

# What indicators should best be used to evaluate progress in transfusion medicine?

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## Introduction

Transfusion Medicine (TM) is a relatively young offspring of the family of sciences which came to development since Karl Landsteiner at the turn of the 19<sup>th</sup> Century discovered the fundamental blood group system ABO in Vienna [1]. For this milestone discovery Kark Landsteiner in 1930 was awarded the Nobel prize [2].

In the beginning of the 1940s his apprentice Peter Levine discovered a second important blood group system doing experiments with Rhesus monkeys and named the Rhesus system [3]. His observation was closely followed by the work of Birger Broman in Sweden [4]. These blood groups or red cell antigens are part of the laboratory science immunohematology, an important element in Transfusion Medicine [5].

Since the early 1900s Syphilis is known as a blood transfusion transmissible infection, caused by the micro-organism *Treponema Pallidum* and in the beginning suspected the cause of posttransfusion jaundice predominantly in pregnant women. However, in the 1940s Birger Broman discovered that posttransfusion jaundice in pregnant women could very well be caused by the major Rhesus blood group antigen D and its antibody [4].

## Awareness

In 1965 Blumberg discovered the Australia antigen in Ab-origines in Australia [6], later recognized as a surface marker or antigen of the hepatitis B virus (HBsAg) [7], transmissible by blood transfusion through contaminated blood components. This alerted WHO in 1975 to establish a World Health Assembly (WHA) Resolution WHA28.72 'Utilization and Supply of Human Blood and Blood Products' [8].

With the test systems for hepatitis virus antigens specific for hepatitis A and B developed in the 1970s it became clear that most of the viral liver infections were caused by a different virus named non-A non-B or NANB virus, later unveiled as the hepatitis C virus [9]. The scientists Harvey Alter, Michael Houghton and Charles Rice were then instrumental in unraveling the mystery of NANB and awarded the 2020 Nobel prize [2].

## Fundamental development system

In the 1980s the World was startled by the outbreak of Human Immunodeficiency Virus (HIV) infection which caused AIDS and showed to be highly infectious through blood transfusion and other body fluids. Immediately after the HIV outbreak in

the early 1980s WHO started to map the world for its TM existence and the related status of development through the Global Blood Safety Initiative (GBSI) consisting of a representative of the WHO, the International Red Cross and Red Crescent League, the World Federation of Hemophilia (WFH) and the International Society of Blood Transfusion (ISBT) [10]. The focus remained on development of safety and availability but not so much on sustainability: governance, legislation and regulation together with education and quality system management.

During the first two decades of the 21<sup>st</sup> Century development started to become noticeable all be it vague and in a slow pace accompanied by the 2010 Resolution WHA63.12 'Availability, Safety and Quality of Blood Products' [11]. This Resolution urged the Member States "to take the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it". However, the Resolution also raised several related issues and challenges in improving access to essential blood products for patients in developing countries:

- The weakness of quality systems resulting in plasma that is not acceptable for fractionation (leading to wastage) in developing countries;
- The excessive and unnecessary use of blood and blood components;
- Less safe transfusion practices and errors that may compromise patient safety;
- The increasing movement of blood and blood products across boundaries.

### The response

Despite the stimulating programs and documents, the challenges did not really diminish and developments moved on in a very slow pace. The Global Status Reports 2016 and 2021 of the mid 2010s and early 2020s presented the same challenges [12,13]. This initiated in 2020 within WHO an Action Framework to advance universal access to safe, effective and quality-assured blood products 2020-2023 [14]. The aim of this initiative was to help and support developing countries to overcome these challenges and accelerate development.

The challenges persisting over time are:

- Deficiencies in national policy, governance, and financing;
- Insufficient supply of safe, effective and quality-assured blood products for transfusion;
- Deficiency in blood product safety, effectiveness and quality;
- Insufficient availability of plasma derived medicinal products (PDMPs);
- Suboptimal clinical practice in transfusion of blood components;
- Insufficient access to blood in emergency situations.

The document lists 6 strategic objectives based on these challenges, each with the expectation of a number of related high-level outcomes. The most prominent high-level outcome

of each strategic objective has been translated in a practical Guidance of which there are eight published plus a Guidance to identify barriers in blood services using the Blood System Self-assessment (BSS) tool [15,16], developed in collaboration with the Boston Consulting Group (BCG) and financed by USAID. The BSS Tool has been published as Web annex [17].

The six strategic objectives deal with the comprehensive organization and structure of a national blood system and are:

- An appropriately structured, well-coordinated and sustainably resourced national blood system;
- An appropriate national framework of regulatory controls, national standards and quality assessment programmes;
- Functional and efficiently managed blood services;
- Effective implementation of Patient Blood Management (PBM) to optimize the clinical practice of transfusion;
- Effective surveillance (hemovigilance and pharmacovigilance), supported by comprehensive and accurate data collection systems;
- Partnerships, collaboration, and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional, and national levels:

These strategic objectives are comprehensive and reflect a recommendation: a well-organized national blood system for the future. Blood Transfusion is obviously more than immunohematology and detection of potential infectious diseases to be implemented with due knowledge on collected voluntary human blood, the Gift of Life [18].

### Declarations

**Conflict of interest:** The author has no conflicts to declare.

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