

Setting up a Regulatory Framework for Blood in Africa

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AABB Experience in Selected African Countries

- Since 2005 AABB has provided blood safety technical assistance in Africa under the President's Emergency Plan for AIDS Relief (PEPFAR)
- Countries included/include:
 - Angola, Kenya, Lesotho, Malawi, Mozambique, Rwanda, South Africa, Swaziland, Tanzania and Zimbabwe



WHO National Blood Policy Framework

- Government commitment to NBP
- Internationally accepted ethical principles for blood donation and transfusion, eg, reliance on Voluntary Non Remunerated Blood Donors
- Promotion of training and education to meet Human Resource needs
- “Quality assured” TTI, blood grouping and compatibility testing



National Blood Policy Framework

- Promotion of appropriate clinical use of blood
- Implementation of total Quality System
- Adoption of internationally accepted standards for all blood activity
- Encouragement of Research, Development and Monitoring and Evaluation
- Financial sustainability of blood program



Factors that Impede Effective Regulation

- Only a few NBPs contemplate regulatory oversight by an independent body, resulting in self-regulation
- Often NBPs require implementing legislation, which can be difficult
- The lack of sufficient numbers of trained professionals in many countries makes it difficult to implement regulatory functions



WHA Resolution 63.12 Availability, safety and quality of blood products (2010)

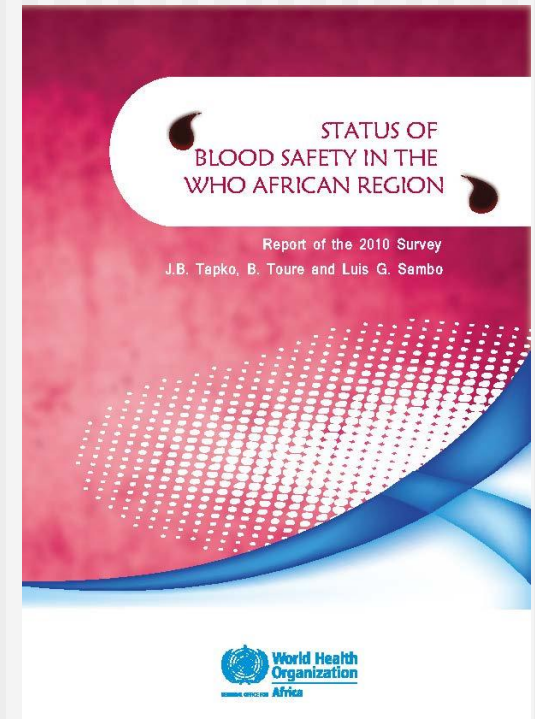
Urged WHO member states to:

- Update national regulations on donor assessment, collection, testing, processing, storage, transportation and use of blood;
- Update regulatory authorities to meet internationally recognized standards and ensure regulatory control across transfusion chain
- Enhance quality of evaluation/ regulatory actions for blood



51st session of WHO Committee for African Region adopted strategies to promote implementation of WHA 63.12

- 2012 Survey on Regulatory issues
 - 36 of 46 Member states responded
 - 29 of 36 respondents had adopted a National Blood Policy (NBP) with implementation underway
 - 11 had blood safety legislation in place



New Catalysts for Change

- Blood added to WHO List of Essential Medicines
- WHO Blood Regulators Network issues guidance
- Development of Africa Society for Blood Transfusion Standards and Step-wise Accreditation Program



WHO Essential Medicines List 2013

11. BLOOD PRODUCTS OF HUMAN ORIGIN AND PLASMA SUBSTITUTES

11.1 Blood and blood components

In accordance with the World Health Assembly resolution WHA63.12, WHO recognizes that achieving self-sufficiency, unless special circumstances preclude it, in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population. All preparations should comply with the WHO requirements.

fresh-frozen plasma

platelets

red blood cells

whole blood



WHO Blood Regulators Network

- Network of leading blood regulatory authorities providing a forum for enabling rapid dialogue and fostering international consensus on effective regulatory approaches
- Developed Assessment Criteria for National Blood Regulatory Systems with recommended core functions



Recommended Core Functions of National Blood Regulatory System

- Licensing and/or registration of blood facilities
- Approval of blood/blood component products
- Regulatory oversight of associated substances and medical devices used in blood production
- Access to a laboratory independent of manufacturers
- Control of clinical trials



Recommended Core Functions of National Blood Regulatory System

- Regulatory inspections and enforcement activities
- Vigilance Systems
- Ensuring traceability and record keeping for all regulated products/functions
- International Cooperation



Africa Society for Blood Transfusion



Africa Society for
Blood Transfusion

- Blood services (collection through transfusion) Standards developed based on internationally accepted practices, but adapted to the African environment (eg, ID NAT for HIV not required)
- Step-wise Accreditation Program developed (Level 1 certification, Level 2 certification and Level 3 accreditation) based on incremental compliance with Standards
- Assessors have been trained; Assessment tool has been piloted in 2 countries; First assessment completed last Friday



Lessons Learned

- Advocacy and opinion of organizations like WBMT and its member societies is critical
- WHO leadership is important in influencing member state governments to adopt appropriate regulation



Lessons Learned

- Inclusion of blood in the National Health System Strategic Planning process ensures attention to regulation
- Standards and accreditation programs that meet international norms and are implementable are an important component of effective regulation
 - National or regional societies play an important role



Lessons Learned

Standards that meet international norms, but which are achievable, are a key element of progress

- National or region-wide societies play an important role



THANK YOU!



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