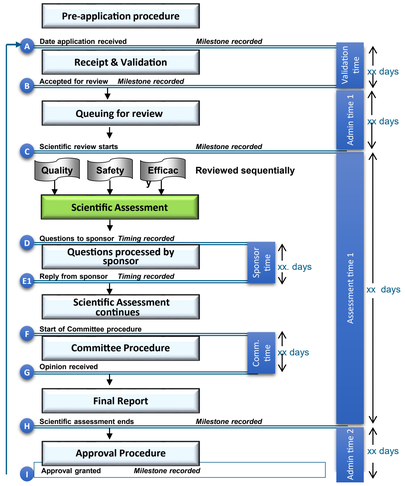
Assessment of Good Review Practices at the Zambia Medicines Regulatory Authority as it strives to achieve the WHO Maturity Level 3 Status

Constance Chisha
University of Witwatersrand
South Africa

DIA Global Conference
Philadelphia, USA
2026

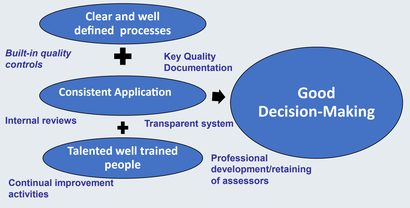
Background
Good Review Practice – Building Blocks for a Quality Review



- **Documented Best Practice** - Related to the process, format, content, and/or management of a review
- **Goal to promote:**
  - Timeliness, predictability, consistency, transparency, clarity, efficiency and high quality of the content and the management of reviews
- **Achieved through:**
  - Use of review tools (SOP, templates etc)
  - reviewer learning activities (training; mentoring)

Background
Key measures essential for Good Regulatory Review Practices

Implementation of GRevPs forms an important component of regulatory systems strengthening and supports progression toward WHO Global Benchmarking Tool Maturity Level 3 status.



Method – Questionnaire:
12 Assessors completed the Questionnaire

- The questionnaire consists of 17 different types of questions intended to establish a baseline with respect to the staff of the agency's knowledge, attitude and practice regarding GRevPs.
- The questions were designed to elicit whether the participants understood the development, adoption and implementation of GRevPs. Satisfaction with the framework and process for the implementation of GRevPs for identifying these practices was also assessed.
- The questionnaire was also designed to enable the understanding of how the participants evaluated the implementation of these practices in terms of achieving the agency's goals as well as supporting regulatory review activities.
- Finally, the participants were asked to state how well implementation of GRevPs were being evaluated at both the departmental/individual and agency levels including how they could be improved.

AIMS

- Identify the current perspective of the Zambia Medicines Regulatory Authority (ZAMRA) in the implementation of Good Review Practices (GRevP)
- Provide a baseline on the knowledge, attitude, practices of GRevP
- Identify areas for improvement
- Determine how these procedures relate to the continuous process improvement within ZAMRA.

Results

Knowledge
- How GRevP are being developed within ZAMRA
- How does GRevP improve ZAMRA and Department
- How important are GRevP to departments and ZAMRA

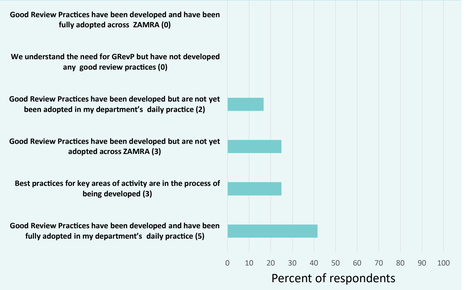
Practice
- Development and adoption of GRevP
- Implementation and maintenance of GRevP
- Informing staff, testing and improving GRevP

Attitude
- Satisfaction with the framework and process for the development of GRevP
- How well do staff rate GRevP development in terms of achieving ZAMRA goals and their support of review activities
- What aspects still require GRevP and what could be done to improve implementation

Results - Knowledge

- According to the twelve respondents GRevPs have not been developed and fully adopted across the agency (Figure 1). Responses indicated variable perceptions regarding the extent of GRevP implementation and adoption across ZAMRA
- This supports the findings in the previous study that guidelines, standard operating procedures and review templates are in place but the majority of indicators for good review practices are yet to be fully implemented.

FIG 1.Q1, To what extent do you feel GRevP are in development at ZAMRA? Please mark only ONE of the following Statements: Percentage of respondents (N=12)



Results - Practice

- Seven of the participants responded that GRevPs were being implemented through the use of standard operating procedures on how to use specific activities that form part of GRevP as well as forming part of induction training.
- Eight of the participants who believed GRevPs were in place formally or informally, reporting that implementation occurs through the distribution of guidelines (Fig 2)
- The participants also provided the reasons for introducing Good Review Practices (Fig 3)

Fig 2. Q 3 , If you feel that GRevP are now in place (Formally/Informally) - How is this being implemented? Mark all that apply (N=12) Percentage of respondents

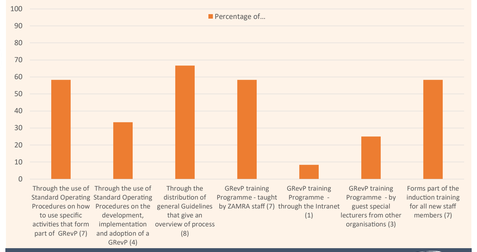
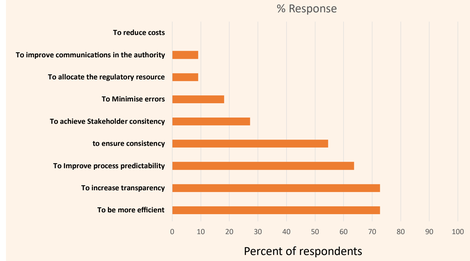


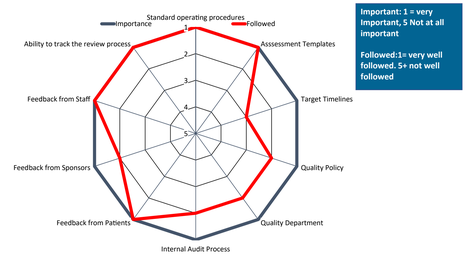
Fig 3 Q4. What do you think are the reasons for introducing quality measures in the ZAMRA? (n=12*) Please select your three most important reasons* Percent of respondents



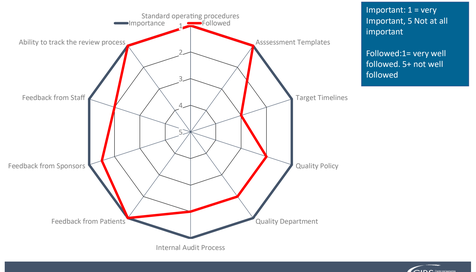
Results - Attitude

- Most respondents believed that the existing GRevPs framework for ZAMRA could be improved
- Most of the respondents commented that the GRevPs system is in an evolving phase within the Agency and believed that additional training would be of value to understand how GRevPs should be incorporated into their daily work.

Q17: GAP Analysis - How important are the activities/functions to build Good Review Practices and how well do you feel these are actually followed: My Department



Q17: GAP Analysis - How important are the activities/functions to build Good Review Practices and how well do you feel these are actually followed: ZAMRA



Recommendations

- To improve the knowledge base on GRevPs for reviewers through in-house training and orientations.
- To enhance the use of the good review practices in the review process of medicines.
- To enhance timeline monitoring through the Integrated Regulatory Information Management System in line with the service charter.

Recommendations

- To finalize and publish the ZAMRA Good Review Practices guidelines.
- Enhance transparency and communication through publishing product information including summary of product characteristics (SmPC) and patient information leaflet (PIL) for approved medicines.

Conclusions

- This study assessed the level of knowledge, practice, and attitude of reviewers and the implementation of Good Review Practices within ZAMRA.
- The Authority has implemented some elements of GRevPs, while other areas, such as transparency, and communication, as well as conducting on-the-job training and mentoring the reviewers on the principles of GRevPs require improvement.
- Implementation of all the elements of the GRevPs will significantly improve the quality of the review process, thereby ensuring timely accessibility of quality medicines for patients.