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Universal health coverage and WHO model list of essential medicines – impact on blood transfusion in lower- and middle-income countries

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Despite the many blood safety initiatives and projects since the first World Health Assembly Resolution WHA28.72 in 1975 [1], there are still remarkable differences in blood availability and safety among countries in the four different Human Development Index (HDI) [2] groups. There is definitely progress, but more on the technical operational side than on organization, regulatory oversight, governance and leadership, and financing of the blood supply and clinical use. The latest WHO Global Status Report on blood safety and availability 2016 [3], based on data collected in 2013 through a survey linked with Global Database on Blood Safety, shows a clear picture in four major areas of attention – availability; quality and testing; clinical use; policy, legislation, regulatory oversight and governance mechanisms.

Essential medicines and universal health coverage

In 2010, during the World Health Assembly, resolution WHA63.12 was adopted [4] which expresses serious concerns on the fact that large groups of patients in developing countries still have no access to safe blood and blood products, including plasma derived medicinal products (PDMP) despite these being listed as Essential Medicines (EMs) since 1979 [5]. The concern expressed regarded the observation that many patients e.g., obstetric, paediatric, trauma, thalassaemia were still left without needed treatment, and of those with severe congenital and acquired disorders e.g., haemophilia, without adequate and safe plasma-derivative treatment. In this Resolution Member States were urged "… to take all the necessary steps to update their national regulations on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood and blood products, and operation of regulatory authorities in order to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards." Two years later in the year 2012 WHO provided countries a useful instrument to assess the existence of blood regulatory systems [6]. However, progress has been very limited and many lower- and middle-income countries still have a long way to go in providing universal access to safe and quality assured blood and blood products. Additionally, a growing number of people being pushed into extreme poverty, because of catastrophic out-of-pocket payments for health care costs [7]. By 2012, this number has grown to over 100 million, where over half of the global population still does not have full coverage of essential health services, medicines and blood products.

In 2012, the UN General Assembly adopted Resolution 67/81 on Global Health and Foreign Policy where all Member States agreed to work towards achieving Universal Health Coverage (UHC) by 2030, which was later included as one of the UN Sustainable Development Goals (SDG) 2016-2030 [8, 9]. UHC means that all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.UHC embodies three related objectives:

1. Equity in access to health services - everyone who needs services should get them, not only those who can afford and pay for them.
2. The quality of health services should be good enough to improve the health of those receiving services.
3. People should be protected against financial risk, ensuring that the cost of using services does not put people at risk of financial harm and/or poverty.

UHC, as pertains to blood and blood products, means that all individuals and communities have access to

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affordable and timely supplies of safe and quality-assured blood and blood products [10]. These products are included in the WHO Model List of Essential Medicines since 1977 with biannual updates. Most recently, the list included blood and labile blood products (components) in 2013 [5], and WHO Model List of Essential in vitro diagnostics established in 2018 [11]. To support countries in the management of blood and blood products as essential medicines, the WHO Expert Committee on Biological Standardization in 2017 developed clear supportive '*guidelines on management of blood and blood components as essential medicines*' [12]. Member States have been and are continuously urged to take appropriate actions to recognize the cruciality of an effective regulation for the establishment of blood and blood products as EMs. The guidelines cover the key aspects needed:

- Blood and blood components as biological therapeutic products;
- Preparation of blood and blood components;
- Comparison of blood components with PDMPs;
- The blood regulatory system;
- The blood supply system;
- The blood transfusion system; and
- Stepwise implementation of a nationally regulated blood system.

From the design and approach of these guidelines a simple and illustrative work scheme can be extracted, recognizing the interrelated triad of operational systems each with its specific responsibilities in the health care – the blood regulatory system, the blood supply system and the blood transfusion system (Figure 1).

National Blood System

The guidelines recommend that a national blood system should consist of three interrelated subsystems, i.e., the blood regulatory system, the blood supply system and the blood transfusion system, with clearly defined roles and responsibilities that are defined. Because blood and blood products are medicines, the production and use of these products should be effectively managed and regulated by a competent regulatory authority (RA).

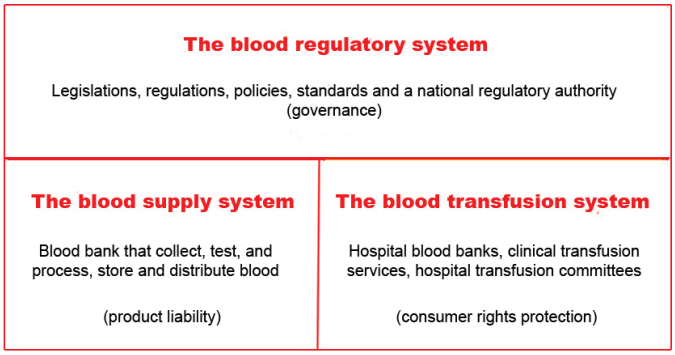

Figure 1: Organization of national blood system.

Blood and blood products are produced by the blood supply system (blood banks/establishments) – similar to manufacturers of medicines. The product liability lies with the manufacturer. The user/customer is the blood transfusion system (hospitals, diagnostic and treatment institutions) – the treating clinicians who prescribe and administer blood products and medicines in hospitals (supported by therapeutic and transfusion committees). These have the legal obligation to protect rights of the final consumer – the patient in need, from faulty products.

Bridging Efforts to Develop

The 2016 Global Status Report [3] presents as most important weaknesses the continued existence of incompetent regulatory oversight due to inappropriate governance; weak leadership and management; weak to absent public and clinical awareness; inconsistent quality, economies of scale and documentation (traceability); and budget constraints with dependence on external donors. Most of the donor financed development projects so far have suffered from lack of vision and adaptation to the local country circumstances, capacities and resilience to change. Additionally they were too short to generate and root any sustainable effect, were largely focused on the day-to-day technical operations, and were limited in their monitoring and evaluation over time of the outcomes within the perspective of a country's health care system and the related UHC development.

However, there is also noticeable a growing political awareness in lower and middle-income countries, focused on the need for an effective regulatory framework consisting of appropriate legislative instruments:

1. Legislation, law or act providing the scope and anchoring the international principles.
2. Regulations supplemented by policies and implementable strategies, standards, guidelines, and guidance documents, spelling out implementation details of the daily management and operation of the blood supply and consumption.
3. National Regulatory Authority (NRA) to oversee and control the systems of procurement and consumption.

In general, it is recommended to allow a risk-based development of the composite triad-system as described. For a stepwise implementation of a nationally well-regulated blood system, fundamental to assuring the quality, safety, availability and affordability of blood and blood products as essential medicines, a risk-based strategy is even recommended and preferred, when considering the development of an effective regulatory structure for the blood system and a national roadmap for its efficacious and sustainable implementation. Despite the observation that there are different starting situations from fragmented and non-coordinated to national and

consolidated, a prime prerequisite is the existence of a documented political commitment of the ministry of (public) health to establish a road map for implementation and maintenance of a nationally regulated blood system. Such road map needs consensus of all stakeholders and related parties and a strong leadership.

Impact on blood transfusion

Key are an initial review and improvement of an existing structure, including the financing mechanisms (e.g., cost recovery, health insurance, mix); development or strengthening of the legal framework and NRA; development and/or adoption of standards, preferably in line with accepted international standards – quality and technical; continued interaction among key stakeholders, including the community and the hospitals; development of a comprehensive quality management system; capacity building (competency) and leadership development (Result Oriented/Based Management); collaboration and cooperation; development of sufficient economies of scale to allow efficient processing and QC/testing to achieve equal standards of practice and reduce costs; strong clinical interface and rational use of blood; development of sustainable awareness campaigns – public, clinical and political.

When these measures are implemented effectively at national level, lives of hundreds of millions of people will be influenced in a positive way, leading to important improvement of quality and efficacy of the health care system in many developing countries. Ensuring appropriate access to affordable and quality assured blood and blood products as EMs based on a sound regulatory system plays an important role in achieving UHC and SDGs targets, reducing the burden of disease (QALY and costs), and need to be given due consideration by all stakeholders working towards achieving these targets.

Keywords: Blood transfusion, Essential medicines, National blood system, Regulatory system, Universal health coverage

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SOURCE OF INFORMATION

Lower- and middle-income countries – Besides personal experience, three sets of UN/WHO recent documents were studied and served as the basic sources of information: WHO Global Status Report on Blood Safety and Availability, 2016; UN Universal Health Coverage (UHC) 2010 and the UN 2012 Resolution 67/81; WHA Resolution 63.12 and WHO Guidelines on Management of Blood and Blood Components as Essential Medicines, 2017.

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Cees Th. Smit Sibinga – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Yetmgeta E. Abdella – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

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