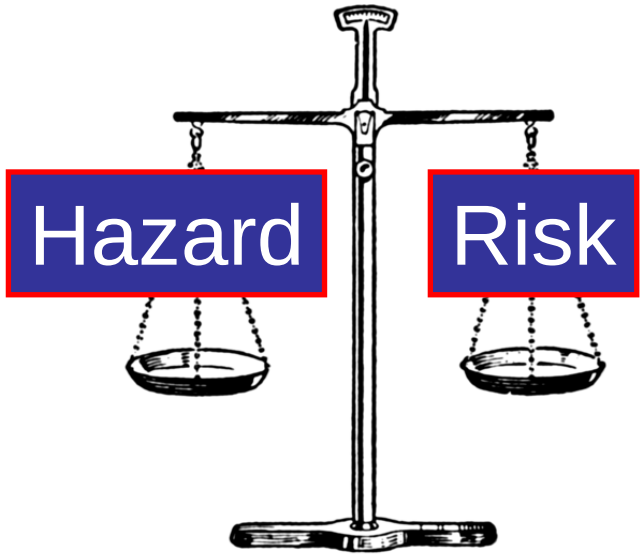
Dr David Roxby
College of Medicine & Public Health
Flinders University, SA
MTAAC Member

Is It a Risk or Hazard

- **Hazard:** something that can cause harm, e.g. electricity, chemicals, working up a ladder, noise, a keyboard, a bully at work, stress, etc.
- **Risk:** the chance, high or low, that any **hazard** will cause somebody harm, whether an employee or patient. For example, wrong blood in tube or incorrect results reported or working a solo shift can be a **hazard**.



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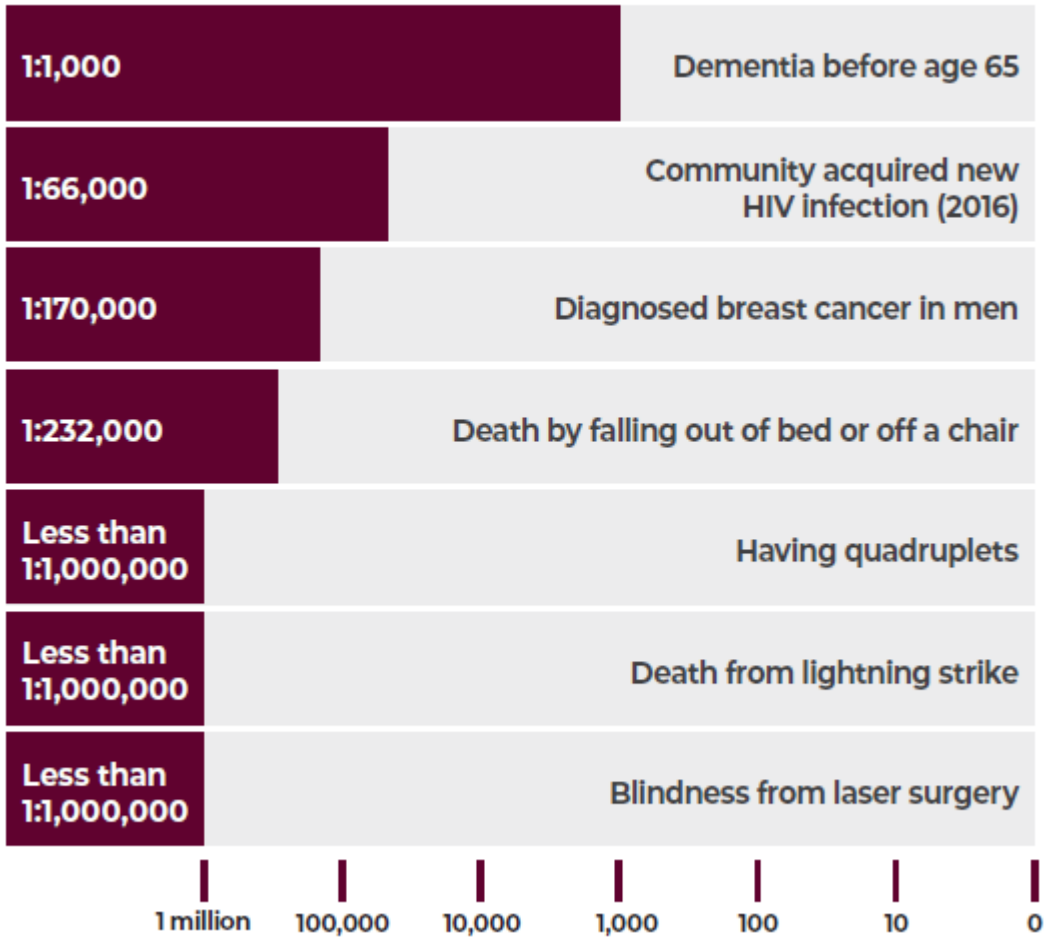
Australian Red Cross Lifeblood

Health risks

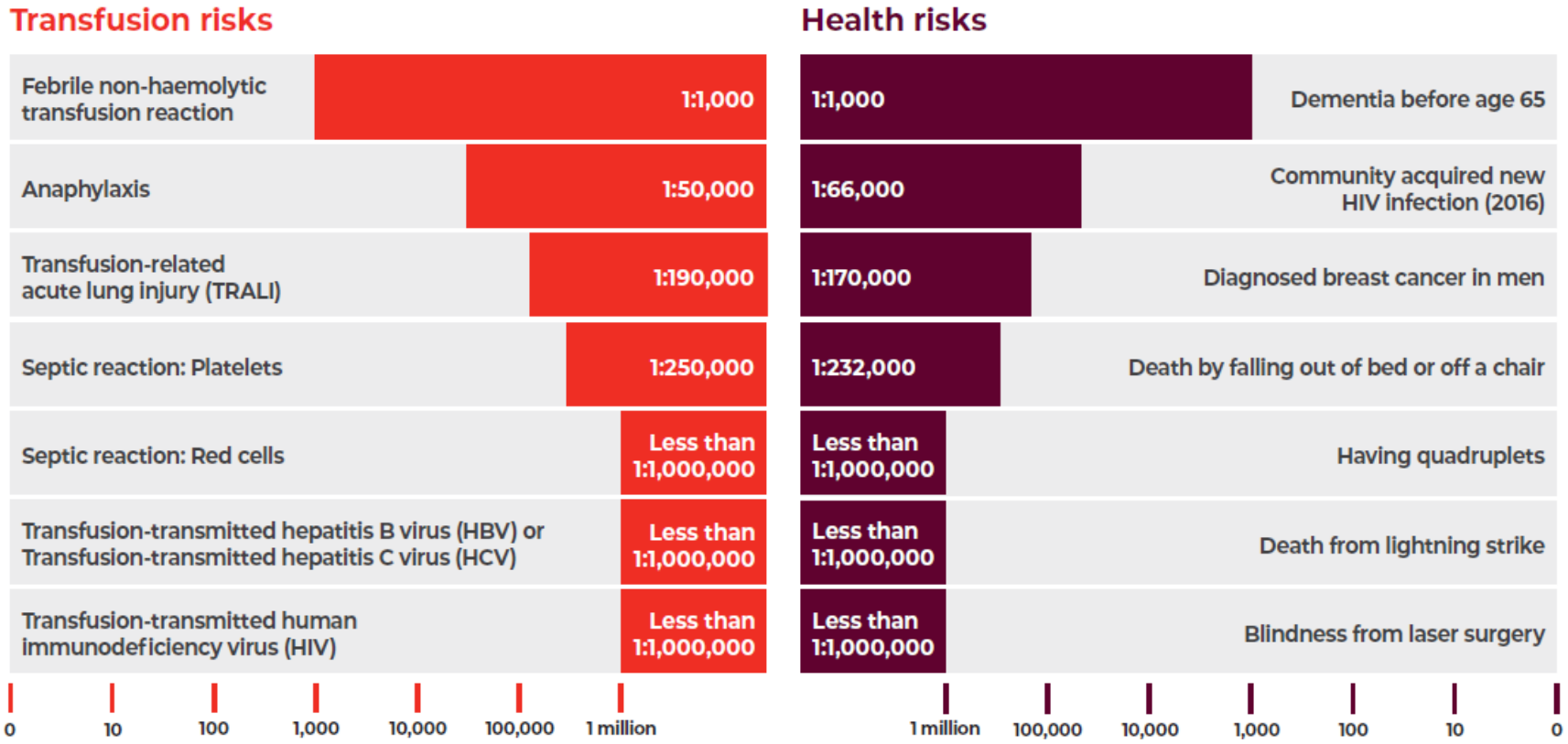


transfusion.com.au

Relative risk of transfusion

Australian Red Cross Lifeblood

The risks from receiving a single unit transfusion compared with other health risks, based on Australian statistics.



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Assessment of Risk

https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.smart-energy.com%2Findustry-sectors%2Fpolicy-regulation%2Fworlds-first-pas-risk-management-standard-utilities%2F&psig=AOvVaw1ZJ965PaShnsZe7HkBMLBT&ust=1596336683543000&source=images&cd=vfe&ved=2ahUKEwiWm_7Y__jqAhVBkuYKHdP_AoIQr4kDegUIARCBAg

How Does Risk Assessment Work?

- Each laboratory or organisation should have their own risk assessment process
  - Operations
  - Laboratory assessment non-conformances
- No set guidelines on how risk assessment should be carried out
- Understand the difference between hazard and risk
  - Identify the hazard
  - Decide who might be harmed
  - Evaluate the associated risks and develop a risk minimisation strategy
  - Record findings and actions
  - Activate
  - Review regularly (annually at least) – amend as necessary

Risk Rating for Operations & Non-Conformances

- Risk matrix
  - Mechanism to increase visibility of risk
  - Assist in decision making

- Level of risk determined through
  - Frequency of an event occurring &
  - Severity of that event
    - Low
    - Medium
    - High

Impact of findings on patient's results & their safety

Strategic and Operational Risk Assessment Matrix

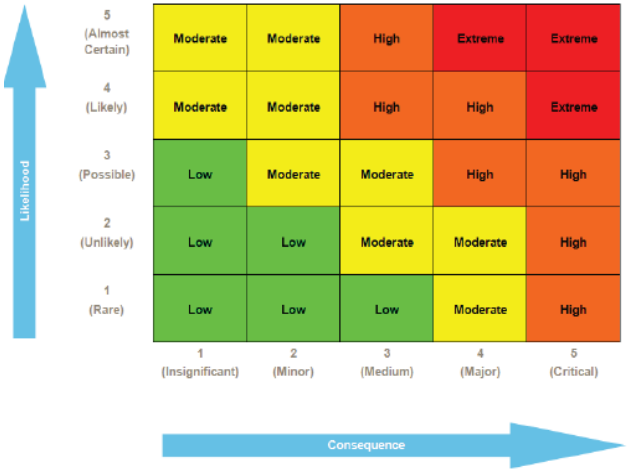
CONSEQUENCE (Impact) RATING GUIDE

Level	Category	Clinical	Financial	Our People	Legal, Policy and Regulatory	Organisation / Consumer	Corporate Reputation and Image
1	Insignificant	Negligible clinical event resolved without impact on Consumer or organisation	Financial loss of either less than $250,000 or 0.05% of budget	Negligible staff injury or near miss accident. Insignificant industrial grievance	Immaterial legal, regulatory or internal policy failure without penalty implication	Event with negligible impact on delivery of services to Consumers. Internal inconvenience only	One off negative media coverage only and no reputation impact
2	Minor	Clinical event resolved with minimal short term impact on Consumer or organisation	Financial loss of either between $250,000 to $1 million or between 0.05% to 0.2% of budget	Staff lost time injury. Local temporary poor engagement. Industrial grievance resolved internally	One-off minor legal, regulatory or internal policy failure resolved without penalty	Event with short term impact on delivery of services. Some impact on Consumers or Partners	Isolated adverse media exposure. Temporary minor negative impact on reputation
3	Medium	Clinical event resulting in temporary injury or impact with considerable effect on Consumer or organisation. Internal investigation required. May require external mediation	Financial loss of either between $1 to $5 million or between 0.2% to 1% of budget	Temporary injury to staff. Ongoing widespread engagement issues. Industrial disputation mediated with no major penalty	Repeated legal, regulatory or internal policy failure with penalty implications requiring internal investigation	Event requiring considerable remedial action with moderate impact on Consumers or Partners. Temporary loss of important information	Repeated isolated negative reporting in media. Temporary breakdown in key relationship. Short term reputation damage
4	Major	Clinical event resulting in serious permanent injury, requiring internal and medico legal investigation, external mediation, major penalties or compensation payments	Financial loss of either between $5 to $10 million or between 1% to 2% of budget	Serious permanent injury to staff. Entrenched engagement problems. Inability to recruit staff with necessary skills in key areas. Staff walkout and Industrial stoppages	Systemic legal, regulatory or internal policy failure with major penalty requiring extensive internal inquiry and external review	Event with major impact on delivery of services. Major impact on Consumers or Partners. Temporary loss of critical information	Widespread negative reporting in media leading to high-level independent investigation with adverse findings and longer term reputation damage. Premier or Ministerial involvement / intervention by Cabinet. Breakdown in key relationship(s)
5	Critical	Failure in clinical governance processes/ systems resulting in fatality requiring extensive internal and medico legal investigation, coroner's notification, significant penalties or compensation payments	Financial loss of either greater than $10 million or 2% of budget	Staff fatality. Simultaneous loss of a number of critical staff (e.g. Executive)	Substantial failure in internal governance and control structures resulting in Royal Commission and significant penalty	Event with significant impact on delivery of services across SA Health for an extended period. Significant impact on Consumers or Partners. Permanent loss of critical information	Sustained adverse media exposure. Total loss of confidence within community and with the Government. Parliamentary enquiry. Serious long term impact on reputation

LIKELIHOOD RATING GUIDE *(Consider historical factors, such as whether the risk has happened before in the past and how frequently it has occurred)*

Level	Category	Probability Description
1	Rare	Once in 10 YEARS < 1% probability of occurrence Event may only occur in exceptional circumstances in the long-term future
2	Unlikely	Once in 5 YEARS 1% - 20% probability of occurrence Event could occur but not anticipated in the foreseeable future
3	Possible	Once a YEAR 20% - 50% probability of occurrence Event could occur within short-term timeframe
4	Likely	Once a MONTH 50% - 99% probability of occurrence Event could occur in most circumstances
5	Almost Certain	Once a WEEK or DAILY >99% probability of occurrence Event is expected to occur in most circumstances, risk is occurring now

RISK ASSESSMENT MATRIX (indicating priority & action)



Step 1: assess the likelihood of recurrent failure occurring using the following table.

Rare *Few to no incidences*	Do not believe this event will happen again except in exceptional circumstances.
Likely to recur *Occurs at least once every 6 months*	Medium level of confidence in facility's capacity to rectify issues and to maintain an acceptable standard of operation
Almost certain to recur *Occurs once a month / week / day*	No/limited confidence in facility's capacity to rectify issues, or to achieve and/or maintain an acceptable standard of operation

Step 2: assess the severity of consequences.

	Low	Moderate	High
Impact	Results delayed or compromised with minor consequence; Minor impact on staff; Minor procedural breach; Evidence of good faith; Little impact.	Moderate consequences -Increased level of care required; Recovery without significant complication; Moderate impact on staff; Negligent breach; Lack of good faith evident; Material harm resulting.	Significant consequences - multiple errors; Significant-increased level of care required; Significant complication; Major impact on staff; Deliberate breach /gross negligence; Significant harm; Serious misconduct.
E.g.	*No evidence of QAP review.* *Staff trained but not signed off.* *Documentation lacking.*	*QAP participation generally good but some gaps.* *Some issues with closing out non-conformances.*	*No QAP / poor performance in QAP with no / incorrect corrective action.* *Inadequate QC.*

Step 3: using the Matrix below determine if the risk is Acceptable or Unacceptable.
(Frequency x Severity= Risk)

FREQUENCY				
	Almost certain	Acceptable Risk	Unacceptable Risk	Unacceptable Risk
	Likely	Acceptable Risk	Acceptable Risk	Unacceptable Risk
	Rare	Acceptable Risk	Acceptable Risk	Unacceptable Risk
	Occurrence/ Impact	Low	Moderate	High

SEVERITY
(how serious is the risk)

Treatment measures

Risk Assessment

- Risk register
- Contingency plan – Business continuity plan
- Clinical governance & laboratory supervision
- Reported incidents or incorrect results
- Single lab or network
- Critical results
- Personnel
  - Staff training & competency
- Manual transcription
- Techniques
- Facilities & equipment
- Quality management, QA & QC
- Internal & external communication
- Results distribution
- Validation processes
  - Equipment
  - IVDs
- IT
  - Interface
  - Electronic medical records (EMR)
    - Patient ID
    - Functionality problems
    - Clinical decision support
    - Data entry and transfer
    - Wrong blood in tube (WBIT) >> adverse transfusion
- Transfusion
  - Pre-tx testing
  - Transport & storage blood products
  - Issuing
  - Products
    - Routine
    - Emergency
- Incidents
  - Reporting
  - Frequency
  - Type

What happens when the risk is found to be unacceptable – What is the plan

1. Define the risk

Title:

Define the risk:

Scope: Choose an item.	**Category**: Choose an item.	**Identified at**: Choose an item.	**Date risk identified**:
INHERENT RISK RATING:	**Consequence**: Choose an item.	**Likelihood**: Choose an item.	**Rating**: Choose an item.

2. Breakdown the problem

- Strategic
- Operational
  - Division
  - Site

- Asset & facility
- Laboratory
  - QAP
- Clinical
- IT
- Personnel
  - HR
  - Training & competency
  - WHS

3. Set a target (that will tell us when

Domain: Choose an item.	**Risk Appetite**: Choose an item.	**Target**: This risk will be considered controlled within the Risk Appetite when: -

4. Cause analysis

- Safety
- Quality
- Service delivery
- Personnel

5. Interventions (known as controls)

This risk might happen because ...	To prevent this from happening we have the following interventions are in place right now	The position leading this is ...	They started this (date)	We check that this is working by	Right now we see this working	If we don't prevent this we will see the following events.....
						•
						•
						•

6. Evaluation

If all the interventions work well all the time and the target is met, this risk is controlled within the risk appetite. Complete the controlled risk rating below and go directly to step 8.	**Evidence against target** -
If the interventions aren't working as well as needed and the target has not been met, as part of continuous improvement, add what further actions to address the causes and make the controls more effective – go to step 7.	

CONTROLLED RISK RATING:	**Consequence**: Choose an item.	**Likelihood**: Choose an item.	**Rating**: Choose an item.

Cause analysis	1. Further actions to strengthen interventions (known as treatments)			
This risk may still happen because …….	**To prevent this from happening we will implement the following further actions ……**	**The position leading this is ……**	**They started this (date)**	**They will complete this action by (date)**

RESIDUAL RISK RATING: **Consequence**: Choose an item. **Likelihood**:Choose an item. **Rating**: Choose an item.

2. Monitoring a risk that is controlled within the Risk Appetite	
Select when this risk will be looked at annually to check the controls are still effective and target is still met: ☐ Feb ☐ Mar ☐ Apr ☐ May ☐ June ☐ July ☐ Aug ☐ Sept ☐ Oct ☐ Nov	What is the trigger that will tell you that this risk has the potential to get out of control and that you need to look at maybe more implementation? The trigger gives you an opportunity to implement action before the target is no longer met. -

3. Accountability				
Risk Owner	Name:	Title:	Signature:	Date: Click here to enter a date.
Monitoring Committee has advised the Risk Owner on the content of this risk assessment.	Name of Chair:		Signature:	Date: Click here to enter a date.

SITE SYSTEM RISK ASSESSMENT

RISK IDENTIFICATION	
Name of System:	**Patient Blood Management Process.** (Version 2: review and amendment of 2016 system risk profile)
Organisation (SALHN/FMC, etc.):	
RISK SYSTEM	
Purpose of system:	To identify risks in the Patient Blood Management process and evaluate the effectiveness of risk management strategies to date. T document applies to all network clinical areas that use blood products including x s w
Setting of system:	✓ Inpatient | ✓ Outpatient | ✓ Community | ✓ Other Pathology services
Stakeholders involved:	All consumers and staff associated with Blood Management processes including preadmission assessment., consent, specimen collectio processing to product administration and adverse reaction or event management
Process components:	1. Transfusion request form completion, specimen collection and labelling including EPLIS interface specimen reques individual patient / specimen tube printing 2. Pre-operative anaemia evaluation and transfusion alternative assessment 3. Decision to transfuse based on National Blood Management Guidelines and patient special requirements (Irradiated/C negative/anti body profile) 4. Consent or refusal of blood product process inclusive of consumer engagement and information provision 5. Critical bleeding management, communication & emergency blood access 6. Specimen reception, data entry, blood group & antibody identification 7. Blood component matching, labelling, issue, and collection 8. Blood component storage, transport and fridge monitoring and maintenance 9. Bedside patient / blood pack / prescription identification 10. Reaction identification and management, investigation and analysis 11. Documentation and retention of records of transfused patients 12. Local / National blood shortage management strategy
ESTABLISHING THE CONTEXT	
References (legislation, standards)	Legislation – Blood Contaminants Act, Consent to Medical Treatment, National Blood Authority Act Policy Directive : Blood Supply Stewardship Policy Directive S Policy & Procedures – Blood Transfusion Policy and Procedures Australian standards and guidelines: • AS 3864.1-2012 Medical refrigeration equipment - For the storage of blood and blood products - Manufacturing requirements

Legislation – Blood Contaminants Act, Consent to Medical Treatment, National Blood Authority Act
Policy Directive : Blood Supply Stewardship Policy Directive
S Policy & Procedures – Blood Transfusion Policy and Procedures
Australian standards and guidelines:

- AS 3864.1-2012 Medical refrigeration equipment - For the storage of blood and blood products - Manufacturing requirements
- AS 3864.2 2012 Medical refrigeration equipment - For the storage of blood and blood products - User-related requirements for care, maintenance, performa verification and calibration
- National Pathology Accreditation Advisory Council (NPAAC) - Requirements for Transfusion Laboratory Practice (Third Edition 2017)
- Australian and New Zealand Society of Blood Transfusion (Publications):
  - Administration of Blood Products 3rd Edition January 2018
  - Prevention of Transfusion-Associated Graft-Versus-Host Disease *(TA-GVHD)* - January 2011
  - Extended Life Plasma: A Framework for Preparation, Storage and Use - April 2009
- Guidelines for Transfusion and Immunohaematology Laboratory Practice 1st Edition 2016National Blood Authority – Patient Blood Management Guidelines
- **Australian Commission on Safety and Quality in Health Care (ACSQHC)** National Blood Standards – **Blood Management Standard** in association with:
  - **Standard 1**: Clinical Governance *(Governance, policy, procedure, guideline meeting waste KPI's & committee processes)*
  - **Standard 2:** Partnering with Consumers *(consent and consumer engagement / information / refusal of products)*
  - **Standard 3**: Preventing and Controlling Healthcare Associated Infection (Hand hygiene / bacterial notification management *(Blood Service /bacterial contamination of blood products / inclusive of suspected bacteraemic reactions)*
  - **Standard 5:** Comprehensive Care *(Patient ID Processes)*
  - **Standard 7:** Communication for Safety *(treatment plans including ordering/prescribing and administering blood products, initiation of critical bleeding/Massiv Transfusion protocols/blood product special requirements)*
  - **Standard 8:** Recognising and Responding to Acute Deterioration *(Monitoring & responding to acute transfusion associated reactions / Critical bleeding event management)*

1. Blood component issues and waste data summary review by Transfusion Committee via Health Quality, Information & Performance Hub.
2. Monthly Specimen rejection and form completion data and audit: trending of pre transfusion specimen rejection and in depth summary of Wrong Blood In T (WBIT) events including investigation and improvement activities
3. Blood Fridge Record monitoring (external blood fridge Noarlunga Infusion Centre) including receipt and issue record completion.
4. Albumin stock record of issue (patient/batch) on issue of product to clinical areas
5. Transfusion clinical practice audits: (red cell audits)
   1. Consent compliance audits – audit results of documented consent for transfusion
   2. Appropriate use of blood product audits and pre-operative anaemia management – Case note & EPAS documentation audits against current nati transfusion guidelines (twice annually based on program priorities) including
      i. Documentation of indication and transfusion history completion rates – paper based, electronic medical and pathology records
      ii. Identification of IDA & the use of or use of iron transfusion alternative strategies

RISK ASSESSMENT

Process component	Risk associated with this process component	Location	Setting	Cause of this risk	Consequences of this risk	Controls	Evidence controls are effective to control/ mitigate this risk. *(Refer: SALHN Transfusion Workbook)*	Post control risk rating	Risk evaluation			
									Accept	Reduce (Treatment Plan)	Avoid (Treatment Plan)	S
1. Transfusion request form completion, specimen collection and labelling	Failure to correctly) identify patients and Wrong labels specimens and request forms E ordered specimen & request process interruption of workflows / specimen collection processes sample expiry prior to surgery (not frozen) or urgency not relayed in documentation	All sites paper based & E interface (E live locations only)	All locations collecting transfusion specimens	Failure of form completion by medical officer. Failure of accurate bedside patient identity and labelling process by individual specimen collectors using paper record or E interfaced process. NEW RISK: E /S interface request & stickers: Failure to label specimens at the bedside checking E labels with patient ID and plain request form details – anecdotally increasing WBIT	Inaccurate clinical information risking wrong blood component, knowledge of urgency WBIT / potential ABO incompatible Transfusion	Strict specimen acceptance criteria as per ANZSBT & NATA guidelines Previous Blood group search in E system. Blood Bank review of PAS/ Theatre IT systems.	No ABO incompatible transfusion related to WBIT on record. (2002-2019). 9 x WBIT incidents identified through previous blood group / incorrect patient admission (20016-2019)	LOW	YES: Pathology reviewing label printing time frames, blank sticker interspacing different patient print outs and increased FONT on request forms.			
1. Specimen reception, data entry, blood group & antibody identification	Delays in results availability, product access	All sites	Clinical	Centralised data entry for transfusion specimens	Issue of O negative blood Delay in blood availability	Identification of urgent requests & prioritisation	Rare delays	LOW	YES			
2. Blood component matching, issue, collection	Ensuring the Correct patient Correct product Correct blood group Correct product collected	Pathology All sites	Lab Clinical	Deviation from hospital policy & procedure regarding labelling, checking or prescribing Override of IT alerts	Wrong product to patient Wrong patients product issued	IT alerts Hospital procedures for labelling Check back process	Multiple miss labelled collection slips – Identified by Blood Bank as no product ordered or no G&s available.	LOW	YES			
3. Blood component storage, transport and fridge monitoring and maintenance	Incorrectly stored blood components Storage outside of monitored transfusion service fridges	Pathology All sites	Lab Clinical Courier	Failure to follow return requirements Inadequately prepared patients requiring interventions after blood collected but prior to commencement (IV access, finishing medications, medical review)	Product waste Increased bacterial risk Reduced product efficacy	30 minute return rules, domestic fridge notices banning blood storage, hospital procedure Pathology fridge QC system meeting AS 3864.1-2012 AS 3864.2 2012	Temperature monitoring, pack temperature checks and shipper packing configurations in alignment with ARCBS shipper requirements. External blood fridge receipt & issue record audit Any suspect temperature products are expired. Central fridge monitoring & maintenance program	LOW	YES			

Example of a Significant Operational Risk

- No Business Continuity Plan >> Operational unacceptable high risk
  - Site
  - Organisation
  - State-wide
  - National
  - Infra-structure
    - IT failure
  - Tests & results
  - Supply
    - Power & water
    - Consumables
    - Blood supply
  - Staff
  - Corrective action & review

Examples of Non-Conformances

- **Inadequate staff training:**
  - Staff returns from long absence
    - Minimal retraining
      - Issues incompatible blood – severe haemolytic reaction >> High risk – Not acceptable
        - » Single or network
          - » Review & update training procedures for all staff (new, return to work, multi-skilled, student placements) for consistency
            - » One process
            - » Consistency over networks with multiple laboratories
          - » Review staff training records
          - » Staff competency
            - » Determine frequency of competency assessment based on level of risk of a particular activity within the laboratory
          - » Ensure all staff trained appropriately

Examples of Non-Conformances (cont.)

- Irregular review of all SOPs >> Low to moderate risk – Is this risk acceptable?
  - Review criticality of SOP
    - Determine frequency of review of SOPs (ie 1, 2 or 3 yrs) based on risk assessment
      - Implement change
      - Monitor frequently

Examples of Non-Conformances (cont.)

- Variable QAP results: no or late return of results, occasional incorrect results >> Moderate/high risk – Requires action
    - Review frequency of non-submitted results
    - Review submitted and expected results
    - Review internal processes
    - Review oversight & frequency of clinical review by pathologist
        - Implement action plan and regularly monitor

Remember: Frequency x Severity = ***Risk***

THANK YOU