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Lessons Learned in Implementing Quality "Real Life" Field Effectiveness Studies in Remote Areas (ASAQ in Liberia)

Quality research studies can be implemented in remote areas provided some main requirements are met. These requirements can be summarized in two main points:

1. Technical Capacity Building
2. Establishment of Institutional Memory

1. Technical Capacity building

Many times there is shortage of technical capacity in disease endemic areas where research studies are conducted. Technical capacity essential for implementation of research studies in remote areas is presented in two areas:

- i. Human Resources; trained personnel with the potential to perform study specific procedures
- ii. Diagnostic Technology; appropriate equipment for performing required test procedures

In the case of the ASAQ Study in Liberia it was quite a challenge to implement the Study. However, with good cooperation between MSF-CH and Epicentre and adequate funding from DNDi the study has been successfully conducted.

- The study site is located 8 hours drive on rough road from the capital Monrovia. No study has been conducted in the area before
- The PI's office is a simple wooden structure. consultation rooms are metal containers improvised into offices
- Tents were raised to increase the capacity of the patient waiting area
- Electricity is provided 2 generators running in turns
- One room of the lab has an AC and is equipped with a 5-part differential Haematology analyzer (the only one in the country) and a dry chemistry analyzer. There is also a freezer in the lab where serum samples are stored at - 20°C
- All staff had to be recruited and given comprehensive training on study procedures and GCP/GCLP



- The study has provided very good opportunity for capacity building for the staff. Besides the SOPs and GCP/GCLP some staff have also taken computer training courses
- DNDi has also offered to sponsor one national staff for the TDR training in Thailand
- Samples are shipped out of the country every month for further analysis and External Quality Control (EQC). Dried blood spots are sent every month to Paris for PK analysis and every 2 months to Mbarara in Uganda for PCR analysis. Malaria slides are sent every month to Thailand for EQC
- Sending samples for testing outside the country is time consuming, a challenging task, and requires large amount of funds. Therefore, this strategy is not sustainable as research institutions will always find it difficult to meet the costs of sample shipment abroad. Besides, overseas samples testing also delays the results of research studies
- Currently the ASAQ Study is facing the challenge of shipping frozen serum samples at - 20°C with dry ice to Europe. Although DNDi has provided the funds for the shipment, this is going to be a very complicated/difficult activity. Making the diagnostic technology required for performing the tests available locally would reduce this huge cost
- In terms of technology transfer DNDi has agreed to donate all lab equipment to the National Malaria Control Program (NMCP) - MOH. Since DNDi will not continue to maintain the equipment after donation, the NMCP is advised to look for funds from other donors for maintaining the equipment. NMCP is confident they will be able to acquire funds from institutions like WHO and Global Fund.

2. Establishment of Institutional Memory

- This applies for both donor institutions like DNDi and research institutions like Epicentre or local research institutions or health authorities and can be achieved through close partnership
- International Research institutions need to involve the local research groups or local health authorities in all steps of a study in order to build a good institutional memory for further research studies
- In the case of the ASAQ study in Liberia all technical procedures and study SOPs had to be developed almost from scratch as this was the first standard malaria study to be conducted in the country



- The health authorities have been involved in the study from the beginning and two MOH officials are Co-investigators of the study. In the future any research institution interested to conduct a standard malaria research study would benefit from information from the ASAQ Study
- One of the factors to the success of the ASAQ Study in Liberia has been the good collaboration between Epicentre, MSF and the health authorities
- The success of the ASAQ study has inspired the NMCP to take the decision of keeping the study site as a malaria research centre when the study is completed. The NMCP plans to maintain the equipment to be donated on the site and keep the trained staff

Therefore, implementing quality field effective studies would be made easier if donor institutions continue to support research institutions build up technical capacity in disease endemic areas and health authorities become keen to maintain this technical capacity. In addition, research institutions need to get health authorities more involved in all research activities in order to establish strong institutional memory and to ensure sustainability.

Reference or Normal Values

Another lesson learned from the ASAQ study is about the reference or normal ranges of tests values from lab equipment.

- Normal ranges obtained from lab equipment manufactured in Europe or America are derived from the populations of those countries. Using these values for routine patient management does not seem to matter much, but using these values in research studies can be crucial as slight variations are considered as AEs
- For example: the haematology analyzer (Beckman Coulter) used in the ASAQ Study in Liberia is manufactured in USA. As there was records for normal values of the local population, the normal values from the manufacturer had to be used
- Most of the blood samples tested showed several CBC/DIFF parameters out of the normal range. This is probably because the normal ranges in the analyzer are taken from American subjects
- I therefore call upon all scientist in this meeting, especially African scientists and laboratory technologist to work together and develop normal values for all lab tests for African subjects