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## Short Communication



# Quality Culture – Lessons Learned from the Low- and Medium Income World

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## Abstract

With the development of safe blood supply and transfusion comes the introduction of quality as a culture, implemented through the introduction of a Quality System (QS) and Quality Management System (QMS). Often the idea is that- 'when instructions are written (SOPs) a quality system is in place. Just follow the instructions, that is it.' However, quality only partly depends on following instructions at the operational level. Generally not understood is the importance of designing and implementing a quality management system, based on 5 key elements 1) organization and structure; 2) standards (technical and quality); 3) documentation - traceability and evidence; 4) education - continued teaching and training; 5) assessment - continued monitoring and evaluation.

Development and implementation of an appropriate quality system and management were evaluated for 15 developing countries (2004-2020) in 4 WHO regions. Projects were based on a step-by-step introduction to the concept and principles of quality following a Quality Management Training (QMT) course – modular, interactive, with improvement score evaluation focused on comprehension and ownership of the teaching and training contents.

For an optimal understanding of the values of quality in Transfusion Medicine (TM), a culture has to be created - ownership development, commitment to and implementation of the principles of *fitness for purpose*, and the *supplier-producer-customer continuum*.

## Introduction

With the development of a safe blood supply and transfusion comes the introduction of quality as a culture, implemented through the implementation of a Quality System (QS) and Quality System Management (QSM) [1]. However, in many situations, the common idea is – 'when operational instructions are written (SOPs) a quality system is in place. Just follow the instructions, that is it.' However, quality only partly depends on following instructions at the operational level.

Generally not understood is the importance of designing and implementing a quality system, based on a Quality Management System (QMS) consisting of 5 key elements:

- 1) Organization and structure – mission and vision, policy and strategies;
- 2) Standards - technical and quality;
- 3) Documentation - traceability and evidence;
- 4) Education - continued teaching and training;

- 5) Assessment - continued monitoring and evaluation.

For an optimal understanding of the values of quality in transfusion medicine (TM), a 24/7 culture has to be created - ownership and stewardship development, commitment to and implementation of the principles of *fitness for purpose*, and the *supplier-producer-customer continuum* [2-4].

### How could we do that?

Development and implementation of an appropriate quality system and management were evaluated for 15 developing countries (2004-2020) in 4 WHO regions (Table 1). Projects were based on a step-by-step introduction of the concept and principles of quality following a Quality Management Training (QMT) course [5] – modular, interactive, with improvement-score evaluation focused on comprehension and ownership of the teaching and training contents.

The WHO QMT consists of two parts (part 1 - basic principles of quality and part 2 - applying quality in the blood transfusion system) with 13 modules, 7 basic and 6 applied, and a completion Module (Table 2). Each module consists

**Table 1:** QMT course: Low and Middle-Income Countries (LMIC) involved.

QMT course				
AFR	EMR	EUR	SEAR	WPR
Ruanda	Iran	Estland	India	Indonesia
Tanzania	Iraq	Montenegro	Pakistan	Montenegro
Uganda	Jordan	Serbia		
Zambia	Yemen			

AFR: Africa Region; EMR: Eaters Mediterranean Region; EUR: European Region; SEAR: South East Asia Region; WPR: Western Pacific Region.

**Table 2:** Modular Curriculum QMT course.

Quality Management Training Course		
Part 1 -General		
Module	Title	Type
Module 1	Introduction to Quality	Pre-course assessment; 2 lectures, 2 activities
Module 2	Quality Systems	3 lectures, 1 activity
Module 3	Organizational Management	4 lectures, 2 activities
Module 4	Standards for Quality	2 lectures
Module 5	Documentation	3 lectures, 3 activities
Module 6	Education (teaching and training)	3 lectures, 1 activity
Module 7	Assessment within the Quality System	7 lectures, 6 activities
Mid-course Assessment		
Part 2 - Applying Quality in the Blood System		
Module 8	Quality Management in the Blood Establishment	3 lectures, 2 activities
Module 9	Hygiene and Safety	3 lectures, 1 activity
Module 10	Quality Systems in Donor Management and Blood Collection	5 lectures, 3 activities
Module 11	Quality Systems in the Laboratory: Testing and Screening	5 lectures, 2 activities
Module 12	Quality Systems in Product Manufacturing and the Issue of Blood	6 lectures, 3 activities
Module 13	Quality Systems and the Clinical Interface	6 lectures, 3 activities
Module 14	Completion of the Course	2 lectures, 2 activities – Action Plans, Post-course Assessment

of lectures alternated by group activities to illustrate and implement the educated knowledge.

The QMT course outcomes were evaluated by comparing and analyzing the pre-course assessment outcomes with the post-course outcomes. That provides both the strong as well as the weak elements in understanding.

### What happened?

Since the introduction of WHO QMT courses in the 4 WHO regions, hundreds of blood establishment and healthcare facility professionals have been exposed.

However, often the selected trainees in these 15 countries were not properly prepared for the objectives and contents of such QMT courses, trainers and facilitators in the 4 WHO Regions had insufficient personal drive and experience, enthusiasm, and competence to conduct such high-level quality management course, and with regard to sustainability in-country follow up was not anticipated by existing leadership and therefore failed.

Nevertheless, a quality culture started to develop, and consistency of *fitness for purpose* and the *supplier-producer-customer chain* development as a healthcare-integrated managerial and operational system was noticed where –

- Selection of trainees was based on more strict criteria focused on future implementation,
- Training cadre had adequate competence, drive, and real-life experience,
- A pre-set follow-up structure for implementation and sustainability by committed and competent leadership was present.

Careful analysis of the outcomes of the QMT courses (post-course assessment) displayed important lessons to learn what the weak and what the strong elements were, in order to improve on the approaches for sustained development. When teaching focuses on outcomes (OBE) rather than on curriculum [6,7] the emphasis shifts from practical skills to a thoughtful understanding of quality culture, being more convinced of conducting active teamwork and implementing the *supplier-producer-customer continuum* and the *fit-for-purpose principle*.

### Conclusion

Although education (teaching of and training) in principles of quality as a manageable system to improve blood safety and availability is important, it is not enough to create a quality culture needed for sustained and guaranteed quality operations in blood establishments and hospitals/healthcare facilities. Learning should be outcome-based rather than curriculum-oriented.

An important lesson learned is that the approach shall be holistic and supported by competent leadership – commitment and stewardship, ownership, and full intellectual understanding. The outcome then needs an active and continued in-country follow-up to allow proper and sustained implementation of knowledge to build on the creation of a 24/7 quality culture based on stewardship. In fact, the QMT course presents a learning tool for implementing SWOT (Strengths, Weaknesses, Opportunities, and Threads) lessons that will strengthen the fit-for-purpose principle and the awareness of the continuum of the supplier-producer-customer chain.

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