Access to Blood Products

Access to safe and effective blood products in low and middle income countries

Blood products include blood and blood components produced as single-donor products for direct transfusion, so-called labile blood components (i.e., red blood cells, platelets and plasma), as well as numerous plasma-derived medicinal products (e.g., albumin, polyvalent and specific immunoglobulins, and blood coagulation factors) that are prepared in fractionation facilities from pools of thousands of plasma units.

In high-income countries (HIC), each unit of whole blood collected is separated into several therapeutic blood components to both deliver the most effective treatment (component therapy) and to make most efficient use of a precious and limited human resource. The plasma component can be used directly for transfusion, or sent for further manufacture into therapeutic plasma protein concentrates.

Access to safe and effective blood products is a major challenge in low and middle income countries (LMIC) where local blood establishments may have very basic facilities and systems, where quality and safety standards need to be established or strengthened, and where blood supplies may be insufficient to meet medical needs.

World Health Assembly resolution WHA63.12, in addressing the availability, quality and safety of blood products, points out that in many LMIC a large percentage of human plasma, separated from whole blood is currently discarded. This wastage occurs in large part because the separated plasma is not suitable for further manufacture. Generally accepted international standards require, among other things, appropriate freezing and cold storage conditions, traceability of donors, testing to lower the residual viral risk, regulatory controls, quality systems and adherence to good manufacturing practices (GMP). Improvement in quality standards, know-how and production processes in blood establishments should therefore directly contribute to reducing the rate of transmission by transfusion of blood-borne infectious diseases.

Even while the need for plasma products grows, a substantial and increasing volume of recovered plasma in LMIC is currently being wasted. This volume has been estimated — based on the global approximations of whole blood donations and the volume of recovered plasma currently used for direct transfusion or for fractionation — to be close to 9.3 million litres each year. This volume corresponds to more than 40% of world supply of recovered plasma.

The volume of discarded plasma is expected to increase substantially as the volume of blood collected to meet projected LMIC needs for red cells (the primary determinant of the number of whole blood collections) increases and as blood component therapy becomes more widely applied. This has been the experience supported by decades of clinical data from HIC.

The challenge now is to support LMIC investment in improving the quality of the blood they collect by improving the knowledge base, infrastructure, production standards and regulatory oversight in blood establishments and by emphasizing the positive impact that such a move...
will have on public health. The short-term investment in improving local production standards in blood establishments of countries currently discarding large volumes of plasma is a means to improve access to essential plasma-derived medicinal products while at the same time improving the quality and safety of the other blood components, the safety and health of the blood donor and the long-term benefits to the public health of national and worldwide populations.

To examine and analyze the available data, the drivers of technology transfer and local production in blood establishments, and the potential benefits and risks that arise from such an initiative, WHO convened a stakeholders’ workshop in Geneva on 14–15 June 2012. Participants included representatives from national regulatory authorities, blood collection organizations, patient organizations, national blood programmes, plasma fractionators, members of the WHO Blood Regulators Network, nongovernmental organizations, public health and funding agencies.

The report of these deliberations will be published in April 2013 and posted at the web site address: http://www.who.int/bloodproducts. The report examines the volume of plasma separated from whole blood that is currently wasted worldwide and identifies challenges and opportunities and the key steps needed to improve the current situation.

The steps proposed should have multiple benefits, at the national, regional and global levels. They include strengthening local production capacity in blood establishments in countries currently discarding plasma, through transfer of technology and know-how, building technical capacity and expertise of national regulatory authorities in the whole-blood area, improving the health of the blood donor and blood-product recipient, and providing data on the epidemiology and demographics of markers of blood-borne infections.

Overall, it is imperative for governments in LMIC to address the large wastage of blood and plasma estimated to occur, and it is clearly in their interest to do so. The process, methods, and timelines for improving blood collection systems will vary in different countries. The gaps between HIC and LMIC are significant, but differ from region to region. Suitable regulatory oversight is often lacking, and in its absence progress will be faltering and at risk. Sustainability of aid provided to many countries, largely because of the AIDS pandemic, will only occur with the exertion of national will and locally appropriate regulatory and legislative action.

Another initiative intended to improve the safety, availability, quality, and accessibility of blood products is the proposal endorsed by the WHO Blood Regulators Network to add whole blood and red blood cells to the WHO Model List of Essential Medicines (EML). This proposal was also endorsed by the 63rd WHO Expert Committee on Biological Standardization and the 15th International Conference of Drug Regulatory Authorities. Whole blood and red cells meet the generally accepted definition of medicines; they are among the most widely prescribed therapies (an estimated 90 million units annually worldwide), and are credited with saving millions of lives each year.

Blood is a national resource, derived from voluntary public donations and processed into medicines to advance that same public’s health. Blood is a unique biological in that the “raw material” is the blood donor and the health of that donor is linked directly to the health of the recipient. The EML designates medicines as essential based on their efficacy and safety, availability, ease of use in different settings, comparative cost-effectiveness, and public health.
need as judged by disease prevalence. The EML is important because in many countries it forms the basis of national drug policies. Governments and health ministries often refer to the EML when making decisions regarding resource allocation and health spending.

Adding blood to the EML should encourage investment in building local systems to provide safe and effective blood which is accessible to more patients. Although the cost of upgrading standards, infrastructure and regulatory oversight requires an initial investment, the result is safer available blood, reduction in the risk of another epidemic of blood-borne disease transmission, and long-term societal benefit. Most HIC already distinguish blood components as a product in terms of preparation, storage and handling, from the process of transfusion which has traditionally been considered medical practice, and many already regulate blood components as medicines.

There is no conflict between the concepts of blood as a medicine and blood donation as an altruistic act. The opposite is true. Addition of whole blood and red blood cells to the EML should benefit the development of voluntary non-remunerated donation by protecting the health of the blood donor and by raising the standards for safe collection, accurate screening and testing, and follow-up of donors who require care. Countries that already regulate blood as a medicine oversee and protect the appropriate care of the donor. Nor is there evidence that regarding blood as a medicine will promote commercialism of human tissue by introducing the sale of blood or payment of donors. In virtually all countries that have regulated blood as a medicine for decades, blood components derive from voluntary, unremunerated donors. Listing blood on a WHO-sponsored document should further emphasize the importance of voluntary non-remunerated blood donation and the not-for-profit status of blood collecting organizations: policies that WHO has endorsed for many years. In all cases, the purpose of the EML is to reduce the burden of disease. The application to add blood to the EML will encourage governments to invest in infrastructure and the governance of blood systems, support safe blood collection and regulated blood preparation, storage and shipment, and improve public health.

At the 15th International Conference of Drug Regulatory Authorities, regulators from more than 100 countries endorsed the recommendations that:

- Member States should take steps to assure the quality, safety and availability of blood for transfusion, including oversight through regulation; and

- Member States are encouraged to establish lists of essential medicines and to include whole blood and blood components for transfusion on their lists.

These recommendations underline the objectives of Resolution WHA63.12 adopted in 2010 which supports access to quality, safe blood products at the global level.