QUALITY ASSURANCE STARTEGIES TO ACCELERATE UPTAKE OF HIV RELATED DIAGNOSTICS IN AFRICA-TANZANIA EXPERIENCE

AFRICAN SOCIETY FOR LABORATORY MEDICINE
2ND INTERNATIONAL CONFERENCE

AGNES SITTA KIJO
Tanzania Food and Drugs Authority (TFDA)
Nelson Mandela Road, Mabibo External
P.O.Box 77150, Dar Es Salaam
Tanzania
Email:agnes.kijo@tfda.or.tz

Strengthening regulatory capacity of diagnostics and PMS

Strategies adopted by Tanzania to strengthen regulation and PMS of diagnostics .

Key elements to consider

1. *Identification of gaps*
2. *Development of action plan*
3. *Implementation of action plan.*

Identification of gaps

– *Overlapping roles in regulation of diagnostics.*

– *Lack of clear regulations and guidelines on control of diagnostics*

– *Limited trained staff for regulatory oversight of diagnostics*

– *Lack of batch release testing of diagnostics*

– *Lack of PMS system for diagnostics*

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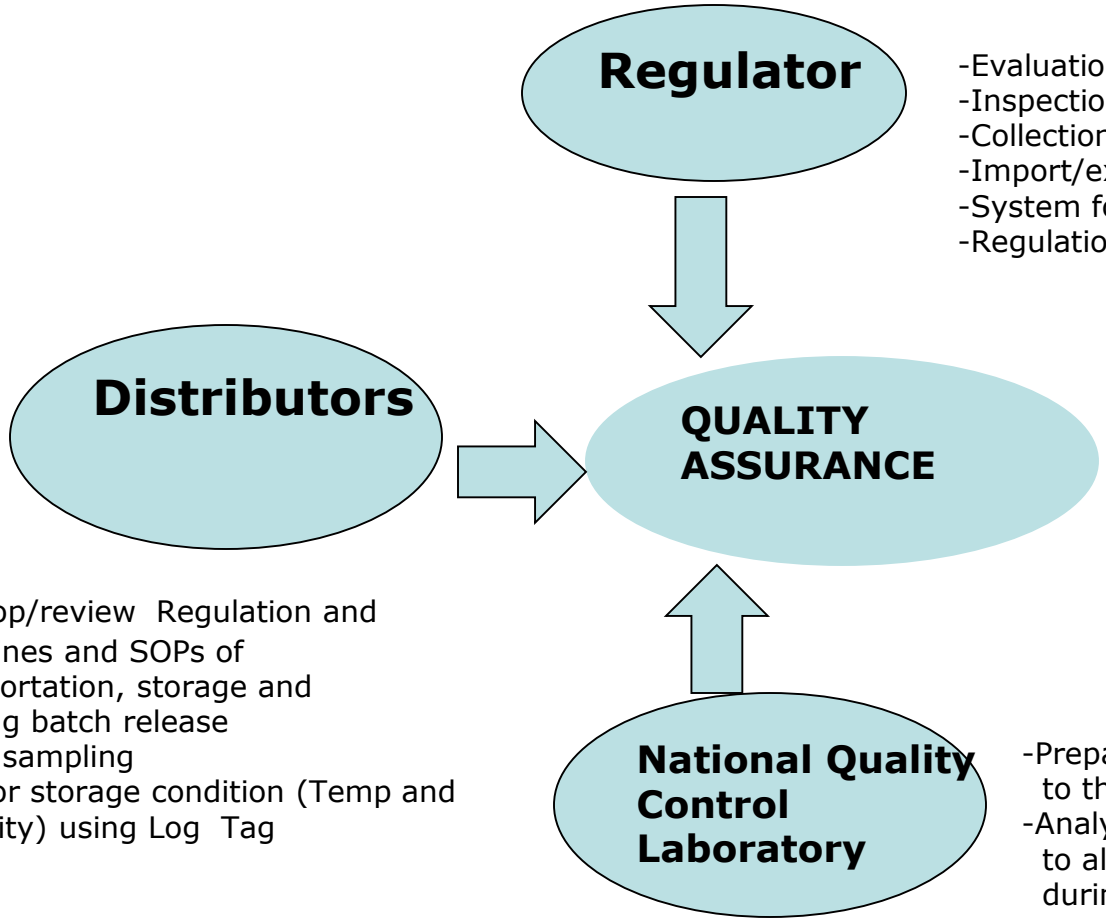
Development of action plan

Action plan to address the gaps identified was developed. It was meant to identify activities and key responsible players for each activity, time frame and milestone for implementation. The activities identified are follows:

Major activities:

- Development of regulations, guidelines and procedures for regulation of diagnostics.
- Recruitment and training of staff at the regulatory body and Main Government distributor for medical supplies (no manufacturers).
- Introduce procedures for batch testing of priority diagnostics e.g. HIV and Malaria.
- Develop capacity to detect, investigate, communicate and contain adverse events linked to poor quality diagnostics.


Regulator
-Evaluation of technical files
-Inspection of diagnostics POE
-Collection of samples
-Import/export control
-System for AE monitoring
-Regulations and guidelines
Distributors
QUALITY ASSURANCE
-Develop/review Regulation and guidelines and SOPs of transportation, storage and sending batch release
- Batch sampling
- Monitor storage condition (Temp and humidity) using Log Tag
National Quality Control Laboratory
-Prepare QC samples, provide them to the HIV testing sites and record data.
-Analyze all new batches according to algorithm and samples collected during PMS.

Implementation of action plan

Commitment of key players throughout the whole process:

to accept that there is a problem.

to carry out the identified activities.

to sustain the success.

Thank you