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Review

Poor economics - Transforming challenges in transfusion medicine and science into opportunities

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ABSTRACT

The prospect of cryopreservation of cellular components in the low and medium income (poor economics) part of the world absolutely needs a solid and sustainable infrastructure to build on in line with science, technology and globalization, based on rational thinking, standardization and harmonization of future advances we are currently witnessing in limited parts of the world. With the stepwise development of the healthcare stimulated by the 2012 UN Universal Health Coverage (UHC) program and supported by WHO Model List of Essential Medicines (EM) and Essential *in vitro* Diagnostics (ED), a slowly growing number of countries will reach a point where quality cryopreservation of cellular components becomes feasible as an advance for implementing specific health care visions, policies and strategies in line with the Sustainable Development Goals 2016–2030.

1. Introduction

Steven Pinker in his 2018 book ‘Enlightenment Now; the case for Reason, Science, Humanism and Progress’ [1] argues strongly for the positive and visible progress noticeable in the world over the past two to three centuries since the early development of the enlightenment in Europe during the end of the 17th and the 18th Centuries. Despite the still prominently existing differences in many existential, science, economy, health and equality aspects of human life, there is a continuous lifting of the baselines for comparison over time. The poor are no longer the poor they were a century ago, not only in terms of wealth and financial welfare, but also in terms of knowledge, health status and inequality. However, the more advanced part of the world progresses in a different pace and with a different prioritizing of life and environmental issues than the less developed part of the world. Unfortunately this last part houses over three times more people than the advanced part does.

Developments that took place in the second half of the 20 st Century, decolonizing large parts of Africa, South and Middle America, Asia, the Western Pacific and the Middle East, created major changes within humanity. Also at the end of the 20 st Century the dismantling of the Soviet Union with the fall of the Berlin wall and the creation of a dozen so called Newly Independent States triggered a landslide in

environmental circumstances initiating major changes in life style, wealth, health and developmental progress to which the advances in information and communication technology (ICT) and the easing of moving and travelling around in the world (including migration) have largely contributed. There is a growing exchange and sharing of experiences and knowledge, science and education contributing to the continuum of baseline uplifting, challenging the need for reappraising and redefining terminology and related philosophies, visions and observational interpretations of progress. In general the poor do not grow poorer although the rich grow richer all over the world. Actually the poor are slowly growing richer in many though not all aspects of life, not in the least in the improvements of standards of living [1].

An important aspect of achieving progress is in the complexity of the necessary infrastructural composition of a society in which people are spending their life. Infrastructure in its multifaceted appearance *de facto* serves as the fundament of existence of which the manifold of aspects and elements is anchored in the 1948 UN Universal Human Rights Declaration [2]. This includes besides e.g., shelter, safety, justice and education also health and access to health care, of which blood transfusion ‘vein-to-vein’ in all its various appearances and practices is an integral part.

Developments and progress, advances and improvements find a major source in knowledge and science, technology and globalization

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based on rational thinking and foreseeing implementation in a humanistic environment and scenery, applicable, accessible and affordable for all. The economics of the creation, development, maintenance and sustainability of such environment and scenery parallel the UNDP and World Bank classification of development – low, lower- and higher-middle, and high human development – index or income. [3,4] Both classifications are widely used, though essentially different. Assignment of a World Bank group is based on Gross National Income (GNI) per capita (current US\$). The Human Development Index (HDI) is a statistical tool used to measure a country's overall achievement in its social and economic dimensions. Economics or social and economic dimensions of a country are based on the health of people, their level of education attainment and their standard of living [3].

2. Concerns on fundamental weaknesses and challenges

The efforts of World Health Organization (WHO) through consensus resolutions, guidance documents, numerous series of workshops, seminars and consultations, so far have not been fully translated to a sustained awareness, solid infrastructure and reliable financing in all countries. The US HHS PEPFAR project (Health and Human Service President's Emergency Plan for AIDS Relief) launched in 2004 and implemented through Centers for Disease Control and Environment (CDC) resulted unfortunately in many benefiting countries a still being at or close to square one when funding was discontinued. [5,6] This should urge development partners and donor agencies to analyse where the root cause is and to identify the fundamental weaknesses and challenges to create opportunities for establishing sustainably operating blood systems build on an adequately functioning and collapse-proof infrastructure in each and every country.

Fundamental weaknesses and challenges of the international blood and bioproducts availability, transfusion safety and clinical efficacy in poor economics are in the regulatory framework, governance and leadership.

The 2010 WHA Resolution 63.12 [7] expressed concern about the unequal levels of access globally to blood products, particularly plasma derived medicinal products (PDMP). Such inequality leaves many patients without needed treatment and aggravates the national burden of disease, both acquired and congenital. However, recently promising research was published on plasma fractionation and virus inactivation of cryoprecipitate in low- and medium-HDI countries [8,9]. Blood transfusion is an integral supportive element of the health-care service and deserves equal attention and efforts to accelerate the transition, starting at supreme governance level. In 2012 the UN Resolution 67/81 Global Health Policy [10] recognized the responsibility of Governments to urgently and significantly scale up efforts to accelerate the challenge transition towards the opportunity to create universal access to affordable and quality health-care services to achieve Universal Health Coverage (UHC). UHC as pertains to blood and blood products, means that all individuals and communities have access to affordable and timely supplies of safe and quality-assured blood and blood product [11].

With the WHA63.12 Resolution, World Health Assembly urged all Member States '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 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' [7]. Achieving self-sufficiency in the availability and supply of safe blood is an important national goal in preventing blood and bio-product shortages and meeting the transfusion needs of the patient population. Consequently blood and blood components (whole blood, red cells, platelets and fresh plasma) were included in the 18th edition of the core list of WHO Model List of Essential Medicines in 2013 [12], where the elementary in-vitro diagnostics were included in the 2018 first edition

of the Model List of Essential In Vitro Diagnostics. [13] To support countries and interested supportive third parties in the development and management of blood and blood components as essential medicines the WHO Expert Committee on Biological Standardization published in 2017 practical guidelines which include a chapter on the blood regulatory system needed and a final recommendation on stepwise implementation of a nationally regulated blood system [14].

3. Future perspectives on implementation of advanced technologies

The theme of this 2020 series of special issues focuses on the manipulation and advanced preservation technologies and methodologies like cryopreservation and freeze-drying of platelets, red cells, PDMPs and mobilized pluripotent stem cells. These bio-products could be applied in a variety of clinical situations e.g., hemato-oncology, thalassemia and sickle cell disease, congenital coagulopathies and regenerative medicine. However, a well-developed and sustained infrastructure is an absolute prerequisite, including appropriate education and specialized skills to implement and operate. In the advanced part of the world these prerequisites and fundamental conditions are taken for granted resulting in reluctance to include the necessary considerations when attempting to export the appropriate knowledge and science to less advanced parts of the world. However, interestingly progress towards pathogen inactivation of whole blood, the general transfusion commodity in Sub-Saharan Africa, has recently been published. [15]

Another paramount element is the need for standards and documentation *in casu* a well designed, comprehensive and operational quality system management based on an established quality culture. [16]

4. Where are we now, what then is the problem?

Over the past decades there has been increased interest in ensuring the support of development and strengthening of availability and safety of blood and blood products including the PDMPs and cellular bio-products in low- and middle-income (LMI) or -HDI countries; the poor economics. Governance and leadership are essential strategies, which are generally lacking and must be addressed more stringently. Without Governments, through their National Health Authorities, approving a legal framework necessary for establishing an effective organisation and quality managed blood service capable of meeting the needs of all patients through each country; ensuring sustainable annual fiscal budgetary allocations; providing a reliable infrastructure and capacity for a sustainable Blood Service, these aspirational recommendations of Leadership and Governance to develop and implement, such advanced technologies and methodologies will not be possible.

However, a slowly growing number of countries will reach a point where the challenge of quality manipulation, cryopreservation and freeze-drying of cellular components becomes an opportunity for implementing specific health care visions, policies and strategies in line with the Sustainable Development Goals 2016–2030 [17].

Declaration of Competing Interest

The authors have no competing interests to report.

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