# Blood, sweat and tears?
# Clinical governance and haemovigilance

# Clinical governance

"A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved by creating an environment in which there is transparent responsibility and accountability for maintaining standards and by allowing excellence in clinical care to flourish."

National Safety and Quality Health Service Standards, 2011

Scally and Donaldson, BMJ 1998;317:61-5



“If clinical governance is to be successful it must be underpinned by the same strengths as corporate governance: it must be rigorous in its application, organisationwide in its emphasis, accountable in its delivery, developmental in its thrust, and positive in its connotations.”

Scally and Donaldson, BMJ 1998;317:61-5

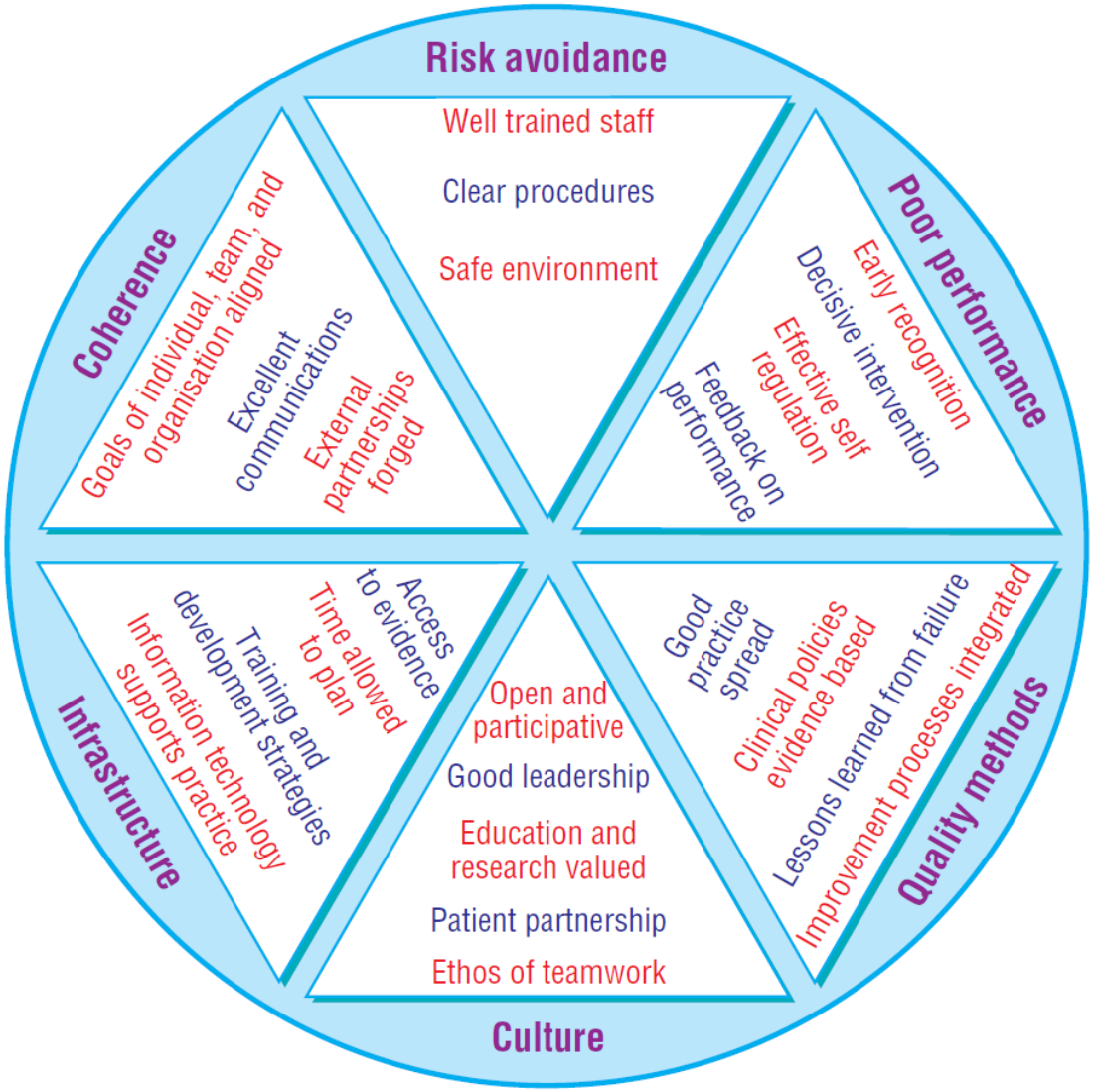


**Fig 2** Integrating approaches of clinical governance

Scally and Donaldson, BMJ 1998;317:61-5

- Advocating for positive attitudes and values about safety and quality
- Planning and organising governance structures for safety and quality
- Organising and using data and evidence
- Sponsoring a patient focus

An overview of clinical governance policies, practices and initiatives
Braithwaite J and Travaglia JF,
Centre for Clinical Governance Research, UNSW
Aust Health Rev 2008;32(1):10-22

# Why do we need it?

“Although clinical governance can be viewed generally as positive and developmental, it will also be seen as a way of addressing concerns about the quality of health care. Some changes in healthcare organisations have been prompted by failings of such seriousness that they have resulted in major inquiries.”

Scally and Donaldson, BMJ 1998;317:61-5

The Report of the Public Inquiry into
children's heart surgery at
the Bristol Royal Infirmary1984–1995

# Learning from Bristol

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
July 2001

CM 5207(I)

£32 (inc. VAT)

# Contributing factors?

- Fragmentation of care
  - Increasing (sub)specialisation
- Education and training
- Supervision
- Data and monitoring
- Culture
- Resources


*"Let's go back to the scenario in which none of this is my fault."*

# Clinical governance

"A system through which organisations are accountable for continuously improving the quality of their services and safeguarding **high standards of care**. This is achieved by creating an environment in which there is transparent responsibility and accountability for **maintaining standards** and by allowing excellence in clinical care to flourish."

National Safety and Quality Health Service Standards, 2011

Scally and Donaldson, BMJ 1998;317:61-5





# Requirements For Transfusion Laboratory Practice (First Edition 2008)

## 1. Patient identification and labelling

Accurate patient identification and sample labelling are crucial to patient safety. Failure to comply with these requirements remains a significant cause of patient morbidity and mortality.

### Patient identification

**S1.1 The laboratory must have a written policy for identifying patients for pretransfusion, antenatal and perinatal testing.**

i. **The patient's identity must be positively confirmed at the time of sample collection: by direct questioning and by checking (where available) the patient's identification name band. The patient must be asked to state their family name, given name(s) and date of birth**
ii. **If the patient is unconscious, irrational or unable to respond to direct questioning, then**
   a. **another person must confirm the patient's identity or**
   b. **a unique identifier must be used and these details linked to the patient's known name once available.**

### Request form

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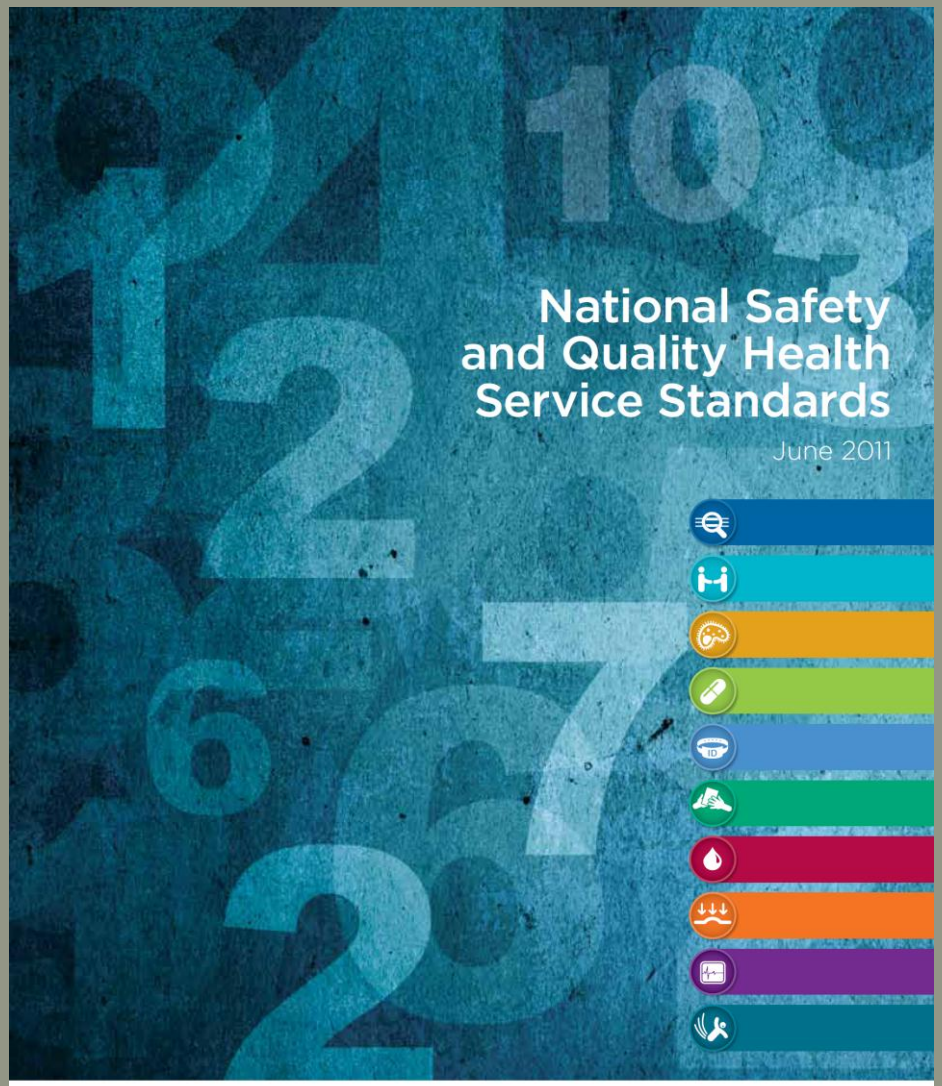
NPAAC Standard 2008



# National Safety and Quality Health Service Standards

June 2011

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

# National Safety and Quality Health Service Standards

1. **Governance for Safety and Quality in Health Service Organisations** which describes the quality framework required for health service organisations to implement safe systems.
2. **Partnering with Consumers** which describes the systems and strategies to create a consumer-centred health system by including consumers in the development and design of quality health care.
3. **Preventing and Controlling Healthcare Associated Infections** which describes the systems and strategies to prevent infection of patients within the healthcare system and to manage infections effectively when they occur to minimise the consequences.
4. **Medication Safety** which describes the systems and strategies to ensure clinicians safely prescribe, dispense and administer appropriate medicines to informed patients.
5. **Patient Identification and Procedure Matching** which describes the systems and strategies to identify patients and correctly match their identity with the correct treatment.
6. **Clinical Handover** which describes the systems and strategies for effective clinical communication whenever accountability and responsibility for a patient's care is transferred.
7. **Blood and Blood Products** which describes the systems and strateiges for the safe, effective and appropriate management of blood and blood products so the patients receiving blood are safe.
8. **Preventing and Managing Pressure Injuries** which describes the systems and strategies to prevent patients developing pressure injuries and best practice management when pressure injuries occur.
9. **Recognising and Responding to Clinical Deterioration in Acute Health Care** which describes the systems and processes to be implemented by health service organisations to respond effectively to patients when their clinical condition deteriorates.
10. **Preventing Falls and Harm from Falls** which describes the systems and strategies to reduce the incidence of patient falls in health service organisations and best practice management when falls do occur.

# Defined roles and responsibilities

**Patient-centred care:** The delivery of health care that is responsive to the needs and preferences of patients. Patient-centred care is a dimension of safety and quality.

*Patients and carers:*

- Partner with organisation and providers to make decisions for service planning, developing models of care, measuring service and evaluating systems of care
- Participate in making decisions about own care
- Need to know and exercise their healthcare rights & be engaged in care and treatment decisions

# Defined roles and responsibilities

- *Clinical workforce:*
  - Essential to delivery of safe and high-quality care
  - Can achieve system improvement when actively participate in organisational processes, safety systems, improvement initiatives, and trained in roles and services for which they are accountable
  - Can make systems safer and more effective if:
    - understand their broad responsibility for safety and quality in care
    - follow safety and quality procedures
    - supervise and educate other members of the workforce
    - participate in review and analysis performance procedures
  - Form partnerships with patients & carers: improve patient experience of care, increase effectiveness of design & planning of organisational processes, safety systems, quality initiatives and training
- *Non-clinical workforce, incl volunteers:*
  - Participate in development and implementation of safety systems, improvement initiatives and related training to identify and address limitations
  - A key role is notifying clinical workforce when concerns exist about a patient

# Defined roles and responsibilities

- *Health service managers:*
  - Implement and maintain systems, materials, education and training that ensure clinical workforce delivers safe, effective and reliable care
  - Support partnerships with patients and carers when designing, implementing & maintaining systems
  - Key role: manage performance & facilitate compliance across organisation
  - Leaders: model behaviours that optimise safe and high quality care
- *Health service executives and owners:*
  - Plan & review integrated governance systems that promote patient safety
  - Clearly articulate organisational and individual accountabilities for safety and quality

# Blood and Blood Products

## Standard 7

### The Blood and Blood Products Standard:

Clinical leaders and senior managers of a health service organisation implement systems to ensure the safe, appropriate, efficient and effective use of blood and blood products. Clinicians and other members of the workforce use the blood and blood product safety systems.

### The intention of this Standard is to:

Ensure that the patients who receive blood and blood products do so appropriately and safely.

### Context:

It is expected that this Standard wil
in conjunction with Standard 1, 'Gov
for Safety and Quality in Health Ser
Organisations' and Standard 2, 'Par
with Consumers'.

**Blood:** Includes homologous and autologous whole blood. Blood including red blood cells, platelets, fresh frozen plasma, cryoprecipitate and cryodepleted plasma.[8]

**Blood products:** Plasma derivatives and recombinant products, excluding medication products.[8]

## Governance and systems for blood and blood product prescribing and clinical use

Health service organisations have systems in place for the safe and appropriate prescribing and clinical use of blood and blood products.

| This criterion will be achieved by: | Actions required: |
|---|---|
| **7.1** Developing governance systems for safe and appropriate prescription, administration and management of blood and blood products | **7.1.1** Blood and blood product policies, procedures and/or protocols are consistent with national evidence-based guidelines for pre-transfusion practices, prescribing and clinical use of blood and blood products |
| | **7.1.2** The use of policies, procedures and/or protocols is regularly monitored |
| | **7.1.3** Action is taken to increase the safety and appropriateness of prescribing and clinically using blood and blood products |
| **7.2** Undertaking a regular, comprehensive assessment of blood and blood product systems to identify risks to patient safety and taking action to reduce risks | **7.2.1** The risks associated with transfusion practices and clinical use of blood and blood products are regularly assessed |
| | **7.2.2** Action is taken to reduce the risks associated with transfusion practices and the clinical use of blood and blood products |
| **7.3** Ensuring blood and blood product adverse events are included in the incidents management and investigation system | **7.3.1** Reporting on blood and blood product incidents is included in regular incident reports |
| | **7.3.2** Adverse blood and blood product incidents are reported to and reviewed by the highest level of governance in the health service organisation |
| | **7.3.3** Health service organisations participate in relevant haemovigilance activities conducted by the organisation or at state or national level |
| **7.4** Undertaking quality improvement activities to improve the safe management of blood and blood products | **7.4.1** Quality improvement activities are undertaken to reduce the risks of patient harm from transfusion practices and the clinical use of blood and blood products |

## Documenting patient information

The clinical workforce accurately records a patient's blood and blood product transfusion history and indications for use of blood and blood products.

| This criterion will be achieved by: | Actions required: |
|---|---|
| **7.5** As part of the patient treatment plan, the clinical workforce accurately documenting:<br>• relevant medical conditions<br>• indications for transfusion<br>• any special product or transfusion requirements<br>• known patient transfusion history<br>• type and volume of product transfusion<br>• patient response to transfusion | **7.5.1** A best possible history of blood product usage and relevant clinical and product information is documented in the patient clinical record |
| | **7.5.2** The patient clinical records of transfused patients are periodically reviewed to assess the proportion of records completed |
| | **7.5.3** Action is taken to increase the proportion of patient clinical records of transfused patients with a complete patient clinical record |
| **7.6** The clinical workforce documenting any adverse reactions to blood or blood products | **7.6.1** Adverse reactions to blood or blood products are documented in the patient clinical record |
| | **7.6.2** Action is taken to reduce the risk of adverse events from administering blood or blood products |
| | **7.6.3** Adverse events are reported internally to the appropriate governance level and externally to the pathology service provider, blood service or product manufacturer whenever appropriate |

## Managing blood and blood product safety

Health services organisations have systems to receive, store, transport and monitor wastage of blood and blood products safely and efficiently.

| This criterion will be achieved by: | Actions required: |
|---|---|
| **7.7** Ensuring the receipt, storage, collection and transport of blood and blood products within the organisation are consistent with best practice and/or guidelines | **7.7.1** Regular review of the risks associated with receipt, storage, collection and transport of blood and blood products is undertaken |
| | **7.7.2** Action is taken to reduce the risk of incidents arising from the use of blood and blood product control systems |
| **7.8** Minimising unnecessary wastage of blood and blood products | **7.8.1** Blood and blood product wastage is regularly monitored |
| | **7.8.2** Action is taken to minimise wastage of blood and blood products |

## Communicating with patients and carers

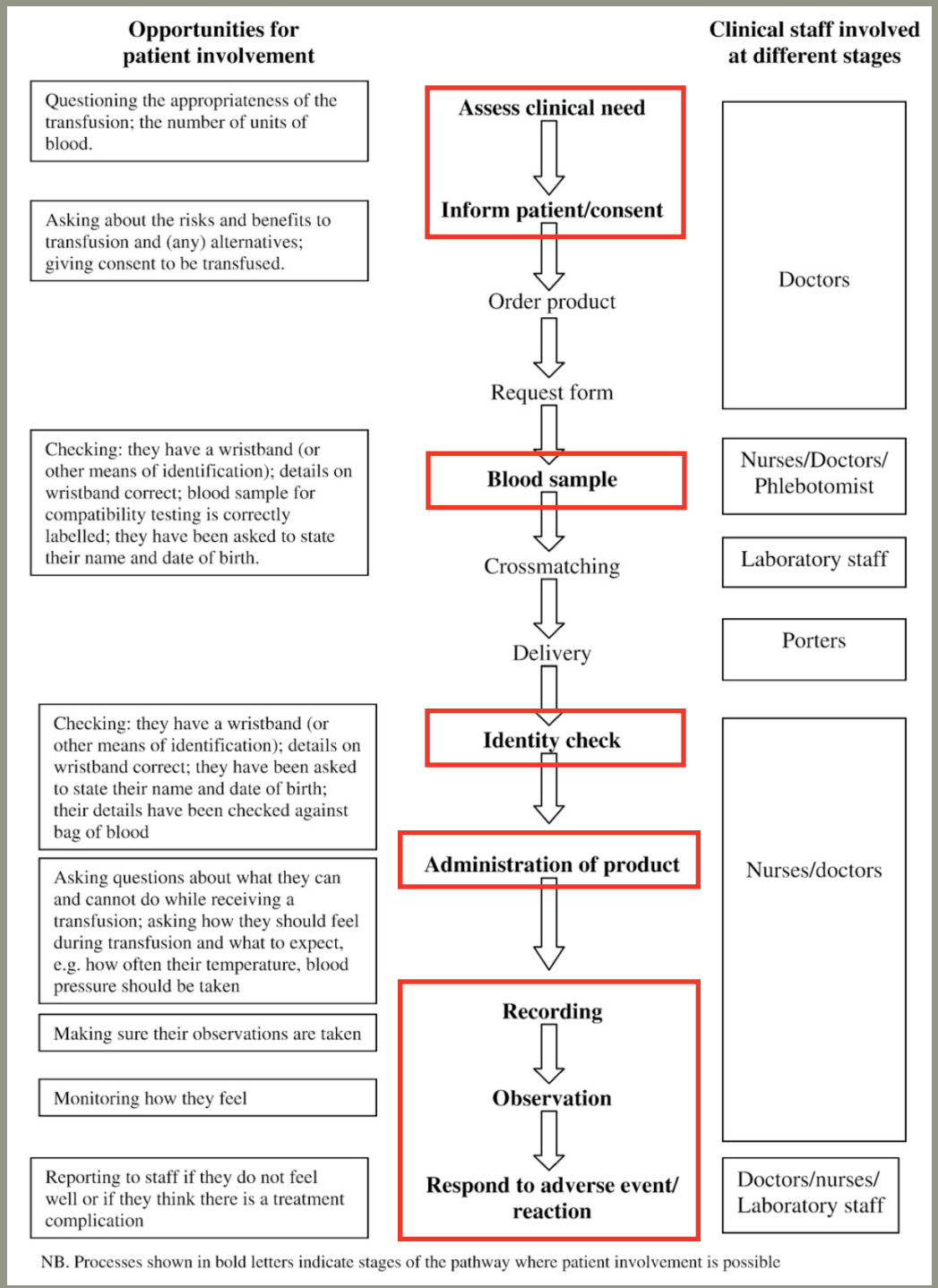
Patients and carers are informed about the risks and benefits of using blood and blood products and about the available alternatives when a plan for treatment is developed.

| This criterion will be achieved by: | Actions required: |
|---|---|
| **7.9** The clinical workforce informing patients and carers about blood and blood product treatment options, and the associated risks and benefits | **7.9.1** Patient information relating to blood and blood products, including risks, benefits and alternatives, is available for distribution by the clinical workforce |
| | **7.9.2** Plans for care that include the use of blood and blood products are developed in partnership with patients and carers |
| **7.10** Providing information to patients about blood and blood product use and possible alternatives in a format that can be understood by patients and carers | **7.10.1** Information on blood and blood products is provided to patients and their carers in a format that is understood and meaningful |
| | nsent is undertaken and documented for all od or blood products in accordance with the policy of the health service organisation |

**Informed consent:** A process of communication between a patient and their medical officer that results in the patient's authorisation or agreement to undergo a specific medical intervention.[22] This communication should ensure the patient has an understanding of all the available options and the expected outcomes such as the success rates and/or side effects for each option.[23]

# Informed consent

- Responsibility for informing patients
  - Institutional (process/framework)
  - Treating (prescribing) clinician
  - Staff administering transfusion




# Involving patients

RE Davis, CA Vincent, MF Murphy:

Blood transfusion safety: the potential role of the patient.

TMR Jan 2011

# Areas for future research on patient involvement in improving transfusion safety

- Consent
- Shared decision-making
- Effectiveness of information provided
- Perception of risk
- Framing of safety information
- Potential adverse effects of patient involvement and information
- Willingness to participate in safety checks
- Healthcare professional education

Blood transfusion safety: the potential role of the patient
Davis, Vincent, Murphy: TMR Jan 2011

# What do we need?

- Need defined framework/processes
- Documented responsibilities
  - Necessary but not sufficient

# What do we need?

- Need defined framework/processes
- Documented responsibilities
  - Necessary but not sufficient

- Need to understand why things don’t work


BD

# Human factors

| Task Demands | Individual Capabilities |
|---|---|
| • High workload (memory requirements)<br>• Time pressure (in a hurry)<br>• Simultaneous, multiple tasks<br>• Repetitive actions/Monotony<br>• Unrecoverable actions<br>• Interpretation requirements<br>• Unclear goals, roles or responsibilities<br>• Lack of or unclear standards | • Unfamiliarity with task/first time<br>• Lack of knowledge<br>• New technique not used before<br>• Imprecise communication habits<br>• Lack of proficiency/Inexperience<br>• Unsystematic problem-solving skills<br>• "Can do" attitude for crucial task<br>• Illness or fatigue |
| **Work Environment** | **Human Nature** |
| • Distractions/Interruptions<br>• Changes/Departure from routine<br>• Confusing procedure/vague guidance<br>• Confusing equipment displays & controls<br>• Work-arounds/Equipment faults<br>• Hidden system response<br>• Unexpected equipment conditions<br>• Lack of indications or alarms | • Stress<br>• Habit Patterns<br>• Assumptions<br>• Complacency/Overconfidence<br>• Mind set (intention)<br>• Inaccurate risk perception<br>• Mental shortcuts (biases)<br>• Limited short-term memory |

http://dkv.columbia.edu/demo/medical_errors_reporting/site/images/module2/workplace-factors-big.gif

# What do we need?

- Need defined framework/processes
- Documented responsibilities
  - Necessary but not sufficient
- Need to understand why things don't work
- Responsibility and authority to change things

# Who and what?

- Governments:
  - policy, planning, structures (eg UK NPSA), resources (transfusion practitioners) etc
- Hospital executive management
  - staff training, competency assessment
  - transfusion practice, clinical audit, RCA
- Health professionals and academia
  - clinical leadership, guidelines, education, research
- Blood Services and industry:
  - research, product development, partnership with hospitals
- Patients and the community: participation

# SHOT recommendations 2010

| Action | Recommendation |
|---|---|
| **NBTC, Trust/hospital CEOs** | There should be a review of the practical aspects of the implementation of NPSA SPN 14 with a view to new guidance being issued and that Trusts should ensure that individual transfusion practitioners are fully supported with the allocation of additional link nurses in the escalation of training and assessment. |
| **BCSH, Transfusion Taskforce** | The existing British Committee for Standards in Haematology (BCSH) guidelines for the Administration of Blood Components should be supplemented by an amendment dealing with measures to avoid the development of TACO and over-transfusion, particularly in vulnerable patients, including pre-transfusion clinical assessment, rate of transfusion, fluid balance, regular monitoring of Hb and prescription of diuretics. |
| **NBTC, NHSBT** | There should be a systematic review of the application of weight-related empirical formulae or algorithms in prescribing for low body weight adults |
| **NBTC Education Working Group** | Transfusion medicine must be part of the core curriculum for doctors in training. |
| **Trusts/hospitals** | To avoid inappropriate and unnecessary transfusions due to lack of adequate clinical handover, decisions made concerning the need for transfusion support should be documented in the handover templates. |
| **Hospital transfusion teams (HTT)s** | All under- and delayed transfusions that have a significant impact on patient outcomes should be reported to SHOT. |
| **SHOT team** | The Dendrite database should be enhanced to fully capture the salient clinical features and details of the timeliness of blood component support. |
| **Trusts/hospitals** | Trusts should implement the recommendations of the UK Transfusion Laboratory Collaborative |
| **Manufacturers of lab IT systems** | Work should continue with suppliers of LIMS to improve the capability of IT systems to generate warning flags and implement component selection algorithms based on data incorporated in the component label. These improvements should be in line with the recommendations of the BCSH guidelines on laboratory IT systems currently in preparation. |

- Historical focus on product safety
- Recent focus on systems and clinical practice
- Making progress – more required


Speak Softly
and carry a big stick
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# Transfusion practice improvement

- Collaborative models at state/territory level – DoH, clinicians, Blood Service
- Focus on:
  - Clinical governance, risk management
  - Establishment of specialist transfusion practitioner role
  - Education for clinical staff, patients
  - Clinical audit
  - Data linkage activities, research
  - Haemovigilance
- National haemovigilance and PBM committees under auspices of National Blood Authority

# Jurisdictional practice improvement and haemovigilance activities

- SA: BloodSafe: South Australia
- NSW: Blood Watch
- ACT: Appropriate Use of Blood Ref Group
- NT: Transfusion Safety Program
- QLD: Queensland Blood Management Program
- VIC/TAS: Blood Matters
- WA: Patient Blood Management Program



BloodSafe
SAFETY AND QUALITY IN ACTION

# Role of the HTC

- Critical element of clinical governance
- Must be
  - Functioning
  - Reviewing adverse reactions
  - Reporting

# Hospital Circular 07/2002
# HTC Terms of Reference

health

**1.** To monitor, review and improve hospital transfusion practices relating to appropriateness of usage of blood and blood products, wastage, expiry and adverse events by:

- reviewing ordering schedules.
- conducting surveys of usage, wastage and expiry of blood/blood products, and providing forums to address these issues.
- implementing quality improvement reporting systems.
- maintaining databases that record clinical indications, blood products requested and administered, and adverse events.
- formulating and evaluating performance indicators that reflect current best practice.

**2.** To assist in development and refinement of transfusion policy by ensuring that current knowledge informs appropriate use.

**3.** To promote transfusion best practice by:

- considering requirements of clinical staff for management of specific conditions
- adopting international and locally recognised best-practice guidelines
- developing and implementing appropriate clinical and laboratory protocols
- providing advice/support regarding alternatives to autologous blood for elective surgical procedures.

**4.** To promote transfusion awareness in relation to:

- transfusion products being a scarce resource
- potential for adverse effects
- laboratory practices, techniques and problems that are encountered
- current status of transfusion guidelines
- current status of blood and blood product safety, quality, supply and demand.

Blood, sweat, tears

…and $

# Quality costs, but poor quality costs more

(David Browning, WHO)

**Bristol Inquiry facts and figures**

- 96 days of oral hearings
- 417 hours of hearing time
- 238 witness statements from parents (553 total witness statements)
- 40 parents, total 127 total witnesses gave oral evidence
- 674,000 pages of medical records received for 2056 children
- 42,071 documents received from 30 different sources
- 7 Phase Two seminars: > 150 participants, 180 submitted papers
- >50 expert papers on a variety of topics
- 150 page Interim Report and Annexes

- Estimated final cost of the Inquiry: £14 million

The Bristol Royal Infirmary Inquiry

www.bristol-inquiry.org.uk


“Never, never, never, never give up.”

“If you are going through hell, keep going.”

"I have nothing to offer but blood, toil, tears and sweat."

"Come then, let us go forward together with our united strength."

Winston Churchill

May 13, 1940

# Acknowledgements


- Transfusion practice improvement collaboratives
  BloodSafe (SA), Blood Matters (Vic/Tas), BloodWatch (NSW)
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- Transfusion Outcomes Research Collaborative
- Mike Murphy and Rachel Davis