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STANDARDS

Transfusion Services

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TRANSFUSION SERVICES

Accreditation Canada's Transfusion Services Standards promote an integrated approach to transfusion services. The transfusion team uses an interdisciplinary approach to deliver safe, quality transfusion services to clients.

Accreditation Canada's Transfusion Services Standards are based on CSA Standards Z902-10 which focus on activities related to planning and evaluating transfusion services.

This set of standards contains the following sections:

- Meeting the demand for transfusion services
- Having the right supports in place for transfusion services
- Providing a safe, suitable environment
- Collecting, testing, and labelling blood in a safe manner
- Safely preparing, storing, releasing, and transporting blood components and blood products
- Providing safe and timely transfusion services
- Monitoring the safety and quality of transfusion services

All Accreditation Canada standards are developed through a rigorous process that includes a comprehensive literature review, consultation with a standards working group or advisory committee comprised of experts in the field, and evaluation by client organizations and other stakeholders.

If you would like to provide feedback on the standards, please complete the feedback form in this document.

Legend

Dimensions


Population Focus: Work with my community to anticipate and meet our needs


Accessibility: Give me timely and equitable services


Safety: Keep me safe


Worklife: Take care of those who take care of me


Client-centred Services: Partner with me and my family in our care


Continuity: Coordinate my care across the continuum


Appropriateness: Do the right thing to achieve the best results


Efficiency: Make the best use of resources

Criterion Types

High Priority High priority criteria are criteria related to safety, ethics, risk management, and quality improvement. They are identified in the standards.

Required Organizational Practices Required Organizational Practices (ROPs) are essential practices that an organization must have in place to enhance client safety and minimize risk.

Tests for Compliance

Minor Minor tests for compliance support safety culture and quality improvement, yet require more time to be implemented.

Major Major tests for compliance have an immediate impact on safety.


Performance Measures Performance measures are evidence-based instruments and indicators that are used to measure and evaluate the degree to which an organization has achieved its goals, objectives, and program activities.

MEETING THE DEMAND FOR TRANSFUSION SERVICES

1.0 The team plans and designs its transfusion services to meet the current and future demand for blood components and products.

Appropriateness

1.1 At least every two years, the team collects information about the demand for transfusion services including service volumes, wait times, client perspectives on services, and trends in service needs across different groups such as age or condition-specific populations.

Guidelines

Collecting this information helps the team evaluate the demand for services, identify patterns in service needs, and determine the resources needed to meet the demand. The team may collect this information through administrative databases, administering questionnaires, or conducting interviews.

Client-centred Services

1.2 At least every two years, the team reviews information collected about the demand for transfusion services to identify strengths and areas for improvement, and makes changes accordingly.

Guidelines

The team should review the information together and share it with other clinical and administrative teams in the organization as appropriate.

Appropriateness

1.3 When transfusion services are contracted to or from external organizations, the team establishes and maintains an agreement with each organization that outlines the requirements and respective responsibilities.

Guidelines

Requirements include meeting consistent levels of quality and adhering to accepted standards of practice. For more information, please see CSA Z902-10, 4.6.4.1.

2.0 The team provides timely access to transfusion services.

Appropriateness

2.1 The team sets targets and tracks response times for elective, urgent, and emergent requests for transfusion services.

Guidelines

Targets and response times will vary depending on the urgency of the request (e.g., urgent or emergent requests will have different targets and response times than elective requests).

Accessibility

2.2 The team identifies and removes, where possible, barriers that prevent access to transfusion services.

Guidelines

Access may be compromised by barriers under the team's control (e.g., hours of operation, physical or language barriers, human resources) or by barriers not under the team's control (e.g., transportation, long wait times).

Appropriateness

2.3 The team regularly seeks input on how to improve access to transfusion services and addresses delays in providing blood components and products for transfusion.

Guidelines

Input should be thoroughly reviewed in cases of excessive delays in service (e.g., having interdisciplinary meetings and discussions about how to improve access to services and prevent delays).

Efficiency

2.4 The team identifies the resources needed to deliver efficient and timely transfusion services.

Guidelines

Resources may be financial, informational, structural, human, or related to equipment. The availability of resources may depend on the continuity of funding as well as opportunities to share resources with other organizations.

Team leaders advocate on the team's behalf for the resources needed to achieve the team's goals and objectives.

HAVING THE RIGHT SUPPORTS IN PLACE FOR TRANSFUSION SERVICES

3.0 The organization has the appropriate mix and number of team members to provide safe and effective transfusion services.

Appropriateness

3.1 The team is made up of a sufficient number of qualified members who are able to carry out the required volume of transfusion services, day-to-day operations, and any other responsibilities.

Guidelines

Having a sufficient number of qualified team members will depend on the size and complexity of the organization and volume of transfusion services that are delivered.

Appropriateness

3.2 The team has position profiles that define each member's qualifications, roles and responsibilities, and level(s) of authority.

Appropriateness

3.3 The team has a management structure with clear reporting relationships and lines of accountability.

Guidelines

Reporting relationships and lines of accountability may be outlined in an organizational chart or other format.

Appropriateness

3.4 The team has a medical director responsible for overseeing transfusion activities within the organization.

Guidelines

The medical director is a physician with the required qualifications and training and/or experience to oversee the transfusion services provided by the organization.

The medical director is responsible for:
• Quality assurance
• Efficient and appropriate use of resources
• Compliance with regulatory requirements and standards of practice
• Clinical and technical policies and standard operating procedures related to the transfusion team and activities they carry out

The medical director may also be responsible for, or provide input into, developing policies and standard operating procedures related to effective, safe care of donors and recipients.

Appropriateness

3.5 The team has a designated technical supervisor who provides leadership, management, and administrative coordination functions for transfusion services.

Guidelines

Some of the functions of the technical supervisor may be the responsibility of a transfusion safety officer. Responsibilities of the technical supervisor may include:
• Allocating resources appropriately
• Defining, implementing, and monitoring standards and quality improvement activities
• Assessing the transfusion team's work
• Overseeing research activities
• Liaising with accrediting and regulatory agencies, administrative officials and leaders, the health care community, and clients
• Verifying there is a sufficient number of team members to carry out the required services, operations, and responsibilities
• Ensuring team members have access to training and professional development opportunities
• Ensuring the work environment is safe and positive
• Addressing complaints or concerns.


Appropriateness

3.6 The designated technical supervisor regularly evaluates staffing requirements and makes changes as required.

4.0 The team participates in education, training, and professional development activities, and regularly assesses training outcomes and competence.


Appropriateness

4.1 The team receives comprehensive orientation and training on the team's standard operating procedures (SOPs), ethics issues, information systems and confidentiality, sanitation, workplace health and safety, infection control and hygiene, and quality improvement and safety activities, including preventing patient safety incidents.


Appropriateness

4.2 The team has access to ongoing professional development, training, and educational activities.


Appropriateness

4.3 The team has a formal program to maintain team members' competence that includes evaluating their theoretical and practical knowledge on transfusion services using a variety of techniques.

Guidelines

The competency assessment program applies to all team members, including prescribing physicians. The team leaders assess competency following orientation and at regular points thereafter.

Techniques used to assess competence may include:
- Observing performance directly
- Monitoring the recording and reporting of results
- Reviewing records and reporting systems
- Assessing problem-solving skills through written tests or case studies
- Assessing knowledge of SOPs and theory
- Assessing performance through proficiency tests for team members who regularly perform routine testing.

Client-centred Services

4.4 Education and training are provided to team members on how to work respectfully and effectively with clients and families with diverse cultural backgrounds, religious beliefs, and care needs.

Guidelines

Cultural education and training build the skills, knowledge, and attitudes that are required to safely and appropriately deliver interventions and services to culturally diverse populations. The training may cover topics such as disability, level of understanding, or mental health.

Cultural education and experience are part of the recruitment (including position advertisements) and selection processes.

Appropriateness

4.5 Team managers document the results of competency assessments and reassessments.

Appropriateness

4.6 The team participates in a proficiency testing program that includes taking remedial actions when sufficient proficiency testing performance is not attained.

Guidelines

For more information on proficiency testing, please see CSA Z902-10, 4.3.3.2-4.

Appropriateness

4.7 The team has a system to regularly evaluate the effectiveness of their training and competency assessment activities.

Guidelines

The team may use performance indicators or a form as part of this evaluation.

Appropriateness

4.8 The organization maintains and retains complete and up-to-date records on qualifications, training, and competence, including competency assessments and reassessments, and remedial actions for each team member.

Guidelines

In addition to information on qualifications, training, and competence, including assessments and reassessments, the staff record may include references from previous employment, relevant position profile(s), reports of incidents or accidents involving the staff member, and personal health information related to exposure to occupational hazards and records of immunization.

Records should be retained according to applicable jurisdictional regulatory or legislative requirements, or standards of practice. For more information on record retention related to specific transfusion responsibilities and activities, please see CSA Z902-10, 20.6.4.2.

5.0 The team consistently follows Standard Operating Procedures (SOPs) for its activities.

Appropriateness

5.1 The team develops and follows clear and concise SOPs for its transfusion activities.

Guidelines

SOPs should comply with applicable jurisdictional regulatory or legislative requirements, or standards of practice.

Appropriateness

5.2 The team has access to SOPs that apply to the activities they carry out.

Guidelines

Team managers confirm that team members have access to and follow the SOPs that apply to their functions and duties, depending on their scope, roles and responsibilities.

Appropriateness

5.3 The team reviews and updates the SOPs every two years or more often if required.

Guidelines

A knowledgeable and qualified team member reviews and updates the SOPs. In addition to a review every two years, the lab reviews the SOPs following patient safety incidents, changes in regulatory or legal requirements, internal or external audits, and other situations as defined in the team's policies.

Appropriateness

5.4 The team follows a document control procedure for developing and maintaining SOPs.

Guidelines

The document control procedure describes:
• Who is authorized to review, update, and authorize the SOPs
• How to track changes and revisions to SOPs
• How to number and control versions
• Which team members need to have access to which SOPs
• How master copies are maintained
• How to identify, collect, file, archive, and manage active and superseded or obsolete SOPs to ensure that only authorized versions of SOPs are in circulation.

Appropriateness

5.5 After approving new or revised SOPs, the team's managers verify that appropriate team members receive information or training as required before new or revised SOPs are implemented.

Guidelines

The team's managers keep records of team members' orientation to and understanding of the SOPs. The team's managers establish processes for communicating changes to SOPs, and document that the team reviews and understands the changes. The team keeps records of observations during information and training sessions and retraining sessions.

Appropriateness

5.6 The team regularly evaluates compliance with its SOPs and makes changes as needed.

Guidelines

At least every two years, the team evaluates compliance with its SOPs and makes changes to them, the training activities, or monitoring processes accordingly.

PROVIDING A SAFE, SUITABLE ENVIRONMENT

6.0 **The design, layout, and physical environment support safe, effective, and efficient service.**

Appropriateness

6.1 The team's physical environment and equipment support efficient functioning and safe activities.

Guidelines

The team's managers determine the physical environment and equipment needed to carry out transfusion services, including access to an emergency power source; areas for record keeping, data entry, and other administrative functions; and storage space for equipment, supplies, samples, documents, files, records, and results. The storage space protects the integrity of samples, products, and supplies.

For more information on safe and efficient layout and design of the work areas, please see CSA Z902-10, 22.1-3.

Efficiency

6.2 The team's physical environment is structured so they can efficiently carry out the volume of requests during peak times.

Safety

6.3 The organization limits access to transfusion work areas to authorized team members only.

Guidelines

This includes areas for preparing, handling, and storing blood components and blood products for transfusion.


Safety

6.4 The team maintains clean work areas.

Guidelines

Cleaning the work area should be based on the organization's environmental services guidelines which address specific cleaning materials and equipment, decontaminating cleaning equipment, and properly storing and using disinfectants.


Safety

6.5 The team prohibits eating, drinking, and smoking in areas where blood components and blood products are prepared, handled, and stored.


Safety

6.6 The team uses biological safety procedures, including standard precautions, when handling, examining, or disposing of biological materials.

Guidelines

Biological safety procedures apply whenever staff or another individual may be exposed to blood, body fluids, or other potentially infectious materials. Procedures should conform to relevant local, provincial/territorial, or national laws and regulations. Standard precautions include using personal protective equipment such as gloves, face and eye protection, and clothing.

For more information on biological safety procedures, please see CSA Z902-10, 4.5.2.


Safety

6.7 The team follows the organization's policies and procedures on infection prevention and control to maintain the safety of team members and clients, and prevent contamination of materials.

Safety

6.8 The team receives training on hand-washing procedures and has access to hand-washing facilities that are adequately supplied.

Guidelines

Hand hygiene is the single most important procedure to prevent the spread of infection. Hand washing facilities are easily accessible (e.g., located within or next to work areas) and include either sinks with soap and towel dispensers, or waterless alcohol-based hand washing agents. Sinks should be automated or supplied with foot-, knee- or wrist-operated handles or electric sensors to prevent hand recontamination.

Safety

6.9 The team safely collects, sorts, and disposes of waste materials in line with applicable regulations.

Guidelines

For more information on safe waste disposal, including using sturdy, labelled containers and disposing of waste at frequent intervals, please see CSA Z902-10, 22.3.4.

Client-centred Services

6.10 Access to spiritual space and care is provided to meet clients' needs.

Guidelines

Spiritual care is available to meet the needs of clients, as required. It includes access to a spiritual leader appropriate to the client's beliefs (e.g., a chaplain, imam, rabbi, or non-denominational counsellor). Clients and families have access to a designated space to observe spiritual practice.

The client's spiritual needs and preferences are seen as integral to the care and healing process, and are discussed when making care decisions that may involve an ethical or spiritual component.

Safety

6.11 Universal fall precautions, applicable to the setting, are identified and implemented to ensure a safe environment that prevents falls and reduces the risk of injuries from falling.

Guidelines

Organizations should identify and adopt precautions for all clients, regardless of risk of falling. The acronym S.A.F.E. (Safe environment; Assist with mobility; Fall-risk reduction; and Engage client and family) describes the key strategies for universal fall precautions. The following are examples of universal fall precautions: familiarize clients to new environments; if you have call buttons (e.g., in washrooms) ensure they are within reach; have sturdy handrails in bathrooms, rooms, and hallways; use appropriate lighting; provide chairs that are appropriate for clients with mobility issues; have mobility aids on hand as appropriate to your client population; keep floor surfaces clean and dry; clean up all spills promptly; keep hallways and care areas uncluttered. It is important to identify precautions that align with the clinical setting and needs of clients in that setting, including their right to live at risk.

7.0 The team selects, uses, and maintains appropriate equipment for transfusion services.

Appropriateness

7.1 The team participates in or follows the organization's process for selecting and prioritizing equipment.

Guidelines

The process for selecting and prioritizing equipment takes into account the types of services provided; the knowledge and skills needed for use; occupational health and safety issues; the latest research and evidence on advances in technology; and whether the benefits are worth the costs.

Other stakeholders involved in the equipment selection process may include biomedical engineers, infection control practitioners, and information technologists.

Population Focus

7.2 The team selects equipment that can be easily cleaned and sanitized.

Guidelines

The team should be able to easily clean and sanitize equipment. Equipment should be made of materials that do not react with or absorb cleaning or sanitizing products.

Appropriateness

7.3 The team regularly cleans and decontaminates equipment, documents that this has been done, and keeps equipment protected when not in use.

Appropriateness

7.4 The team follows a preventive maintenance schedule for its equipment.

Appropriateness

7.5 The team follows SOPs for maintaining, inspecting, validating, and calibrating equipment that comply with manufacturer's instructions.

Guidelines

Instructions for maintaining, inspecting, validating, and calibrating equipment cover laboratory and transfusion-related equipment (e.g., blood warmer), and include the calibration and inspection limits to be set before first use. The team should regularly compare calibration devices to a reference standard and document the results.

Appropriateness

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7.6 The team identifies, investigates, and corrects problems with equipment as required.

Appropriateness

7.7 The team has a complete and up-to-date record of inspections, validations, calibrations, and maintenance conducted on each piece of equipment.

Guidelines

The record includes:
• Name of the equipment, location, and serial number or other unique identifier
• Name of manufacturer and manufacturer's instructions
• Up-to-date contact information
• Whether the equipment was obtained new, used, or reconditioned; and pertinent dates, (e.g., the date the laboratory began using the equipment and dates when the equipment was serviced)
• Data collected on parameters measured
• General notes on performance, malfunctions or deviations
• Actions taken
• Service reports for preventive maintenance or repair specifying the service contractor and any parts replaced

The team establishes a regular maintenance and calibration schedule and maintains a record of when they plan to replace the equipment.

Appropriateness

7.8 The team maintains records that include information on the day-to-day operation of equipment, according to the manufacturer's instructions, including quality control results observed and criteria for acceptable ranges.

8.0 The team maintains appropriate environmental conditions in the laboratory and for all equipment used for storing blood components and blood products.

Appropriateness

8.1 The team has the equipment needed to maintain appropriate environmental conditions in refrigerators and other equipment used to store blood components and blood products.

Guidelines

Environmental conditions include temperature and humidity levels. For example, refrigerators used for blood components and blood products have an air-circulating fan or some other way to maintain proper temperatures.

Appropriateness

8.2 The team regularly monitors and records environmental conditions within the laboratory including temperature and humidity levels.

Guidelines

Requirements for temperature recording differ depending on the sample or product. For more information on temperature monitoring, please see CSA Z902-10, 9.4.

Safety

8.3 The team maintains and regularly tests an alarm system to alert staff to changes in conditions or malfunctions.

Guidelines

The alarm has an audible signal and sounds in a location that is continuously monitored or staffed, so that corrective action can be taken before temperatures or other conditions reach unacceptable levels.

Safety

8.4 The team regularly monitors and records that a functioning emergency backup system is available for equipment used for storing blood components and blood products.

COLLECTING, TESTING, AND LABELLING BLOOD IN A SAFE MANNER

9.0 The team follows SOPs when collecting blood for autologous donation.

Appropriateness

9.1 The organization has been approved for an autologous donor program.

Guidelines

Approval for an autologous donor program may come from the provincial or territorial ministry of health, as applicable.

Appropriateness

9.2 The team follows SOPs for requesting, collecting, and using autologous blood.

Guidelines

The SOP for autologous collection is consistent with all other SOPs for collecting, labelling, storing, and transporting blood. The SOP states that a donor-recipient's autologous donations must be used before resorting to allogeneic products.

For more information on autologous blood collection and transfusion, please see CSA Z902-10, 12.

Appropriateness

9.3 An appointed medical director is responsible for setting and updating the SOPs for autologous donation.

Guidelines

When developing and updating the SOPs, the medical director also identifies all staff involved in the autologous program.

Appropriateness

9.4 The team collects autologous blood only when there is a prescription from the donor-recipient's attending physician and written approval from the medical director of the autologous program.

Guidelines

The written approval for obtaining autologous blood includes the following:
- Client's name and contact information
- A unique identifier
- Number of units to be collected
- Type of product needed
- Type, date, and location of surgery
- Name, contact information, and signature of the prescribing physician

For more information on autologous blood collection and transfusion, please see CSA Z902-10, 12.1.

Safety

9.5 The team applies explicit acceptance and exclusion criteria for autologous donation.

Guidelines

The criteria for selecting allogeneic donors do not apply to autologous donation. There is no age limit for collection of autologous donations.

The program develops its own acceptance and exclusion criteria that should include at a minimum the following:
- Refraining from collecting blood within 72 hours of planned surgery or transfusion except in the case of perioperative collection
- Refraining from collecting blood if the donor has been diagnosed with or is receiving treatment for bacteremia
- Basing the volume of blood to be collected on the donor-recipient's weight
- Refraining from collecting blood if hemoglobin and hematocrit rates are below established thresholds
- Verifying there is a healthy and normal looking venipuncture site
- Reviewing the frequency of donations.

In addition, the criteria should specify which surgical procedures are eligible for autologous donation. For more information on criteria for donation, please see CSA Z902-10, 12.2.

Client-centred Services

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9.6 The team verifies that all benefits and risks have been explained to the donor-recipient and obtains the donor-recipient's free and informed consent.

Appropriateness

9.7 The medical director determines the intervals between donations in consultation with the attending physician.

Guidelines

The intervals between donations may vary depending on the type of donation and should maintain the donor's safety. For more information on donation intervals, please see CSA Z902-10, 5.2, 13.1, 13.3).

Appropriateness

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9.8 The team follows SOPs for collecting low volume blood that specify the ratio of anticoagulant to collected blood required to maintain the safety of the recipient.

Appropriateness

9.9 Following donation, the team correctly labels the blood bags and sends them to the blood bank as soon as possible.

Guidelines

Autologous blood donation labels must correctly identify the donor-recipient and be clearly labelled "For Autologous Use Only" to prevent the blood from being distributed or stored with the regular blood supply. For more information on labelling, please see Z902-10, 12.3.2.


Safety

9.10 The team follows SOPs for testing autologous blood components for transmissible diseases.

Guidelines

The minimum testing that is done for autologous donation is for HIV 1 and 2, HBV, HCV, and HTLV I/II. Nucleic acid testing and syphilis testing are not required for autologous donors. For more information on donor testing to prevent disease transmission, please see Z902-10, 12.3.1.


Safety

9.11 The team takes precautions to safely handle autologous blood components when they are repeatedly reactive to one or more tests.

Guidelines

The team's precautions include getting written confirmation that the products will be accepted by the transfusion service, labelling all donations that are repeatedly reactive or positive for transmissible diseases as “biohazard,” and informing the donor-recipient and prescribing physician of any abnormal or unexpected result.

If blood with repeatedly reactive or uncertain results must be shipped to another facility, it is the shipping facility's responsibility to advise the receiving facility of the reactive tests. The team follows Transport Canada shipping regulations and notifies the receiving organization when shipping blood components that have been confirmed positive for the above disease markers.

For more information on precautions to safely handle blood components that are repeatedly reactive, please see CSA Z902-10, 12.3.1.4, 12.3.1.5, and 12.3.2.


Safety

9.12 The team maintains a record of how each unit of blood component collected for autologous donation is stored and transported so it can be accurately tracked.

Safety

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9.13 The team destroys all autologous blood after its expiry date to prevent it from being used.

10.0 The team follows SOPs when collecting blood for directed donations.

Appropriateness

10.1 The team follows SOPs for directed donations.

Guidelines

The SOPs for directed donations are consistent with all other SOPs for collecting, labelling, storing, and transporting blood. In addition, the SOPs address meeting criteria for allogeneic blood donations as appropriate, determining donor-recipient compatibility before collecting a directed donation, storing blood for directed donations separately, and ensuring donations from blood relatives are irradiated.

For more information on directed donations, please see CSA Z902-10, 15.1.

Client-centred Services

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10.2 The team verifies that all benefits and risks associated with directed donations have been explained to the donor and recipient and obtains their free and informed consent.

Guidelines

For more information on directed donations, please see CSA Z902-10, 15.1.5.


Appropriateness

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10.3 The team complies with specific requirements for labelling directed donations.

Guidelines

For more information on labelling, please see CSA Z902-10, 15.1.6.

11.0 The team follows SOPs when collecting blood for designated donations.


Appropriateness

11.1 The team follows SOPs for designated donations.

Guidelines

The SOPs for designated donations are consistent with all other SOPs for collecting, labelling, storing, and transporting blood. In addition, the SOPs address storing designated donations in the allogeneic supply if the donor has met the requirements for allogeneic donation, and ensuring that designated donations are irradiated.

For more information on designated donations, please see CSA Z902-10, 15.2.


Appropriateness

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11.2 The team uses specific requirements for labelling designated donations.

Guidelines

For more information on labelling, please see CSA Z902-10, 15.2.6.

12.0 The team follows SOPs to collect and recover perioperative blood safely.


Appropriateness

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12.1 The organization designates a physician to be responsible for the perioperative blood collection and recovery program and its policies and procedures.

Guidelines

Perioperative donations are collected outside the blood bank, monitored by a designated physician, and carried out in the following situations: collecting blood just prior to surgery (acute normovolemic hemodilution); collecting blood throughout surgery from the surgical site or other location (intraoperative); and collecting blood following surgery or trauma from body cavities, joint spaces, or other closed sites (post-operative). For more information on labelling, please see Z902-10, 12.5.

Appropriateness

12.2 The team processes intraoperative and post-operative blood to remove potentially detrimental particles, and transfuses perioperative blood within designated timeframes.

Guidelines

Blood collected for acute normovolemic hemodilution must be transfused within 8 hours of initiating the collection, or 24 hours if it is stored at 1-6 degrees Celsius. Other blood collected perioperatively must be transfused within 6 hours of initiating the collection. For more information on perioperative collection time limits, please see CSA Z902-10, 12.5.

Safety

12.3 The organization has quality control, assurance, and safety SOPs for perioperative blood collection.

Guidelines

The SOPs for quality control, assurance, and safety should be developed with input from the various team members involved in providing perioperative transfusion services. For more information on quality control and safety requirements, please see CSA Z902-10, 12.5.

Appropriateness

12.4 The organization maintains a record of the blood it collects under perioperative conditions.

Guidelines

The record includes the anticoagulants and solutions used for processing, the labelling of collected blood, measures taken to prevent or manage patient safety incidents, and the results of quality reviews. For more information on maintaining records, please see CSA Z902-10, 12.5.

13.0 The organization's labelling system provides the proper and unique identification of each blood component.


Safety

13.1 The team has specific predetermined acceptance and rejection criteria for visual inspection and sets rejected blood components aside for further testing.

Guidelines

The team visually inspects each blood component immediately before placing it into inventory to verify there is proper labelling and no leakage, discoloration, or abnormality, e.g., clotting, hemolysis. All results are documented and blood components that fail the required testing are not put into inventory (Z902-10, 8.5).


Appropriateness

13.2 The team labels blood bags using a standardized labelling system that meets applicable laws and regulations.

Guidelines

The blood bag label should contain the information necessary to trace the blood components to the donor. For more information on labelling blood bags, please see CSA Z902-10, 8.6).


Safety

13.3 The team verifies that all required tests have been confirmed before applying test results grouping information to the label (e.g., ABO and Rh).

Guidelines

For more information on labelling, please see CSA Z902-10, 8.6.1.1.

Appropriateness

13.4 The team appropriately labels all red blood cell (RBC) components.

Guidelines

The label contains the expiration date (calculated based on time and temperature recommendations from the blood bag manufacturers); the anticoagulant and additives used; and whether a low-volume unit of whole blood was used in preparing the red blood cells. For more information, please see CSA Z902-10, 7.5.

Safety

13.5 If changes, modifications, or transformations are made to the blood component, the team creates a new label and verifies that it is accurate.

SAFELY PREPARING, STORING, RELEASING, AND TRANSPORTING BLOOD COMPONENTS AND BLOOD PRODUCTS

14.0 The team follows SOPs when preparing blood components and blood products.

Appropriateness

14.1 The team follows SOPs for preparing blood components and blood products.

Guidelines

There should be an SOP that complies with manufacturers' instructions for each type of blood component and blood product that the organization prepares, including washing, mixing, pooling, aliquotting, irradiating, rejuvenating, or thawing. The SOPs should describe the responsibilities of each team member involved in blood component and blood product processing. For more information on preparing blood components and blood products, please see CSA Z902-10, 7.1.

Safety

14.2 The team sets an appropriate expiration date for each blood component.

Guidelines

For more detailed information on expiration dates, please see CSA Z902-10, 7.

Safety

14.3 The team verifies that specific precautions have been followed for red blood cells prepared for recipients with anti-IgA.

Guidelines

Recipients with anti-IgA or with an IgA deficiency and a history of severe allergic reaction to transfusion should receive RBCs from IgA-deficient donors or from non-IgA deficient donors that have been washed with a minimum of 2000mL of 0.9% NaCl per component. For more information, please see CSA Z902-10, 7.5.4.1.

15.0 The team takes precautions to maintain the sterility and integrity of blood components and blood products.

Appropriateness

15.1 The team follows SOPs to maintain the sterility of the blood components and blood products by using aseptic methods and sterile, pyrogen-free equipment and solutions, including sterile connecting devices.

Guidelines

The organization has SOPs for using sterile connecting devices that include:
- Specifications on when they may be used
- Instructions for use
- Testing protocols including random sterility checks
- Documentation requirements for tracking, quality control, and lot numbers

For more information, please see CSA Z902-10, 7.1.3, 7.3.

Safety

15.2 The team maintains the integrity of the sterile seal, and in the event the seal is breached treats the blood component or blood product as an open system.

Guidelines

In an open system, if the team stores the blood component at 1-6 degrees Celsius, it has a reduced expiration time of 24 hours, and if stored at 20-24 degrees Celsius, it has a reduced expiration time of 4 hours. For more information on open systems, please see CSA Z902-10, 7.2.


Safety

15.3 For recipients at risk of transfusion-associated graft versus host disease (TA-GVHD), the team verifies that all cellular components have been irradiated.

Guidelines

The team verifies that cellular components have been irradiated as required, using a minimum of 25 Gy gamma irradiation, targeted appropriately according to the type of irradiator or radiotherapy equipment, such that the minimum dose at any point is 15 Gy and the maximum dose does not exceed 50 Gy.

The team tests all components to verify the required dose of irradiation has been applied; this includes testing and documenting the dose delivery of the irradiator at least annually.

Following irradiation, the blood components are appropriately labelled and stored for up to 28 days, unless a shorter expiration date applies. The date of irradiation must always be available if requested.

For more information on irradiation of blood components, please see CSA Z902-10, 7.12.

16.0 The team stores prepared blood components and blood products in the appropriate environmental conditions.


Safety

16.1 The organization follows SOPs for storing each type of blood component and blood product within acceptable temperature ranges and storage conditions, including in the event of power failure.

Guidelines

All SOPs provide detailed instructions to maintain blood components and blood products within appropriate temperatures during storage and transport, including instructions in the event of an equipment or power failure. For more information on storage and transport, please see CSA Z902-10, 9.4 and 7.1.2.

Appropriateness

16.2 The team stores all red blood cells at 1-6 degrees Celsius, unless specific requirements for freezing are followed.

Guidelines

Except in cases of rare phenotypes, the organization should store RBCs for no more than 10 years. During this time there should be ongoing monitoring to verify proper storage conditions including temperature.

Specific requirements for freezing may include:
• Freezing within six days of collection if not in a nutrient solution, prior to the expiration date if in a nutrient solution, or past the expiration date if rejuvenated prior to freezing
• Storing a sample of serum or plasma for future testing purposes
• For frozen RBCs for autologous purposes, informing the donor of any changes in the status of their frozen blood components
• If frozen for cryopreservation, using an appropriate cryoprotective agent and freezing the cells to the appropriate temperature
• For frozen cells used for autologous or allogeneic transfusion, first thawing and washing to remove the cryoprotective agent

For more information, please see CSA Z902-10, 7.5.

Appropriateness

16.3 The team follows SOPs for storing, freezing, and thawing plasma.

Guidelines

Specific requirements for plasma include:
• Freezing at <= -18 degrees Celsius for up to 12 months
• Thawing at 30-37 degrees Celsius using an approved and appropriate process
• Storing at 1-6 degrees Celsius
• Using within 24 hours, or five days (whichever is applicable to the product)

For more information on plasma and specific information on cryoprecipitated antihemophilic factor and Cryosupernatant plasma, please see CSA Z902-10, 7.6.

Appropriateness

16.4 The organization stores platelets and pooled platelets and apheresis platelets at 20-24 degrees Celsius with gentle agitation for up to five days.

Appropriateness

16.5 The organization stores granulocytes at 20-24 degrees Celsius without agitation for up to 24 hours.

Safety

16.6 The team isolates blood products and blood components from donor and recipient samples, tissues for transplantation, or blood centre reagents.

Guidelines

Isolation may be accomplished using separate storage equipment or by clearly identifying isolated areas within one piece of storage equipment.

17.0 The team preserves blood components and blood products during packing and transport.

Safety

17.1 The team visually inspects each blood bag and documents that it is free from leakage or abnormalities, and is within the expiration date.

Safety

17.2 The team affixes a label to the shipping container that indicates the site of origin and final destination, a notice that human blood components are contained within, and any other cautions or descriptions required by federal, provincial/territorial or local transport regulations.

Appropriateness

17.3 The team maintains the specified environmental conditions at all times when packing and transporting blood components and blood products.

Guidelines

All blood components and blood products with a stated storage temperature of 1-6 degrees Celsius may be transported between 1-10 degrees Celsius if the transit time is under 24 hours. Blood components that can be stored between 20-24 degrees Celsius must be transported within that same temperature interval. All frozen components and products must be transported at a temperature that preserves their frozen state. Overall transportation time should not exceed the limit of the validated transport container. For more information on transporting blood components and blood products, please see CSA Z902-10, 9.5.2.

Appropriateness

17.4 The team verifies that each shipment of blood component and blood product is accompanied by a standardized, comprehensive release voucher.

Guidelines

The standardized release voucher includes:
- Name of the receiving site
- Unique serial number
- Description of the blood component and blood product being shipped, including a notice of quarantined products if applicable
- Donation numbers of each blood component and blood product
- Total number of items
- Date and time
- Identity and signature(s) of the individual(s) responsible for packing

For more information, please see CSA Z902-10, 9.5.2.7.

Appropriateness

17.5 If blood components or blood products are sent with a client from facility to facility, the team notifies the receiving transfusion team, and is responsible for the component or product until it reaches the receiving organization.

Guidelines

The receiving transfusion team is responsible for communicating with the sending team to confirm transfusion or traceability of the product to its final disposition (e.g., disposal). For more information, please see CSA Z902-10, 9.5.2.8.

Appropriateness

17.6 The team follows an SOP when transporting blood components and blood products within the organization.

Guidelines

The SOP for transporting blood components and blood products within the organization defines who is authorized or may sign out blood components and blood products and transport them to the recipient's location, the acceptable time intervals for transportation and from release to transfusion, and the proper processing and storage requirements. For more information, please see CSA Z902-10, 9.5.3.

18.0 The team releases only safe blood components and blood products for use.

Safety

18.1 The team follows an SOP for releasing blood components and blood products for use.


Safety

18.2 Immediately prior to release, the team visually inspects and documents all blood bags for leakage or other abnormalities.

Guidelines

Blood bags should not be released from inventory if visual leakage or abnormalities are discovered. For more information, please see CSA Z902-10, 10.10.2.


Safety

18.3 The team is able to demonstrate that all of the requirements for collecting, processing, and testing blood components have been met prior to release.

Guidelines

For more information, please see CSA Z902-10, 9.2 and 9.3.


Safety

18.4 When tested blood components are not available, the organization has a policy for releasing untested blood components in emergency situations that requires the inclusion of a comprehensive release voucher, documented client informed consent, and documented approval of the recipient's attending physician.

Guidelines

The release voucher includes:
- A statement that the blood has not been fully tested
- The results of any tests that have been completed to date
- Lists of tests not yet completed

For more information, please see CSA Z902-10, 9.3.


Safety

18.5 When untested blood is released, the team immediately communicates the results to the appropriate team members when they are received from the appropriate organization.

Guidelines

Outstanding testing may be completed by Canadian Blood Services, or Héma-Québec, depending on the jurisdiction.


Safety

18.6 The team maintains a record of each case where blood is released prior to completion of testing.

Guidelines

Each record contains the following:
• Reason for release prior to completion of testing
• Confirmation that no tested blood components for the intended recipient were available
• Approval of the recipient's attending physician, as well as the authorized team member
• All testing information completed prior to and following release

For more information, please see CSA Z902-10, 9.3.5.


Safety

18.7 The team stores blood components that do not meet criteria for release in an identified and secured quarantine location until they are released from quarantine or are disposed of appropriately.

Guidelines

Procedures for storage include quarantining blood components that do not meet criteria for release to prevent unintended release prior to authorization and completion of mandatory testing with acceptable results. Blood components without this authorization are properly stored in an identified and secured quarantine location. This procedure includes instructions on who in the blood bank is responsible for release from quarantine. If acceptable results are not achieved, the team disposes of the blood components, as well as any other labelled "not for use" for any reason, in compliance with provincial/territorial or local laws and regulations. For more information, please see Z902-10, 9.4.

PROVIDING SAFE AND TIMELY TRANSFUSION SERVICES

19.0 The team responds to requests for blood components and blood products in a timely way.

Appropriateness

19.1 The organization has a transfusion committee that provides consultation and support on transfusion practices and activities.

Guidelines

The transfusion committee:
- Helps to define blood transfusion policies to the local clinical activities
- Ensures that regular evaluations of blood transfusion practices are conducted
- Sets criteria for evaluating ordering practices, usage, administration policies, and the ability of services to meet recipient needs
- Recommends corrective measures if necessary
- Disseminates transfusion medicine information and education
- Evaluates reports of adverse reactions and transfusion errors within the facility, as well as relevant federal and provincial or territorial reports on adverse transfusion events
- Reviews available alternatives to allogeneic blood transfusion and makes appropriate recommendations on their use

For more information on the transfusion committee, please see CSA Z902-10, 4.4.

Appropriateness

19.2 The team has an SOP for handling requests for blood components and blood products.

Guidelines

For more information on requesting blood components and blood products, please see CSA Z902-10, 10.1 and 10.2.1.

Appropriateness

19.3 The team follows an SOP for responding to verbal requests.

Guidelines

The SOP ensures that verbal requests are verified using a read-back process and followed by a request form within a timeframe set by the organization.

Appropriateness

19.4 The team responds to written or electronic requests that are complete, accurate, and legible.

Guidelines

Blood components and blood products, including the rate of infusion, must be prescribed by a practicing physician, or health professional functioning within their scope of practice.

A written or electronic request for the component or product must contain at a minimum:
- Recipient's first and last name
- Recipient's identification number
- Recipient's location
- Type of product being requested, e.g. whole blood, platelets
- Volume of the product needed

For more information on requesting blood components and blood products, please see CSA Z902-10, 10.2.1.

Safety

19.5 The organization has an SOP for verifying the recipient's identity using two client identifiers.

Guidelines

This is SOP is required in order to verify the recipient's identity before taking blood samples and processing the transfusion request, as well as for urgent requests or other situations where the recipient's identity is unknown. If discrepancies in identifying the recipient are detected, the processing of the request is halted and no blood samples collected until the identification is unmistakably resolved. For more information, please see CSA Z902-10, 10.2.2 to 10.2.4.

20.0 **The team performs the appropriate tests and correctly identifies and selects the appropriate blood components and blood products for transfusion.**

Appropriateness

20.1 The team member taking the recipient's blood follows SOPs for taking blood samples.

Guidelines

The SOP should include documenting the date and time and the name and a unique identifier of the team member responsible for taking the recipient's blood sample.

For more information, please see CSA Z902-10, 10.3.1.

Appropriateness

20.2 The team member taking the recipient's blood takes enough blood samples to conduct the necessary tests, and records the information in the recipient's file.

Safety

20.3 The team member taking the recipient's blood labels the samples in the presence of the recipient, and verifies that all samples and all documentation are clearly linked to the recipient and his or her blood samples.

Guidelines

For more information, please see CSA Z902-10, 10.3.2.

Safety

20.4 The team verifies all labels and accompanying documents, and requests a new sample if there are any discrepancies.

Guidelines

For more information, please see CSA Z902-10, 10.3.3.

Appropriateness

20.5 The team takes the recipient's blood sample within 96 hours of transfusion if the recipient has been pregnant within the last three months; if the recipient's history is uncertain or unavailable; or if the recipient has received a transfusion of red cells or a component containing red cells within the previous three months.

Guidelines

For more information, please see CSA Z902-10, 10.4.1.

Appropriateness

20.6 The team follows SOPs for testing the recipient's blood and does not proceed with transfusion until any discrepancies are resolved.

Guidelines

For more information on testing the recipient's blood, please see CSA Z902-10, 10.4.4 to 10.4.8.

Safety

20.7 Before transfusing red cells, the team follows SOPs for cross-matching the donor's and recipient's blood to verify compatibility.

Guidelines

For more information on testing recipient blood, please see CSA Z902-10, 10.4.5 to 10.4.6.

Appropriateness

20.8 Based on the results of the compatibility testing and known client history, the team selects the appropriate components for transfusion.

Guidelines

Selecting the appropriate components includes ensuring that the donor's whole blood is ABO-specific or that red blood cells are ABO-compatible.

Rh-positive clients may receive both Rh-positive or Rh-negative whole blood and red blood cells. Rh-negative clients should receive Rh-negative products, but may receive Rh-positive when Rh-negative units are unavailable or in short supply, with the medical director's approval and with respect to approved policies.

If the recipient has clinically significant red cell antibodies, or a history of such antibodies, the recipient receives blood that is demonstrated to be free of the corresponding antigen using cross-matching methods, except in certain clinical exceptions approved by the medical director.

For more information on selection of blood components, please see CSA Z902 -10, 10.7.

Appropriateness

20.9 The team follows specific SOPs for selecting and handling components for infants.

Guidelines

In the case of infants under four months, a pre-transfusion sample is collected to conduct the ABO and Rh blood groupings and to detect clinically significant red cell antibodies. For ABO grouping, only testing with anti-A and anti-B reagents is required; if the infant is to receive A, B, or AB red cells, the serum or plasma is first tested for maternally derived anti-A or anti-B, using an antiglobulin test or equivalent.

Similar to an adult, if anti-A or anti-B is found, the team chooses appropriate blood that is free from the corresponding ABO antigens. ABO and Rh groupings do not need to be repeated for the duration of the infant's hospital admission. To detect clinically significant red cell antibodies, the serum or plasma of either the infant or his/her mother can be used and, if present, the appropriate donation must be used until antibodies are no longer detected.

If the infant is negative for red cell antibodies, cross-matching need only be done to ensure ABO compatibility, and the transfusion service does not need to repeat the screens during the infant's hospital admission.

The team selects and/or processes the appropriate cellular blood components to reduce the risk of CMV transmission in the following situations: intrauterine transfusions and infant transfusions when the recipient weighs less than 1200 g at birth and the infant or mother is CMV antibody-negative (or that information is unknown). If the infant requires massive transfusion that includes exchange transfusion, the transfusion service uses preferably only red blood cells that have been screened and are negative for hemoglobin S.

For more information on selection of blood components for infants, please see CSA Z902-10, 10.9.1.

Safety

! 20.10 In situations where delaying transfusion may cause harm to the recipient, the team follows SOPs for releasing blood components for which infectious disease testing and/or pre-transfusion compatibility testing is incomplete.

Guidelines

In emergent or urgent cases (e.g., when delaying transfusion may cause harm to the recipient), the team may use blood components that have not been fully tested for infectious diseases or use blood when the recipient's pre-transfusion samples have not been fully tested or cross-matched. In these cases, the team complies with existing standards for the release of untested blood components.

If blood components are released prior to completing infectious disease testing or pre-transfusion testing, the blood bag is appropriately labelled and the team records the requesting physician's authorization stating it was significantly urgent to release the blood components prior to completion of testing. All compatibility testing is completed as soon as possible, and any incompatibilities reported immediately. For more information on emergency transfusions, please see CSA Z902-10, 10.9.3.

In the case of massive transfusion, the team's SOPs established by the medical director may dictate that pre-transfusion testing be abbreviated. For more information on massive transfusions, please see CSA Z902-10, 10.9.2.

Appropriateness

20.11 For each red cell component or whole blood unit selected, the team stores an aliquot of red cells and the recipient's pre-transfusion sample under appropriate environmental conditions for at least seven days.

Guidelines

The recipient's pre-transfusion sample is stored between 1-6 degrees Celsius.

For more information, please see CSA Z902-10, 11.1.2.5.

21.0 The team obtains the recipient's free and informed consent according to the organization's policy, prior to transfusion.

Safety

21.1 The team has access to the most up-to-date information about the risks associated with transfusion.

Guidelines

This information may be provided in the form of a checklist.

For more information, please see CSA Z902-10, 11.2.3.

Safety

21.2 The team provides the recipient with information that includes a description of the blood component and/or blood product, the risks and benefits associated with transfusion, and any alternatives including their risks and benefits.

Guidelines

For more information, please see CSA Z902-10, 11.2.1.

In the case of an emergency, where it is deemed necessary to provide the recipient with blood components that have not been fully tested for infectious diseases, or prior to completing pre-transfusion testing of the recipient's sample, the team explains these risks to the recipient, and, if possible, obtains the recipient's free and informed consent.

For more information, please see CSA Z902-10, 10.9.3.5.

When services are provided in the home, the team member explains the increased risks associated with receiving a transfusion in the home environment prior to obtaining the recipient's free and informed consent.

For more information, please see CSA Z902-10, 17.3.2.

Client-centred Services

21.3 There is a procedure for notifying recipients about the blood product(s) they received that includes documenting the notification in the client record.

Guidelines

In order to be fully informed about the care and treatment they have received, it is important that recipients are aware that they have been administered a blood product, in addition to the consent they provide prior to a procedure. The team has a procedure in place to provide information to recipients about the blood products they have received that includes documenting the information provided in the client record. The procedure should be consistent throughout the organization and apply across care settings. Written or verbal notification can come from the care team, or blood bank team, at the time of administration, discharge, or transfer or in a systematic way according to a schedule for those requiring frequent transfusions.

Client-centred Services

21.4 The team documents the client's consent in the client record.

Client-centred Services

21.5 When clients are incapable of giving free and informed consent, the team refers to the client's advance directives if available, or obtains consent using a substitute decision-maker.

Guidelines

Clients who are incapable of providing consent may have advance directives to guide certain or all decisions. The team records advance directives in the client record and shares this information with the appropriate team members in and outside of the organization as appropriate.

The team may also consult with a substitute decision-maker when clients are unable to make their own decisions. In these cases, the team provides the substitute decision-maker with information on the roles and responsibilities involved in being a substitute decision-maker, and discusses questions, concerns, and options. A substitute decision-maker may be specified in legislation, or may be an advocate, family member, legal guardian, or caregiver.

If consent is given by a substitute decision-maker, his or her name, relationship with the patient, and the decision made is recorded in the client record.

22.0 Team members providing transfusion services follow SOPs when transfusing blood components and blood products.

Appropriateness

22.1 The team follows SOPs for administering blood components and blood products, and using infusion devices and any other transfusion-related equipment approved by Health Canada.

Guidelines

For more information on SOPs for transfusion of blood components and blood products, please see CSA Z902-10, 11.1.1, 11.4.

The SOP also has instructions on which recipients should receive cellular blood components chosen or processed to reduce the risk of CMV transmission, irradiated blood components, and Rh globulin.

The following categories of clients should receive irradiated components:
• Certain immuno-compromised recipients
• Recipients receiving blood components from a known blood relative
• Recipients who have had hematopoietic progenitor cell (stem cell) transplantation
• Recipients of HLA-selected platelets or platelets known to be HLA homozygous

For more information on which clients should receive which components, please see CSA Z902-10, 11.6, 11.7, and 11.9.

The transfusion service provides Rh-globulin to all women at 28 weeks gestation as well as within 72 hours of delivery, abortion, amniocentesis, or other procedure that could cause fetomaternal hemorrhage, unless the fetus is confirmed to be Rh-negative, or, there is evidence of immunization to D unrelated to Rh-immune globulin therapy. If not provided within 72 hours of delivery, Rh-globulin may be provided up to 28 days following delivery. The team takes a postpartum maternal blood sample from Rh-negative women at risk for fetomaternal hemorrhage to detect the need for more than a single dose of Rh-immune globulin.

For more information, please see CSA Z902-10, 11.9.4 to 11.9.6.

Safety

ROP

22.2

REQUIRED ORGANIZATIONAL PRACTICE: Working in partnership with clients and families, at least two person-specific identifiers are used to confirm that clients receive the service or procedure intended for them.

Guidelines

Using person-specific identifiers to confirm that clients receive the service or procedure intended for them can avoid harmful incidents such as privacy breaches, allergic reactions, discharge of clients to the wrong families, medication errors, and wrong-person procedures.

The person-specific identifiers used depends on the population served and client preferences. Examples of person-specific identifiers include the client's full name, home address (when confirmed by the client or family), date of birth, personal identification number, or an accurate photograph. In settings where there is long-term or continuing care and the team member is familiar with the client, one person-specific identifier can be facial recognition. The client's room or bed number, or using a home address without confirming it with the client or family, is not person-specific and should not be used as an identifier.

Client identification is done in partnership with clients and families by explaining the reason for this important safety practice and asking them for the identifiers (e.g., “What is your name?”). When clients and families are not able to provide this information, other sources of identifiers can include wristbands, health records, or government-issued identification. Two identifiers may be taken from the same source.

Test(s) for Compliance

Major	22.2.1	At least two person-specific identifiers are used to confirm that clients receive the service or procedure intended for them, in partnership with clients and families.

Safety

	22.3	Immediately prior to transfusion, and in the presence of the recipient, the team verifies and documents that the blood components or blood products matches the compatibility label/tag and that all identifying information linking the recipient and the blood component or blood product matches.

Guidelines

The recipient's identity, the blood component or blood product, and all accompanying documentation are reviewed and verified by the team member providing the transfusion, in the physical presence of the recipient. Any inconsistency must be resolved before the transfusion can take place. For more information, please see CSA Z902-10, 11.3.

A compatibility label/tag should be securely attached to all blood components issued that includes:
- Recipient's family and given name(s)
- Identification number
- Rh of the recipient
- Compatibility status
- ABO group
- ABO group of the blood component
- Identification number of the blood component
- Type of blood component
- Date and time of issue.

Safety

22.4 The team stores blood components and blood products under controlled conditions at an optimal temperature up until the time of transfusion.

Guidelines

The team stores blood awaiting transfusion according to established controlled storage requirements (e.g., when outside the blood bank, in places such as the operating room).

For more information, please see CSA Z902-10 Table 2 for specific environmental storage conditions for blood components.

Unused whole blood and red blood cells may be returned to inventory if they have been outside the controlled environment for less than 30 minutes, or if a suitable temperature monitoring system indicates they have been maintained within acceptable temperatures since their release.

For more information, please see CSA Z902-10, 11.4.7.

Population Focus

22.5

At the time of transfusion, the team member providing the transfusion verifies the acceptability of the blood components and/or blood products and the recipient's special requirements, if applicable.

Guidelines

The team verifies that the current blood component is irradiated and there is a mechanism to verify the patient receives irradiated product in future. The team may use irradiated blood for recipients even if not required. For more information, please see CSA Z902-10, 11.7.3 and 11.7.4.

Safety

22.6

The team provides transfusions using a sterile, pyrogen-free administration set.

Guidelines

Prior to transfusion, the appropriate team member should fill the administration line and the filter with a compatible solution such as 0.9% sodium chloride (NaCl). Air should be kept from entering the blood bag and the administration set at all times. For repeated transfusions, the administration set should be changed a minimum of every 24 hours, or as recommended by the manufacturer. The administration set should also be changed after every four units for red cells or in the event of occlusion. For more information, please see CSA Z902-10, 11.4.

If warming is required, the team uses a validated and approved device that will not cause clinically significant hemolysis and meets national or provincial safety standards. All devices used for warming blood during transfusion are equipped with alarms to alert staff to temperatures outside the accepted range. For more information, please see CSA Z902-10, 11.5.

In the case of transfusion of granulocytes, the team does not use microaggregate or leukocyte-reduction filters in the administration set. For more information, please see CSA Z902-10, 11.8.

Safety

22.7 The team member providing the transfusion does not add any drugs or medications to blood components and blood products, even those meant for intravenous use.

Guidelines

For more information, please see CSA Z902-10, 11.4.11.

Appropriateness

22.8 Throughout the transfusion, the team member providing the transfusion verifies that all clinical and identifying information attached to the blood bag remains intact.

Guidelines

For more information, please see CSA Z902-10, 11.3.4.

Safety

22.9 If transfusing whole blood or red blood cells, the team member providing the transfusion completes the transfusion within four hours of the unit's removal from the controlled-temperature environment.

Guidelines

For more information, please see CSA Z902-10, 11.4.6.

Safety

22.10 The team member providing the transfusion continues monitoring the recipient for complications during and after transfusion.

Guidelines

Monitoring the recipient before, during, and following transfusion includes ongoing monitoring and recording of vital signs. If direct observation of the recipient is not possible following transfusion, the appropriate team member provides the recipient or their caregiver with information and instructions regarding possible adverse transfusion events, including adverse reactions. For more information, please see CSA Z902-10, 11.4.13 and 11.4.14.


Safety

22.11 The team member providing the transfusion follows an SOP to quickly inform the appropriate team members of all signs or symptoms that may be associated with a transfusion-related adverse event.

23.0 When providing transfusion services in the home, team members follow SOPs for transfusing blood safely and monitor clients for complications.


Appropriateness

23.1 The organization has SOPs for home transfusion services.

Guidelines

Transfusion in the home poses risks due to the distance from emergency medical services and the need for the team to respond to adverse transfusion events with limited resources.

The team follows all applicable SOPs for obtaining free and informed consent, conducting pre-transfusion testing and selecting appropriate blood components, transporting blood components, completing transfusion, handling adverse transfusion events, and disposing of biohazardous waste. For more information, please see CSA Z902-10, 17.1.


Safety

23.2 The organization establishes eligibility criteria for recipients of home transfusion services.

Guidelines

Only clients who have received a blood transfusion in the past and who have not experienced an adverse reaction are eligible. The recipient may have clinically significant alloantibodies to red cells; however, the antibody specificities are clearly identified with no outstanding tests or discrepant serologic findings. For more information, please see CSA Z902-10, 17.2.

Safety

23.3 The organization verifies that home transfusion services are provided only to eligible recipients that meet the established eligibility criteria and when absolutely necessary.

Guidelines

Home transfusion services are provided only when it is expected that the overall benefits of choosing the home setting will outweigh the risks (distance from emergency medical services, and the need to respond to adverse transfusion events with limited resources). The team member providing the transfusion advises the recipient of all increased risks associated with home transfusion. For more information, please see CSA Z902-10, 17.1.1 and 17.3.2.

Worklife

23.4 The organization verifies that all team members providing home transfusion services are health professionals functioning within their scope of practice with formal home transfusion training, experience in providing blood and transfusions, and training and experience in recognizing and managing adverse transfusion events.

Guidelines

Both acute and community-based care experience is desirable. For more information, please see CSA Z902-10, 17.1.1 and 17.1.5.

Safety

23.5 Prior to providing home transfusion services, the team member providing the transfusion evaluates the safety of the home environment.

Guidelines

A safe home environment includes access to a working telephone to call emergency assistance if needed; access to a physician via telephone for immediate consultation if urgent care is required; and the necessary medications that might be needed to treat an adverse transfusion reaction. These medications should be used only when specified by a physician's prescription and their use is governed by a written protocol. For more information, please see CSA Z902-10,17.2.4, 17.6.2, and 17.6.4.

Continuity

23.6 While providing transfusion services in the home, the team member providing the transfusion has access to another competent adult who can assist throughout the duration of the transfusion and remain available to assist the recipient for at least 60 minutes following transfusion.

Guidelines

For more information, please see CSA Z902-10, 17.2.5.

Continuity

23.7 The team member providing the transfusion remains in the home and monitors the recipient for complications for at least 30 minutes after the transfusion.

Guidelines

For more information, please see CSA Z902-10, 17.6.5.

24.0 The team maintains an accurate, accessible, and up-to-date record of each transfusion.

Appropriateness

24.1 The team follows SOPs to generate and maintain an accessible record for each transfusion.

Appropriateness

24.2 The team's record system generates a standardized transfusion tag that contains the necessary identification and clinical information.

Guidelines

The transfusion tag, sometimes an issue voucher, contains at least the following:

- Recipient's full name and unique identifier
- Recipient's ABO group for red cells, plasma, cryoprecipitate, and platelets
- Recipient's Rh group, for red cells, granulocytes, and platelets
- Recipient's compatibility status for red cells and granulocytes
- Date and time of the bag's issue from inventory
- Unit's number, or pooled unit number, as appropriate.

The tag is securely attached to the bag and is not removed at any time. For more information, please see CSA Z902-10, 11.1.2.2.


Safety

24.3 Using the records system, the team is able to trace all blood bags as well as accompanying documentation, from their original receipt to final destination (e.g., transfusion, further manufacturing, or destruction).

Guidelines

Tracing is accomplished using a numeric or alphanumeric labelling identification system on the blood bag itself, or the accompanying set of records that travels with the blood bag throughout the process. This system allows any team member to locate and access the necessary records related to a given unit as needed.

No more than two unique identifiers should be visible on the blood bag: one applied at the original collecting facility, and one applied by the intermediate shipping or transfusing facility if applicable. A compatibility label/tag should be securely attached to all blood components issued. For more information, see CSA Z902-10, 11.1.2.1 and 8.6.2.


Safety

24.4 The team completes and maintains an up-to-date transfusion record for each blood component or product, or pooled or mixed component or product.

Guidelines

The complete transfusion record contains all of the information on the transfusion tag, as well as the date and time of transfusion, the team member responsible for providing the transfusion, and any adverse reactions to the transfusion. For more information, please see CSA Z902-10, 11.1.2.3.

Safety

24.5 Following transfusion, the team updates the recipient's medical record to include the type of blood component and/or blood product transfused, the date and time of transfusion, the identity of the team member who provided the transfusion, and all transfusion-related adverse reactions.

Guidelines

For more information, please see CSA Z902-10, 11.1.2.4.

Appropriateness

24.6 The team follows SOPs for retaining records.

Guidelines

This includes complying with federal, provincial or territorial regulations and standards set by organizations such as the Canadian Society for Transfusion Medicine and the Canadian Standards Association.

For transfusion recipient records, federal, provincial, and territorial regulations and/or standards require keeping:
- The recipient transfusion file, release vouchers, all transfusion records, and records of serious recipient adverse transfusion events indefinitely
- Records of all other transfusion events for five years
- Transfusion requests forms for serological tests for one month
- Records of non-transfusion serological tests results for three years
- All look-back or trace-back process records indefinitely
- Records of temperature storage, quality control testing, quality assurance reports, internal audits, and product complaints for five years
- Slides from the Kleihauer-Betke Acid-Elution test for three months

For more information, please see CSA Z902-10, 20.6.3 and 20.6.4.

MONITORING THE SAFETY AND QUALITY OF TRANSFUSION SERVICES

25.0 The team collects and uses indicator data to guide its quality improvement initiatives.

Client-centred Services

25.1 The team collects information and feedback from clients, families, staff, service providers, organization leaders, and other organizations about the quality of its services to guide its quality improvement initiatives.

Guidelines

The team gathers information and feedback in a consistent manner from its key stakeholders about the quality of its services. Feedback, in the form of client and family satisfaction or experience data, complaints, indicators, outcomes, scorecards, incident analysis information and financial reports, may be gathered by a variety of methods, including surveys, focus groups, interviews, meetings, or records of complaints.

Appropriateness

25.2 The team uses the information and feedback it has gathered to identify opportunities for quality improvement initiatives.

Guidelines

The team uses feedback as well as other forms of information, and observation and experience, to identify and prioritize areas for quality improvement initiatives. This is done using a standardized process based on criteria such as client-reported outcomes, risk, volume, or cost.

Appropriateness

25.3 The team identifies measurable objectives for its quality improvement initiatives and specifies the timeframe in which they will be reached.

Guidelines

Quality improvement objectives define what the team is trying to achieve, and by when. Appropriate quality improvement objectives have targets that exceed current performance. Quality improvement objectives are typically short term and are aligned with longer-term strategic priorities or patient safety areas. The timeframe will vary based on the nature of the area for improvement.

The SMART acronym is a useful tool for setting meaningful objectives, in that they should be Specific, Measurable, Achievable, Realistic, and Time-bound. The United States Centers for Disease Control and Prevention offers a guide to writing SMART objectives.

Appropriateness

25.4 The team identifies the indicator(s) that will be used to monitor progress for each quality improvement objective.

Guidelines

The team uses indicators to monitor whether the activities resulted in change and if the change is an improvement. Primarily, indicators are selected based on their relevance and ability to accurately monitor progress. When there are multiple potential indicators, the team uses criteria to select indicators, such as scientific validity and feasibility. If the team has difficulty selecting indicators, it may mean the quality improvement objective needs further clarification.

Appropriateness

25.5 The team participates in external quality control programs through proficiency testing and inter-laboratory comparisons, where available.

Guidelines

Where proficiency testing programs are not available, the team should implement processes to verify the accuracy of testing results. The results should be reviewed by the team's managers and analyzed for trends or patterns. If nonconformities are identified, corrective actions should be taken to make improvements.

Appropriateness

25.6 The team designs and tests quality improvement activities to meet its objectives.

Guidelines

Quality improvement activities are the actions used to initiate improvements, and are part of the larger quality improvement plan. Activities are first designed and tested on a small scale to determine their effect prior to implementing them more broadly.

The Getting Started Kit for Improvement Frameworks is a resource created by the Canadian Patient Safety Institute and is based on the Model for Improvement. The Institute for Healthcare Improvement offers a framework to guide quality improvement activities using Plan, Do, Study, Act cycles.

Appropriateness

25.7 The team collects new or uses existing data to establish a baseline for each indicator.

Guidelines

Establishing a baseline reference point makes it possible to monitor progress towards meeting quality improvement objectives by comparing pre- and post-activity data and noting changes. Establishing a baseline may require one or many data points, and occurs over a defined period of time. Once the baseline is established, the team may need to reevaluate their quality improvement objectives to ensure they remain feasible and relevant.

Appropriateness

25.8 The team follows a process to regularly collect indicator data to track its progress.

Guidelines

The team determines how the data will be collected and how often it will be collected. Regularly collecting data allows the team to track its progress over time and understand the normal variation of values.

Appropriateness

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25.9 The team regularly analyzes and evaluates its indicator data to determine the effectiveness of its quality improvement activities.

Guidelines

The team compares the intended and actual effects of its quality improvement activities, and, if the objective has not been achieved, adjusts its actions accordingly to meet the objective.
Analyzing data identifies trends and may reveal service areas that may need to be considered for quality improvement initiatives. Indicator data collected over time can be displayed in a run chart or control chart, both of which are valid means of data analysis. Safer Healthcare Now! offers Patient Safety Metrics, a web-based tool where organizations can submit data on various interventions, analyze results over time, and generate reports.
If it is not within the team's capacity to analyze the data, it seeks qualified internal or external assistance.

Appropriateness

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25.10 The team implements effective quality improvement activities broadly.

Guidelines

The team broadly implements the quality improvement activities that were shown to be effective in the testing phase. The way in which the team implements activities broadly will vary based on the scope and scale of the team's services and considers the timeframe, e.g., an effective activity is implemented in more than one area of care and for a longer period of time.

Population Focus

25.11 The team shares information about its quality improvement activities, results, and learnings with clients, families, staff, service providers, organization leaders, and other organizations, as appropriate.

Guidelines

The team tailors the information to the audience and considers the messaging and language level that is appropriate for each audience.

Sharing the results of evaluations and improvements helps staff, service providers, and stakeholders become familiar with the philosophy and benefits of quality improvement and engages the organization's leaders in the process. It also helps the organization to spread successful quality improvement activities within and outside the organization and demonstrate its commitment to ongoing quality improvement. Among other benefits, sharing indicator data externally allows for comparison with organizations offering similar services.

Appropriateness

25.12 The team regularly reviews and evaluates its quality improvement initiatives for feasibility, relevance and usefulness.

Guidelines

The team regularly reviews and evaluates its quality improvement initiatives, including its activities, objectives, and indicators. The team uses the information to plan its future quality improvement initiatives including how and when to sustain or spread existing initiatives within the organization. The team considers outcomes of the quality improvement initiatives as they align with the organization's overall quality improvement plan, goals and objectives, mission and values, and strategic plan. The team evaluates whether objectives were met within their timeframes and whether the timeframes remains relevant.

Based on the review of the initiatives, objectives and indicators may be added, amended, or removed as appropriate. The rationale for amending or removing them is documented.

26.0 The team identifies, reports, evaluates, and follows-up on all adverse transfusion events.

Appropriateness

26.1 The team follows SOPs for identifying, reporting, evaluating and following up on adverse transfusion events.

Guidelines

Possible adverse transfusion events include immediate hemolytic reactions; delayed hemolysis reactions; transfusion-related acute lung injury; systemic allergic reactions, including anaphylactic shock; bacterial sepsis; other transfusion-transmissible infections; transfusion-associated graft-versus-host disease; post-transfusion purpura; other severe reactions; and death. For more information, please see CSA Z902-10, 18.1.1, 18.2.1, 18.2.3, and 18.2.5.

Safety

26.2 The team has access to a list of common signs and symptoms to help identify transfusion-related adverse events.

Guidelines

For more information, please see CSA Z902-10, 18.2.1.

Safety

26.3 The team responds quickly to suspected hemolytic or other serious transfusion reactions, as well as suspected bacterial sepsis.

Guidelines

All serious adverse transfusion events should be promptly reported to the transfusion service.

In the case of suspected hemolytic transfusion reactions, the team member providing the transfusion should stop the transfusion as soon as possible and immediately begin an investigation; any remaining blood component should be returned to the transfusion service.

The investigation should include verifying the recipient's identification, the recipient's pre-transfusion specimen and associated testing, the matched blood component, and all other associated documents to eliminate the possibility of clerical error. It should also include collecting a new blood sample from the recipient for testing, ensuring that hemolysis is avoided during collection. Minimum testing should include a visual check for hemoglobin in plasma and a direct antiglobulin test. For more information, please see CSA Z902-10, 18.3.

In the case of suspected bacterial sepsis, the team member providing the transfusion should stop the transfusion, return all remaining product to the transfusion service, and begin an investigation, preventing further contamination.

The team should contact the blood centre to inform them of suspected bacterial sepsis to ensure other possibly implicated products can be quarantined. Microbiological investigation of blood components should be performed according to established guidelines. Blood cultures should also be taken from the recipient. Any bacterial strains isolated from the recipient or the blood unit should be kept for further analysis, if indicated.

For more information, please see CSA Z902-10, 18.4.

Safety

26.4 The team immediately reports all sentinel events and adverse transfusion events that can be attributed to the blood component or blood product to the blood supplier or blood product manufacturer.

Guidelines

In the case of events related or attributed to the blood component or blood product, the team should report the incident to the blood supplier within 24 hours. For a list of serious adverse events, please see CSA Z902-10, 18.2.1.


Safety

26.5 The team conducts investigations, including laboratory testing to determine the cause of the adverse transfusion event.

Guidelines

For more information, please see CSA Z902-10, 18.2.2.


Safety

26.6 The team documents appropriate corrective measures and takes action to prevent the recurrence of adverse transfusion events.

Guidelines

The team documents corrective measures that are put in place to prevent recurrences. The team uses information about adverse transfusion events to establish processes to prevent recurrences; this could include retraining or changing policies or procedures. For more information, please see CSA Z902-10, 18.1.2.


Safety

26.7 The team retains a copy of the investigation report and includes adverse transfusion event information, including recommendations for future transfusions, in the recipient's medical record.

Guidelines

The team should have a system in place for checking adverse transfusion event information if the recipient requires a subsequent transfusion. For more information, please see CSA Z902-10, 18.2.7.

27.0 **The team follows notification, lookback and recall SOPs for removing and disposing of unsafe blood components and blood products.**


Safety

27.1 The team follows SOPs for quarantining and destroying unsafe blood components and blood products.


Safety

27.2 If the team is notified by the blood supplier that an allogeneic donation is found positive for any transmissible disease agent, the team quarantines the blood in a separate area until they receive further instructions.

Guidelines

For more information on recalls of allogeneic donations found positive for transmissible disease agents, please see CSA Reference: Z902-10, 19.2.


Appropriateness

27.3 The team participates in investigations and tracebacks related to transfusion-transmissible diseases when needed.

Guidelines

As soon as the team is advised of a possible transmission of a transfusion-transmissible disease to a recipient, it supports traceability by providing the list of blood components and/or products that were transfused to the recipient. For more information on traceback procedures, please see CSA Reference: Z902-10, 18.5.


Safety

27.4 The team follows SOPs and a control system that allows for the complete and timely recall of any released blood components and blood products.

Guidelines

A recall is initiated any time the team receives information that questions the safety, quality, or efficacy of the final blood component or product. Recall procedures may be put into operation at any time, during or outside normal working hours. The recall SOPs identify those team members within the organization who are responsible for initiating and coordinating all recalls and associated activities. Any recalled blood components and blood products are identified, quarantined, and stored in a separate area until a decision is made regarding disposal. For more information, please see CSA Z902-10, 19.4.3 to 19.4.5.

Safety

27.5 The team follows SOPs for notifying the recipient(s) involved in the event of a lookback procedure.

Guidelines

When a lookback is performed, the supplier of blood products (i.e., Canadian Blood Services or Héma-Québec) or the blood centre informs the blood bank and transfusion team within 30 days. Once the team has been notified, it has 30 days to notify the recipient. If the recipient's physician is unable or unavailable to notify the recipient, this may be done by the team along with health care facility authorities. All documents outlining the recipient's notification are included in the recipient's medical record and are kept confidential. For more information, please see CSA Z902-10, 19.3.3 to 19.3.6.

Appropriateness

27.6 The team maintains a full record of all lookbacks and recalls.

Appropriateness

27.7 The team regularly monitors the effectiveness of its procedures for responding to lookback notifications and recalls and makes changes as needed.

Accreditation Canada would appreciate your feedback on these standards

Your Name: _____

Organization Name: _____

Email address or telephone number: _____

(A Product Development Specialist may contact you about your feedback.)

Feedback: Please indicate the name of the standard, as well as the criterion number in your comments. Please be as specific as possible in your comments.

For example: I would like to provide comments on the Long-Term Care Services standards, criterion 3.12. Clients should be included in this process. I suggest you change the wording to "The team engages staff, service providers, and clients in the process to plan services."

You may also submit your feedback online HERE

[YOUR COMMENTS HERE]

Thank you for your input! Please send this page to:
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