
"Code Orange" (Disaster Plan Notification)	• On receipt of a "code orange" notification, whether external (e.g. major transportation crash) or internal (e.g. extended computer downtime or power failure)
Miscellaneous issues	• Patient with refusal to consent to transfusion: » Blood components or products are subsequently requested for or transfused to a patient who refused transfusion based on religious or other beliefs • Unusual situations not covered above: » Immediate notification at the discretion of medical laboratory technologist

Table 1.2: Transfusion Emergency and TM Medical Director or delegate is not responding

If	Then
Transfusion is urgently required	• Contact patient's physician immediately to confirm patient's clinical needs outweigh potential hazards of transfusion • Prepare and release requested products • Continue to try to contact Transfusion Medicine Director or delegate • Document the episode

The patient is at risk of hemolytic transfusion reaction or other identifiable severe hazard of transfusion	• Information emerges (e.g. technical error) putting a patient at risk of hemolytic transfusion reaction or other identifiable severe hazard of transfusion: » Contact patient location immediately to request transfusion be stopped » Notify the patient's physician as soon as possible » Continue to try to contact Transfusion Medicine Director or delegate

REFERENCES

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