Regional Workshop on the development of regional strategy for blood safety and the establishment of national regulatory systems for blood and blood products Cotonou 23-25 July 2015

Summary report

By

JB Tapko

Outline of the presentation

- Objectives and expected results of the workshop
- Background
- Outcomes of the workshop
- Recommendations
- Next steps

Objectives of the workshop

General objective

To review:

1. The draft of the regional strategy for blood safety and
2. The draft guidelines for the establishment of national regulatory system for blood and blood products

Objectives of the workshop

Specific objectives

1. To share country experiences in the:
   - Implementation of the regional strategy and
   - Establishment of national regulatory systems
2. To identify strengths, weaknesses, opportunities and threats in implementing the above
3. To review the draft regional strategy and
4. To develop guidelines for establishment of national regulatory systems for blood services

Expected results

- Experiences shared
- Strengths, weaknesses, opportunities and threats identified
- Draft Regional strategy for Blood Safety reviewed
- Guidelines for the establishment of National Regulatory System for blood and blood products developed

Background for the workshop

Background for the Regional Strategy

- The Regional Strategy for Blood Safety was adopted in 2001 By resolution AFR/RC51/R2)
- The strategy had 4 targets for to be achieved by 2012

Background for the Regional Strategy

- Targets of the Regional Strategy
  1. All the Member States will have carried out a situational analysis of blood transfusion services
  2. At least 75% of countries will have drawn up, adopted or implemented their national blood policy,
  3. 100% of blood units transfused will be screened, beforehand for the 4 major TTI
  4. At least 80% of blood donations will be collected from voluntary non remunerated blood donors

Background for the Regional Strategy

- Findings of evaluation of the implementation of the regional strategy for blood safety – were presented (AFRO)

Implementation of the Regional Strategy

Key indicators	Number of countries
Situation analysis done	45
National Blood policy adopted	35
VNRBD (80–100%)	24
Annual blood collection rate /1000 population	4.5

Implementation of the Regional Strategy

Key indicators	Average
VNRBD (%)	77
Blood units tested for HIV (%)	99.95
Blood units tested for HBV (%)	98.5
Blood units tested for HCV (%)	96.9
Blood units tested for Syphilis (%)	97.5
Blood donations separated into components (%)	62

Implementation of the Regional Strategy

Key indicators	Number of countries
Quality management programme in BTS	34
Programme of continuing education	21
Participation to EQAS	30
Guidelines on clinical use of blood	29
National hemovigilance system	9
PDMP production	1

REGULATION

Background for the Regulatory systems

- **Key findings on the regulatory systems in Africa**
  - Legislation adopted by 23 countries
  - Legislations adopted but not implemented
  - The delineation between law and regulations/standards vary according to the country's health legal system infrastructures state of development and tradition.

Background for the Regulatory systems

- **Key findings on the regulatory systems in Africa**
  - Need for clear definitions of the terms used by countries
    - There was need for clarification on what is meant by legislation, regulation, regulatory framework and regulatory body

Background for the Regulatory systems

- **Key findings on the regulatory systems in Africa**
  - Countries are at different levels of development in the development of regulation on blood and blood products (Ghana and Kenya)
  - South Africa is regulated by the medicinal control council for plasma including imported plasma.

Background for the Regulatory systems

- **Key findings on the regulatory systems in Africa**
  - No specific binding regulations for the collection, testing, processing, distribution and transfusion of blood and blood components
    - Although it does exists: general controls on personnel (for example, professional registration of medical and nursing practitioners), premises, and processes.
  - Manufacturing of (plasma derived) medicinal products is usually regulated.

Background for the Regulatory systems

- **Key findings on the regulatory systems in Africa**
  - Even though policies/regulations are in place, there is no effective oversight/monitoring by Ministry of Health
  - Self-regulation, or self standards enforcement are very common

Experiences from Western Countries

- Paul-Ehrlich-Institut (PEI) Germany
  - The role of the PEI was presented
  - Its national and international integration
  - Its historical and medicinal responsibility
  - its activities as related to blood and blood products emphasizing the criteria as being quality, safety and efficacy and not cost.
  - Also gave details of the regulatory activities along the blood transfusion value chain

Experiences from Western Countries

- Blood Regulatory Network (BRN) Canada Assessment Criteria
  - Highlighted the need for assessment criteria, the reason the network was given the task, contents of the document, the essential elements and core functions, the structure of the document.

Background for the Regulation

- Renewed EU/ACP/WHO Partnership focusing on 15 countries to improve quality of medicines
- Workshop on blood regulatory systems to improve availability and safety of the blood supply held in 2013
- New initiatives regarding attainment of MDGs, Reproductive, Maternal, Newborn and Child Health.

Background for the Regulation

- Recommendations of the 2013 workshop
  - Assess the situation of essential medicines, blood and blood products,
  - Strengthen the capacity of National Regulatory Authorities (NRAs) and reinforce the legal frameworks for Blood Transfusion Services,
  - Promote Good Manufacturing Practices (GMP).

Milestone achieved

Milestones achieved

- **Regional Strategy**
- **The draft Regional strategy document include**
  - **Justification, highlighting the level of achievement using data from the situation analysis/GDBS 2012**
  - **The outline of the strategy gives details of the aim, objectives, targets to be achieved in the next 10 years (2017-2026), guiding principles, priority interventions and responsibilities for countries and various organisations**

Milestones achieved

Regional Strategy

- **Feedback from groups discussions**
  - **Need to agree on definitions that will be used in the document**
  - **The formula to estimate blood requirements (1% overestimate the needs): this need to be reviewed**
  - **Importance of realistic targets**

Milestones achieved

Regional Strategy

- Feedback from the discussion groups
  - Need to update the figures presented
  - Give references for the figure on training institutions
  - Identify areas of research in interventions section

Milestones achieved

- **Regional Strategy**

- **Feedback from the discussion groups**
  - Establishment of the link between regulatory body and blood services
  - The strategy should address issues of equity in accessing blood from transfusion centers
  - Countries should avail the required resources for blood transfusion services for sustainable financing

Milestones achieved Regulation

- **Draft guidelines .**
  - **Presented the justification for the regulatory framework**
  - **The outline of the document includes: objectives, standards, regulatory mechanisms, essential functions of the regulatory authority, and description of the system**

Milestones achieved Regulation

- Elements of the legislation(1)
  - Expression of the government commitment
  - The ethical/legal principles that govern the blood transfusion system
  - Ensuring the protection of health of blood donors
  - Ensuring protection of the health of recipients

Milestones achieved Regulation

- Elements of the legislation(2)
  - Creation of the administrative bodies necessary for the implementation of blood service operation
  - Statement of the roles, responsibilities, rights and functions of all parties involved with blood regulation, including those of the regulator and regulated
  - Setting up the human, financial and technical resources

Milestones achieved Regulation

- Elements of the legislation(3)
  - Setting the qualifications and standards required for those handling blood and plasma.
  - Creation of mechanisms to control whether the practice complies with the legislation and regulations.

Milestones achieved Regulation

- Elements of the legislation(4)
  - Statement of the terms and conditions under which licenses and accreditation will be suspended, revoked or cancelled.
  - Establishment of the administrative measures and legal sanctions that will apply when provisions of blood transfusion legislation are violated.

Milestones achieved Regulation

- Levels of legislation
  - Primary legislation:
    - statutes/acts passed by Parliament.
  - secondary legislation or regulation
    - Making of regulations prepared by the Health Ministry or other body mandated by the government.
    - Regulations spell out the details of the policies and Acts to which Parliament has given statutory approval.

Milestones achieved: Regulation

- Feed back from discussion groups
  - Need for clear definitions of terms used
  - The role of government
  - Priorities for blood regulatory systems and
  - challenges faced by the NRA in Africa as well as interventions for improvement

Milestones achieved: Regulation

- Feed back from discussion groups
  - Carry out an independent assessment
  - Some specific objectives thought to be irrelevant to the regulatory system
  - Regulatory oversight and regulatory authority: need to maintain one of the terms
  - Standards should be a separate document and not part of guide

Recommendations -1

- Need for proper definitions for blood, blood products and components
- Standards needs to be flexible and country specific
- Administration of regulatory authority could be part of the ministry functions
- Need to work out the need for blood in Africa

Recommendations -2

- Multidisciplinary nature of the components of transfusions chain should be recognised
- Regulatory body needs to be independent
- Capacity building – training especially in the area of quality
- Member states to share best practices

Recommendations -3

- WHO should support countries to do situation analysis
- Mobilize resources for the development of the strategy and plan
- Regional economic communities to be included among partners
- Research to cover all areas of blood safety
- Each country to define monitoring indicators to monitor their own progress
- Management of blood service to be founded on good governance

Next steps

- WHO will finalize the two documents and they will be circulated
- Regarding regional strategy it will be submitted to regional committee for adoption
- Regulatory system: WHO will get some funding to support the implementation

Participants

- 31 participants representing NBTS and National Regulatory Authorities (NRAs)
- AFRO Countries represented (Benin, Burundi, Cameroon, Congo, Côte d'Ivoire, Ghana, Kenya, Mauritius, Senegal, South Africa, Tanzania and Zimbabwe)
- Institutions:
  - Blood Regulatory Network Canada
  - Paul-Ehrlich Institute Germany
  - OCEAC
- WHO/AFRO and WHO/HQ

THANK YOU