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GUIDELINES FOR THE IMPLEMENTATION AND USE OF ELECTRONIC MEDICAL RECORDS FOR TRANSFUSION



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Guidelines for the implementation and use of electronic medical records for transfusion

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Foreword

The Australian and New Zealand Society of Blood Transfusion (ANZSBT) Council is pleased to publish this first edition of new *Guidelines for the implementation and use of electronic medical records for transfusion* which have been developed by the ANZSBT Clinical Practice Improvement Committee (CPIC). The increasing presence of electronic medical records (EMR) offers a range of potential benefits to the healthcare system however they can present a challenge to transfusion providers. These guidelines are therefore intended to assist health service organisations implement safer transfusion practice using EMRs

On behalf of Council and members I wish to acknowledge the commitment of the CPIC members who provided their time and expertise in developing these guidelines. The ANZSBT's library of guideline documents are widely accepted and I am confident that these new guidelines will similarly prove to be an extremely valuable addition to the Australasian transfusion community.

Simon Benson President

ANZSBT

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Abbreviations

ACSQHC Australian Commission on safety and Quality of Health Care

ANZSBT Australian and New Zealand Society of Blood Transfusion

EMR Electronic Medical Records

ISBT International Society of Blood Transfusion

PBM Patient Blood Management

RFID Radiofrequency identification

LIS Laboratory information system

Introduction

Electronic medical records (EMR) have the potential to improve delivery of health care. Reported benefits include improved continuity of care, increased efficiency of rapid call responses with reduced intensive care admissions and hospital mortality, improved data accuracy and integrity, improved event monitoring and adverse events monitoring.^{1,2} Medication management software may reduce medication errors^{3,4} and in transfusion, barcode or radiofrequency identification (RFID) may reduce errors in patient identification, both at the time of transfusion and at the point of blood collection.⁵⁻⁸ Biometric data have been used in the same way, but have limitations due to the storage of this information in many jurisdictions.⁹ EMRs may also improve clinical transfusion practice by the integration of physician decision support tools at the time of order entry¹⁰⁻¹⁵ and monitoring of observations.¹⁶ Detection of adverse transfusion reactions and decision support for managing reactions is a further, as yet unrealised, opportunity for EMRs.¹⁷

Improvements are not universal. Errors may occur relating to systems failure, transitions between written or manual processes and the EMR and failure of interactions between the system and users. ^{18,19} Clinician workarounds may offset potential benefits of identification safety systems. ²⁰ Clinical content, the computer-human interface and human factors are responsible for the largest proportions of contributing factors for reported medication safety events. ²¹ Health care services and vendors need to consider safety and workflow integration of any proposed hardware and software solutions, promoting best practice, especially in matters of safety. Implementation and use of electronic medical records need to ensure compliance by the electronic system itself and consider the integration into the process and human systems of the health care services.

It is important to recognise that electronic records at the patient's side *per se* does not make transfusion process safer. Improvement in patient safety has led to recommendations for their use, but cost limitations, with a large amount of specific infrastructure required, have limited the rate of implementation. There are many aspects to the transfusion process and a particular EMR implementation may serve only to passively document or may actively integrate to improve safety. Integrating transfusion, EMR and medication management systems may create efficiencies, shaping safe practice rather than just recording care. To enable this, compatibility at all steps in the process requires significant integration between information technology systems, both software and hardware, as well as the human factors in the healthcare environment. Where a system is perceived by users as contributing to safety, but is not designed to do so, risks are potentially increased.

Transfusion specific solutions for patient identification have been developed and implemented for more than 20 years^{22,23} along with guidance on implementation.²⁴ Electronic systems that assist patient identification from the patients' side, through the laboratory and back, reduce identification errors and sample recollections.^{2,5-7,25-27} They may also improve data integrity and product traceability,²⁸ if appropriately designed and implemented to ensure the correct identity of the patient and their intended blood product, the need for a second person to conduct an independent double check may be safely withdrawn, leading to improved efficiency.

There is very little guidance on the use of EMR to assist transfusion-related processes. International guidance for RFID in transfusion are available, and highlight the need to consider RFID integration into business processes, not just as stand-alone technology.²⁹ Recommendations from the Japan Society of Transfusion require that a two person check be undertaken pre-transfusion, and that the electronic check is additional to that just prior to transfusion.³⁰ While this is a safe approach, it precludes the realisation of efficiencies, without compromising safety, that may be achieved with some EMR systems.

Scope

This guidance is to help services implement safer transfusion practice using EMRs. It defines the requirements for systems where the EMR can be used as the second independent checker for blood product administration. One person, authorized to do so by the health service, can perform the checks with the EMR and appropriate software at the bedside. It also outlines important safety considerations when designing transfusion processes in an EMR that does not fulfil the requirements for replacing the double independent check. Even without a completely integrated system, benefits such as prompting during the transfusion process, may be gained from appropriate implementation.

The decision to transfuse

- 1.1 Prescription of blood products via an EMR is an opportunity to offer prescriber decision support tools. These take a variety of forms:
 - Links to current guidelines are the simplest option, but require clinicians to access these through additional steps and are necessarily generic.
 - General advice within the information system which is actively presented to clinicians as they
 prescribe.
 - Specific advice to clinicians as they prescribe, based on specific patients' characteristics, providing evidence-based best-practice tailored to the patient, for example based on recent laboratory results if they are available within the EMR.
- 1.2 Where EMRs have decision support, standardised prescription protocols or product information, these need to be regularly reviewed, maintained and updated by transfusion professionals to accommodate new products, new evidence and guidelines. While decision support should not be easily bypassed for routine transfusions, implementation needs to balance the advantages of decision support tools and the need for urgent supply and administration of blood in patients with critical bleeding.

Consent for blood products

- 2.1 Institutions must have processes for obtaining consent in accordance with the ANZSBT Guidelines for the Administration of Blood Products.
- 2.2 In developing processes within the EMR, there should be consideration given to the availability of consumer information and resources to obtain informed consent.
- 2.3 Must have a process for documenting informed consent for transfusion within the EMR in line with the institution consent policies.
- 2.4 In developing EMRs, consideration should be given to the documentation and accessibility of transfusion refusal and other treatment limiting orders.
- 2.5 Organisations should consider consumer involvement in the development of informed consent models and documentation within EMRs.

Prescription of blood products

- 3.1 The prescription of blood products should be compliant with the ANZSBT *Guidelines for the Administration of Blood Products*.
- 3.2 Where an EMR is used to prescribe blood products, it:
 - must ensure that all blood products are available in the EMR for use and the organisation must maintain an up-to-date list of available products. Interfacing with supplier information technology systems may assist;
 - should have alerts to known special transfusion needs at the time of prescription, such as the need for IgA deficient or irradiated blood products;
 - must be able to prescribe products using the commonly recognised units for the products (such
 as bags, as is typical for fresh blood products in adults, mL, as is typical for fresh blood products
 in children, grams, as is typical for immunoglobulin or by international units, as is typical for
 manufactured coagulation products). This must be available for both total dose and rates of
 infusion;
 - should support patient weight-based dosing.
- 3.2.1 Consideration should be given to institution wide protocols for infusion rates and protocols, however flexibility needs to be maintained to accommodate individual patient circumstances.

Requests for blood products and pretransfusion sample collection

- 4.1 Electronic requests may include:
 - Requests for blood sample collection and testing.
 These requests will be necessary to initiate blood sample collection by ward staff, pathology collection rounds in hospitals or community settings or in pathology collection centres. Request must be compliant with the ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice.
 - Requests for blood products.
 These may include requests for products where a current sample may not be required, for example fresh frozen plasma.
 - Requests for blood product delivery only.
- 4.2 The request types listed in 4.1 are expected to have different levels of delegation. EMRs used to submit requests should restrict the ability to order blood products to groups or individuals with appropriate delegation.
- 4.3 Processes must be in place for urgent requests.
 - Where an urgent request is placed through an EMR there must be a mechanism to ensure that
 the laboratory is actively informed and requestor immediately notified that laboratory
 personnel have received the request. This may be through the EMR or by other means (such as
 telephoning urgent orders).
- 4.4 Positive patient identification must occur in accordance with the ANZSBT *Guidelines for Transfusion* and *Immunohaematology Laboratory Practice* prior to electronic confirmation of identity.
- Where possible, the EMR should be used to assist in patient identification at the point of sample collection. This is not always practical, for example where pre-transfusion samples are collected at outpatient pathology collection centres and it is not a requirement that the EMR be used to confirm patient identification in order to enable subsequent single operator pre-transfusion identification. The following guidance should be used when the EMR assists sample collection and identification.
- 4.6 Sample collection processes must identify the blood collector and patient.
- 4.7 Patients must be identified by a barcode or RFID attached to the patient. The identification code should be unique for the patient identity and unique to the patient as a site (i.e. the code should distinguish patient from patient records or sample) to ensure that identification has occurred at the bedside.
- 4.8 Sample labelling is required after collection. Where possible, systems should prevent pre-labelling (for example by printing labels at the patient's side after collection).
- 4.9 Where possible, EMRs should facilitate labelling at the patient's side (for example, by printing only at the bedside). Systems must not force labelling away from the bedside. For example, sample labels must not be printed at a distant printer such as at a nurses' station, once samples have been collected. Hand-written labelling may be required.
- 4.10 Sample labelling should conform to ANZSBT *Guidelines for Transfusion and Immunohaematology Laboratory Practice*, including the declaration by the collector that they have collected and identified the sample, and with local laboratory requirements.

Section 5Storage, collection and transport of blood products

- 5.1 EMRs may be used to monitor the collection and transport times of blood products to ensure compliance with ANZSBT *Guidelines for Transfusion and Immunohaematology Laboratory Practice*.
- 5.2 Where blood is issued to a refrigerator external to the laboratory, processes for blood product tracking, identification and collection are required.

EMR assisted administration of blood products

6.1 Background

6.1.1 This section defines the minimum system and process requirements to enable safe single operator identification for transfusion. Where compliant, health services may enable a practitioner to transfuse with the information technology replacing the double independent check prior to transfusion. In all other respects, transfusion sampling and administration must be compliant with ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice and Guidelines for the Administration of Blood Products.

6.2 EMR interfaced with the laboratory information system (LIS)

- 6.2.1 Where the EMR is interfaced with the Laboratory Information System (LIS), the EMR may be used as the second independent check of correct product to patient. This still requires the individual clinician to perform positive patient identification in the first instance.
- 6.2.2 In order for the EMR to independently confirm the patient identity it should comply with the mandatory requirements noted in Section 9, Clinical Governance.
- 6.2.3 Identification must be performed at the patient's side.
- 6.2.4 Positive patient identification must be confirmed verbally with the patient if they are able to do so; (i.e. ask patient to state their name and DOB and compare with the patient ID band and blood product issue label).
- 6.2.5 Once positive patient identification is completed by one practitioner, further patient identification must be performed either electronically or by a second health professional.
- 6.2.6 In order for an electronic system to confirm patient identity, the electronic system at the patient's side must be able to:
 - Confirm the patient identity using the machine-readable identification band on the patient (barcode or RFID).
 - Identify the blood product, including blood group; and
 - Confirm that the blood product has been issued specifically to the identified patient either through interrogating data stored on the 2D barcode, RFID chips or by reference to the electronic issue by linkage to the LIS, including any special transfusion requirements.
- 6.2.7 Patients must be identified by a barcode or RFID attached to the patient. The identification code should be unique for the patient identity and unique to the patient as a site (i.e. the code should distinguish patient from patient records or sample) to ensure that identification has occurred at the bedside.
- 6.2.8 Where there is an inconsistency between the patient wristband and product identifiers, the system should clearly indicate this to the user, prevent progression until resolved and if possible raise an alert with a suitable governance structure in real time for follow up.
- 6.2.9 EMR must not enable the assignment of a unit of blood to a patient except in the laboratory or where a unit has been issued unassigned (or assigned to an unknown recipient) in an emergency, or the product is a manufactured product (in which case the batch number is assigned rather than a unit number).
- 6.2.10 For downtime and information technology system failure procedures double independent patient identification must be performed in accordance with ANZSBT Guidelines for the Administration of Blood Products.

6.3 EMRs independent of the laboratory information system (LIS)

- 6.3.1 Where the EMR is not interfaced with the LIS, there are still many opportunities for improvement. For example, the EMR may be used to provide a checklist of steps to complete patient and product identification and record the product in the EMR. In this case two-person independent checking is still required.
- 6.3.2 Identification must be performed at the patient's side.
- 6.3.3 Positive patient identification must be confirmed verbally and by inspection of the patient identification band with the patient if they are able to do so; (i.e. ask patient to state their name and DOB and compare with the patient ID band and blood product issue label).
- 6.3.4 The practitioner undertaking primary identification must be recorded in the notes and must indicate compliance with positive patient identification procedures.
- 6.3.5 Once positive patient identification is completed by one practitioner, secondary patient identification must then be performed.
- 6.3.6 Observations should be recorded before, during and after transfusion in accordance with local policies and the ANZSBT *Guidelines for the Administration of Blood Products*.

Special transfusion circumstances

7.1 Critical event management and communications

7.1.1 Critical bleeding, massive transfusion and transfusion of uncrossmatched emergency blood need robust clinical, laboratory and electronic processes that enable rapid ordering, delivery and administration of blood products while minimising unnecessary administrative tasks and maintaining critical safety functions.

Transfusion-related adverse events

8.1 Adverse reactions

- 8.1.1 The EMR should record any adverse transfusion reactions.
- 8.1.2 Where a patient has an adverse transfusion reaction that indicates a potential risk or need to modify future transfusions, these should be recorded with warnings accessible to clinicians in the EMR (for example, anaphylaxis to IgA containing products).
- 8.1.3 Direct notification of the laboratory of suspected or confirmed adverse transfusion reactions to enable appropriate investigations to be performed and reporting to suppliers is required. EMRs may facilitate this process.
- 8.1.4 The role of the EMR in an adverse event (if any) should be captured in order to determine whether system improvements are required. This includes human interactions with the EMR, such as work arounds and overrides.
- 8.1.5 Consideration of electronic decision support tools for the management of adverse transfusion reactions may be considered in accordance with local policies and practice.

Clinical governance

9.1 User roles

- 9.1.1 User roles must be:
 - defined and controlled in the system; and
 - restricted to the purpose specific user functions. For example, an administering practitioner should not be able to override or approve blood product issuances from the blood bank.

9.2 Sample and product identification

- 9.2.1 All processes in which EMRs are required to identify samples, labels and blood products must use machine readable codes (e.g. ISBT128, CODABAR or 2D barcodes or RFID) to ensure positive identification by scanning
- 9.2.2 Samples, labels and blood products must have written identification visible at all times so that identification can be performed or confirmed manually

9.3 Data recording

- 9.3.1 The system should indelibly record each process, including the staff involved.
- 9.3.2 Data storage should comply with all jurisdictional and regulatory requirements for privacy, access and duration of storage
- 9.3.3 Where more than one individual is required for a process, the EMR should record each person involved.
- 9.3.4 Wherever possible, automated data entry such as the use of barcodes or RFID, should be utilised to prevent manual data entry errors.

9.4 Overrides

- 9.4.1 System overrides may be required to overcome barriers implemented to improve safety in the event of partial system failure (for example, unable to scan barcodes).
- 9.4.2 Opportunities to override should be minimal and safety based.
- 9.4.3 Wherever possible, overrides should not create a process easier than the electronically assisted process.
- 9.4.4 Once an override occurs, directions on how to complete the process safely should prompt best manual practice.
- 9.4.5 A system for logging overrides and evaluating the causes should be integrated and actively managed to identify sources of error or need for improvements.
- 9.4.6 The system itself may be used to improve practice when system overrides occur, such as reporting scan failures or prompting identification band replacement.

9.5 Traceability

- 9.5.1 EMRs must record the fate of blood products given to patients, even when only a small fraction of a product is given.
- 9.5.2 The transfusion of a product to a recipient should be recorded and this data returned to the laboratory so that the laboratory maintains traceability of the product to the recipient.

9.6 Implementation

- 9.6.1 Implementation must ensure appropriate integration in the human factors in healthcare systems. This should include:
 - Clear indications within policies and procedures about the functions included in the EMR.
 - Directions from within the EMR to ensure compliance with correct protocols and procedures.
 - Encouragement to follow, or where possible mandating, the correct transfusion processes for that institution, taking into consideration the potential for different experiences of transfusion processes and EMRs within the workforce that may impact safety.

For example, a healthcare professional may work in a facility with a completely integrated EMR and perform the pre-transfusion check individually with the assistance of an EMR, but at another facility the EMR may be scanned to record the unit rather than confirm identity. To the practitioner these two processes may look similar, but in the latter a double independent check is still required.

- Clinical users and the transfusion laboratory must be involved in the design and implementation process for transfusion related aspects of electronic medical records.
- Ensuring that manual or "down time" processes are, except where required for safety (such as double independent checking) are aligned on similar policy lines to enable staff to transition between manual and electronically assisted processes

9.6.2 Systems must be designed for safety

- 9.6.2.1 Clinicians frequently operate in high workload and high stress environments. Therefore, electronic system design should facilitate avoidance of inadvertent errors.
- 9.6.2.2 The EMR and associated workflows should consider human factors during system design
- 9.6.2.3 Health professionals with knowledge on blood collection, laboratory transfusion practice, transfusion medicine and transfusion administration processes should be involved in local system design, development and implementation.
- 9.6.2.4 Electronic system design should promote, and where possible mandate, best-practice.
- 9.6.2.5 Appropriate education and training should be provided for the level of usage required.
- 9.6.2.6 Education and training should not be relied upon to overcome process deficiencies or as the sole tool for maintaining a safe process. Systems should not be developed that require (with the exception of key operators) specific education and training to maintain safety.

EMRs facilitate healthcare delivery. Practitioners work with a variety of electronic systems, many are mobile and some practitioners may conduct transfusions sporadically and at different facilities. An adequately trained healthcare worker (for example having completed appropriate modules of the nationally supported BloodSafe e-learning program) who is also familiar with a particular EMR should ideally be able to undertake transfusion-related tasks for their patients without intensive EMR training specific to transfusion.

- 9.6.2.7 Education and training should not be relied upon to explain the limits or differences between systems or particular deployments of a system. These should be clear to users during normal clinical use of systems.
- 9.6.2.8 Directions on conducting a particular process safely should be available, wherever that process is included in the EMR.
- 9.6.2.9 Where an EMR is only recording an activity rather than actively contributing to the safe conduct of a process (such as recording a blood unit transfused rather than confirming it has been issued to this patient), the EMR may assist by delivering guidance on the tasks that need to be undertaken manually at the point of care.

- 9.6.2.10 Directions for completing a manual process in the event that part of a system fails (for example, barcode scanner or printer failure) must be included in hospital procedures and are recommended to be included within the electronic process at the time of process failure.
- 9.6.2.11 Standard operating procedures should be readily available and held external to the EMR to complete any or all transfusion related tasks in the event of EMR failure.

9.7 Integration

- 9.7.1 Systems may be developed by integrating of a number of different modules or software packages.
- 9.7.2 Electronic systems must be interfaced with data transfer from the LIS to the EMR including the patient demographics (as defined in the ANZSBT Guidelines for the Administration of Blood Products) and the product details (product type, unit number, expiry time and date and blood group (where applicable).
- 9.7.3 Bidirectional interfaces should be considered best-practice to minimise the chance of error, provide additional checking during sample collection and capture the fate of the product.

9.8 Validation

- 9.8.1 Prior to implementation, all transfusion processes included within an EMR should undergo validation.
- 9.8.2 Where more than one software solution is used, the interfaces should be specifically validated.
- 9.8.3 In undertaking validation more broadly, institutions should consider not only software and hardware issues, but also the integration into the human systems of the healthcare environment, workflow and culture.
- 9.8.4 Validation should consider the role of forcing functions within the system and consider ways in which these impact on workflow to improve safe practice. It is possible that forcing functions incorrectly deployed could enforce or reinforce poor practice (for example, printing sample barcoded labels after collection at a printer not adjacent to the patient).
- 9.8.5 Validation of RFID systems should include assessment of the potential for misreading adjacent RFID chips
- 9.8.6 Validation should include partial system failure and override functionalities.

9.9 Maintenance and review

- 9.9.1 Policies and procedures should be kept under regular review to ensure compliance with current guidelines and best-practice.
- 9.9.2 When policies and procedures are updated, consideration should be given to both manual and electronic processes.
- 9.9.3 Health professionals with knowledge on blood collection, laboratory transfusion practice, transfusion medicine and transfusion administration processes should be involved in policy, procedure and electronic system review.
- 9.9.4 System errors and overrides should be regularly monitored to inform practice improvement.

Glossary

Barcode A visual representation of data that may be scanned to read

complex identifying information.

Double independent check The process of confirming patient identification whereby two

professionals independently confirm, and take responsibility for confirming patient identification, prescription and product issued immediately prior to transfusion at the patient's side in line with ANZSBT *Guidelines for the Administration of Blood Products*

Electronic Medical Records (EMR) Electronic systems that record the clinical assessments of and

care received by a patient. These systems may also facilitate care, such as the prescription of treatment, requesting investigations, scheduling and monitoring, provide decision support at the point of care and facilitate safe health care by facilitating safe processes within complex health care environments. Usually an institution has multiple specialised software components within the total EMR (such as clinical and laboratory systems) that may or may not

be interfaced.

Interface A connection between two separate software components within

EMRs, often provided by different vendors, or to external

information systems

Laboratory Information System (LIS)

The electronic system in the transfusion laboratory for managing

requests, blood products and results. This is a subset of an

electronic medical record.

Patient Blood Management The timely application of evidence-based medical and surgical

concepts designed to maintain haemoglobin concentration, optimize haemostasis and minimize blood loss in an effort to improve patient outcome. (from the Society for the Advancement

of Blood Management)

Override Bypassing a process designed to assist with safety and quality

within an electronic medical record. The ability to override may be built in to system designs to enable a process to proceed in the event of a single step in a process failing (for example, a failed barcode or RFID read) and usually requires an alternate process.

Radiofrequency identification (RFID) The process of detecting and identifying the close presence of an

object or individual using an attached electronic chip that can be

detected by radiofrequency detectors in close proximity

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