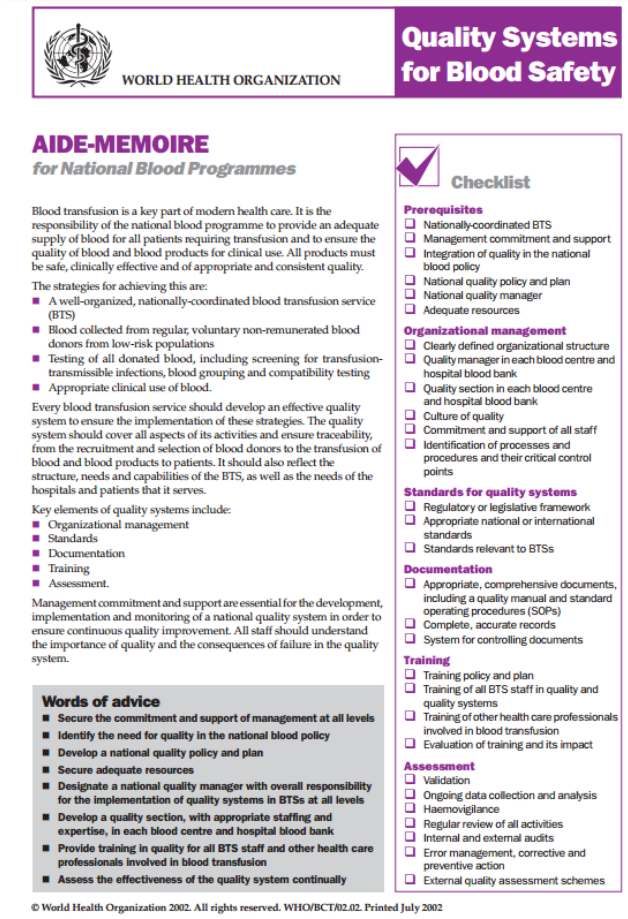
Developing a Culture of Quality in Blood Establishments

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Quality – A WHO Perspective



WORLD HEALTH ORGANIZATION

Quality Systems for Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

Words of advice

- **Secure the commitment and support of management at all levels**
- **Identify the need for quality in the national blood policy**
- **Develop a national quality policy and plan**
- **Secure adequate resources**
- **Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels**
- **Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank**
- **Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion**
- **Assess the effectiveness of the quality system continually**

Checklist

Prerequisites

- ❑ Nationally-coordinated BTS
- ❑ Management commitment and support
- ❑ Integration of quality in the national blood policy
- ❑ National quality policy and plan
- ❑ National quality manager
- ❑ Adequate resources

Organizational management

- ❑ Clearly defined organizational structure
- ❑ Quality manager in each blood centre and hospital blood bank
- ❑ Quality section in each blood centre and hospital blood bank
- ❑ Culture of quality
- ❑ Commitment and support of all staff
- ❑ Identification of processes and procedures and their critical control points

Standards for quality systems

- ❑ Regulatory or legislative framework
- ❑ Appropriate national or international standards
- ❑ Standards relevant to BTSs

Documentation

- ❑ Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- ❑ Complete, accurate records
- ❑ System for controlling documents

Training

- ❑ Training policy and plan
- ❑ Training of all BTS staff in quality and quality systems
- ❑ Training of other health care professionals involved in blood transfusion
- ❑ Evaluation of training and its impact

Assessment

- ❑ Validation
- ❑ Ongoing data collection and analysis
- ❑ Haemovigilance
- ❑ Regular review of all activities
- ❑ Internal and external audits
- ❑ Error management, corrective and preventive action
- ❑ External quality assessment schemes

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WHO Technical Report Series, No. 961, 2011

Annex 4

WHO guidelines on good manufacturing practices for blood establishments

- A quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients.
- It should also reflect the structure, needs and capabilities of the blood transfusion service, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management;
- Standards;
- Documentation;
- Training;
- Assessment.

Good Practice Guidelines for blood establishments and hospital blood banks required to comply with EU Directive 2005/62/EC

Quality must be recognised as being the responsibility of **all persons involved in the processes of the blood establishment**, with management ensuring a systematic approach towards quality and the implementation and maintenance of a Quality System (Directive 2005/62/EC/Annex 1.1.1).

Attainment of this quality objective is the responsibility of executive management. It requires the **participation and commitment of staff** in many different departments and at all levels within the organisation by the organisation's suppliers and by its distributors.

He aha te mea nui?

He Tangata. He Tangata. He Tangata



What is the most important thing?

It is people. It is people. It is people.

Old Maori proverb

What is a Quality Culture?

We define a “true culture of quality” as an environment in which employees not only follow quality guidelines but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them.

Harvard Business Review
April 2014

Quality culture is a set of group values that guide how improvements are made to everyday working practices and consequent outputs.

Quality Research International

Essentials for a Quality Culture

Culture is a simple way of saying how an organization expresses itself internally and externally. It is driven by values, whether by purpose or default. **It is driven by leadership and determines how the organization responds to all things, both good and bad.** As a matter of fact, there isn't a part of an organization that isn't influenced or affected by the type of culture that has either been developed or allowed to exist.

Culture must be demonstrated by the actions of those in leadership and not relegated to a few finely framed posters strategically positioned above work spaces. It must be more than a few paragraphs in the employee handbook that is briefly mentioned during the on boarding process, never to again see the light of day. **The people in your organisation will only take your culture as seriously as you do.**

http://www.theleadershipadvisor.com

NZBLOOD
Te Ratonga Toto O Aotearoa

QUALITY
STARTS WITH
YOU

Process Excellence





NZBLOOD
Te Ratonga Toto O Aotearoa

Five essential ingredients for a quality culture	
A mentality of "we're all in this together" (the company, suppliers, and customers)	The company not just as the buildings, assets, and employees, but also customers and suppliers. The goal is consistently win-win-win for all parties.
Open, honest communication is vital	An important way to encourage truth-telling is by creating a culture where people listen to one another.
Information is accessible	Business leaders should be open about sharing information on the company's strategic goals because this information provides direction for what we will do next and - more importantly - direction for how to improve.
Focused on processes	Everyone should move away from a "blame the person" mentality to a "blame the process and let's fix it" approach to problems and improvement.
There are no successes or failures, just learning experiences	An important insight is that failure and success are always value judgments we form after the fact

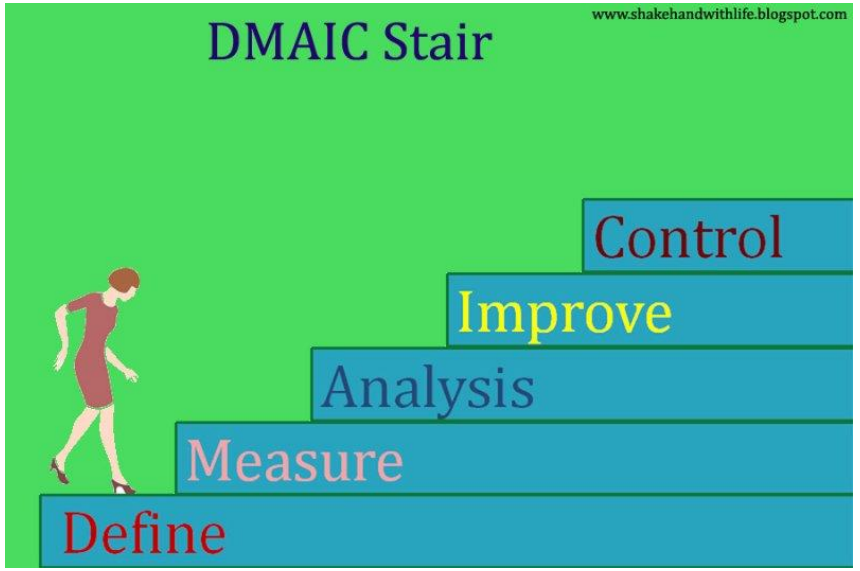
http://www.processexcellencenetwork.com

Lean Six Sigma

Lean Six Sigma is a methodology that relies on a collaborative team effort to improve performance by systematically removing waste, combining lean manufacturing/lean enterprise and Six Sigma to eliminate the eight kinds of waste (muda)

Key Principles

- Focus on the customer.
- Identify and understand how the work gets done (the *value stream*).
- Manage, improve and smooth the process flow.
- Remove Non-Value-Added steps and waste.
- Manage by fact and reduce variation.
- Involve and equip the people in the process.
- Undertake improvement activity in a systematic way.



Benefits of an effective Quality Culture

- Employees are more engaged and effective
- Productivity and overall efficiency increases
- Reduction in errors
- Improved staff retention
- Reduced sickness absenteeism
- Easier to recruit good employees
- Improved responsiveness to change
- Generally a better place to work

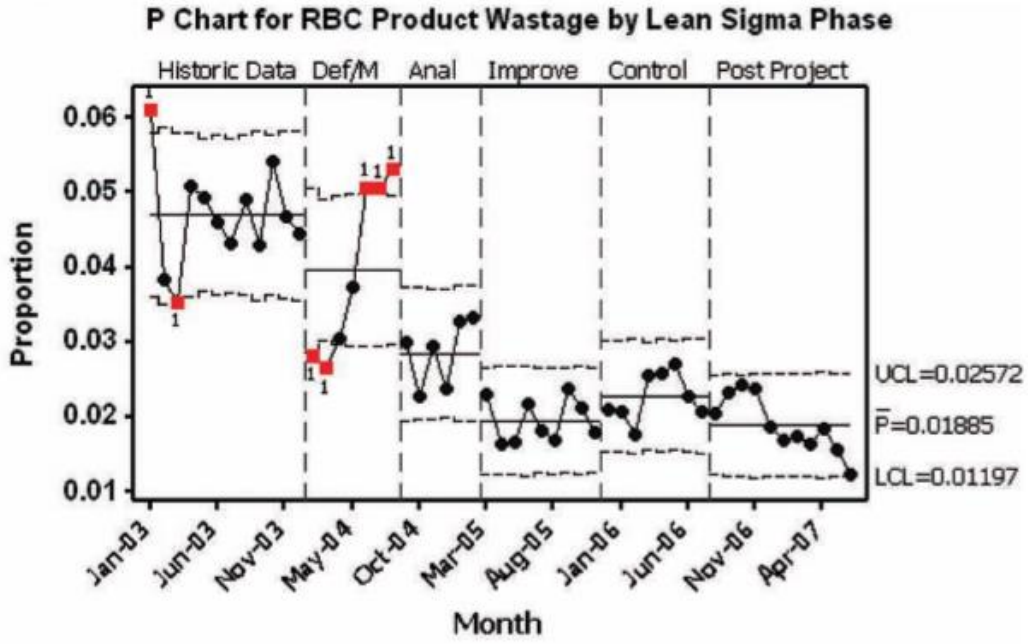
Gallup Q12 survey results show that organisations in the **top quartile for employee engagement** have:

- **37% less absenteeism and employee turnover**
- **48% fewer safety incidents**
- **41% fewer product defects**
- **21% higher productivity**

TRANSFUSION PRACTICE

Blood wastage reduction using Lean Sigma methodology

Eugenie S. Heitmiller, Richard B. Hill, Christi E. Marshall, Barbara J. Parsons, Lauren C. Berkow, Christine A. Barrasso, Elizabeth K. Zink, and Paul M. Ness



TRANSFUSION 2010;50:1887-1896

First steps into lean at the Australian Red Cross Blood Service

T. R. Jones & G. Wilkie

Manufacturing, Australian Red Cross Blood Service, Sydney, NSW, Australia

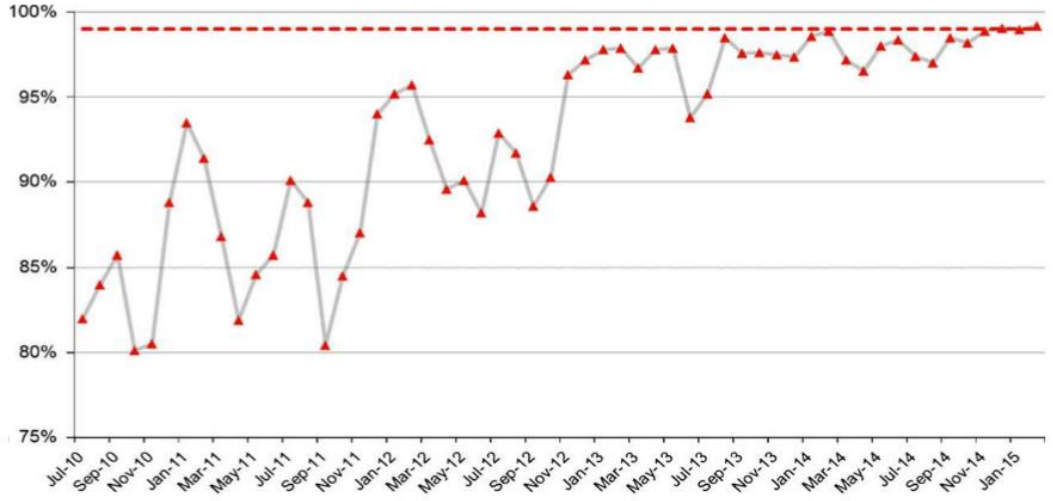


Fig. 4 Manufacturing Productivity Measures – Delivery In Full, On Time (DIFOT). The percentage of red cell, platelet and clinical plasma orders from Customers that are delivered in full and on time. Order fulfilment target of 98% achieved in February 2014.

ISBT Science Series (2016) 11 (Suppl. 2), 99–104

Improving the Efficiency of Component Processing

The Challenge

- Auckland Blood Centre severely space constrained
- Component processing team under pressure
- PEX initiative to investigate process flow and identify improvement opportunities



The Solution

- Process flow changed resulting in
  - Better time utilisation
  - Removal of unnecessary equipment
  - Happier staff



Process replicated at other sites. Capital replacement cost of unnecessary equipment estimated at 630K NZD

HPC Processing at the Wellington Blood Centre

- Decision made in 2015 to implement HPC processing in Wellington Blood Centre
- Initial assessment indicated that this could only be achieved by moving routine processing to Christchurch with significant loss of jobs
- Logistic plan developed and indicated this would be cost effective
- Cost of freight increased significantly as a consequence of the Kaikoura earthquake

Kaikoura Earthquake November 2016



- PEX processing improvements introduced into Wellington released space and will allow routine processing to co-exist with new clean room for HPC processing
- Costs reduced and HPC work able to be introduced with no increase in staff.

System Accountability

"People make errors, which lead to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong. The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems will continue."

Don Norman
Author, the Design of Everyday Things

"We cannot change the human condition but we can change the conditions under which people work"

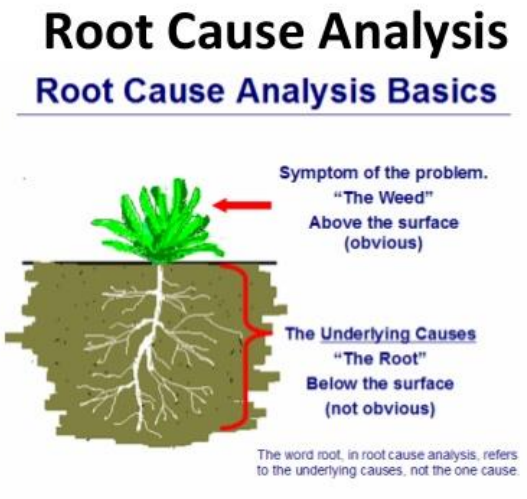
To err is Human, Institute of Medicine 2000

Why do errors occur?









Tracing a problem to its origins

Accountability for our Behaviours

Human Error

Inadvertent action: slip, lapse, mistake

Manage through changes in:

Environment
Processes
Procedures
Design
Training

CONSOLE

At-Risk Behaviour

A choice: risk not recognised or believed to be justified

Manage through:

Removing incentives for at risk behaviours

Creating incentives for healthy behaviors

Increasing situational awareness

COACH

Reckless Behaviour

Conscious disregard of unreasonable risk

Manage through:

Remedial action

Punitive action

PUNISH

Concluding Comments

- A commitment to Quality is integral component of an effective and successful Blood Establishment
- Compliance with the principles of Good Manufacturing Practice is an essential part of the process
- Ultimately success or failure will be determined by our people as well as our processes
- A quality culture commits a Blood Establishment to a set of behaviours that will improve overall outcomes and ensure a happy and engaged workforce