

PO 8475 ENHANCING THE CAPACITY OF THE LIBERIA MEDICINES AND HEALTH PRODUCTS REGULATORY AUTHORITY IN POST-MARKETING SURVEILLANCE OF *IN VITRO* DIAGNOSTICS

¹Alexander E George*, ¹Joseph N Somwarbi, ¹David Sumo, ²Guillermo Martínez Pérez, ²Alfredo Mayor. ¹Medicines and Health Products Regulatory Authority, Monrovia, Liberia; ²ISGlobal, Hospital Clínic – Universitat de Barcelona, Barcelona, Spain

10.1136/bmjgh-2019-EDC.112

Background The Quality Control Laboratory (QCL) of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) lacks capacity to assess the quality of *in vitro* diagnostics (IVDs). The LMHRA needs be strengthened to develop post-market surveillance (PostMS) regulations in order to fulfil its supervisory role for IVDs used in research and healthcare settings. IGORCADIA, an EDCTP-funded project of LMHRA and the Barcelona Institute for Global Health (ISGlobal) started in December 2017 with the aim of building LMHRA diagnostics assessment capacity.

Methods Project activities targeting the QCL include: the constitution of an in-house Technical Working Group and a Diagnostic Steering Committee involving national stakeholders to develop PostMS regulation; a Training Programme in Diagnostics Research (TPDxR) including a malaria diagnostics performance study as its post-TPDxR exercise.

Results The QCL is developing with its new knowledge and networks improved mechanisms to enact its supervisory mandate. QCL staff contributed to the development of guidance for Post-MS. Private sector and government stakeholders helped the LMHRA identify unlicensed premises where IVDs of presumably poor accuracy are available over the counter. Following the TPDxR, the QCL planned quality assurance to oversee the quality assessments on suspected substandard IVDs. Quality control tools, staff training requirements, standard inspection procedures, and PostMS registers and reports were re-designed in accordance with Good Laboratory Practice and guidance from the TPDxR.

Conclusion The LMHRA is strengthening its regulatory, inspection and PostMS capacities thanks to a partnership with a European research institution with expertise in malaria diagnostics development. To ensure that the Liberian population has access to safe quality diagnostics in routine healthcare provision and in future infectious diseases outbreaks, it is of utmost importance that the LMHRA has capacity to assess the accuracy of the non-WHO prequalified IVDs that are currently available outside the healthcare system, and is well-equipped to recall those IVDs identified as substandard.

PO 8476 USER EXPERIENCE OF SMS REMINDERS TO TAKE MEDICATION AMONG PREGNANT AND BREASTFEEDING WOMEN LIVING WITH HIV IN KILIMANJARO, TANZANIA

¹Kennedy M Ngowi*, ²Eusibios Maro, ³Pythia T Nieuwkerk, ⁴Rob E Aarnoutse, ^{1,2}Blandina T Mmbaga, ^{1,5}Marion Sumari-De Boer. ¹Kilimanjaro Clinical Research Institute, Moshi, Tanzania; ²Kilimanjaro Christian Medical Center, Moshi, Tanzania; ³Department of Medical Psychology, Academic Medical Center, Amsterdam, the Netherlands; ⁴Department of Pharmacy and with the Radboud Institute for Health Sciences, Radboud UMC, Nijmegen, the Netherlands; ⁵Department of International Health, Radboud UMC, Nijmegen, the Netherlands

10.1136/bmjgh-2019-EDC.113

Background Pregnant women living with HIV have difficulties in reaching adequate levels of treatment adherence. One way to intervene is sending reminder cues using short message service (SMS) texts. We conducted a pilot study on the use of SMS among pregnant and breastfeeding women living with HIV in Kilimanjaro, Tanzania. One objective was to investigate user experiences of SMS reminders.

Methods We enrolled adult (age 18–45) pregnant or breastfeeding women living with HIV from Kilimanjaro region, Tanzania. Women received a reminder SMS 30 min before usual time of intake. One hour after usual time of intake, they received an SMS asking whether medication was taken. SMSes were sent less-than-daily and randomly distributed over the week. During consultation we listened to their feedback on the system. After six-months, we interviewed women using a semi-structured exit interview.

Results Twenty-five women were enrolled. Two women were lost to follow-up. We received feedback from 18 women. Sixteen (89%) said they were content about the SMS reminding. One said she had problems with privacy issues (6%), but 5 specifically mentioned no privacy issues (28%). Preliminary results of 18 exit interviews show that 16 women (89%) had a good experience with the SMS. Fourteen women (78%) found the content of SMS good; 2 women (11%) said it was not good at all due to risk of unwanted disclosure. Three women (17%) experienced stigma. Eleven women (61%) told they were always able to reply to the SMS and 16 (89%) believed it really improves adherence.

Conclusion We believe most women were satisfied with the SMS system. A few women had trouble with risks or fear of unwanted disclosure. One way to solve that, may be to send more neutral language messages. The results can be used for clinical trial design to investigate the effect on adherence.

PO 8480 TECHNICAL FEASIBILITY OF SENDING SMS TO REMIND TAKING MEDICATION AMONG PREGNANT AND BREASTFEEDING WOMEN LIVING WITH HIV IN KILIMANJARO, TANZANIA

¹Kennedy M Ngowi*, ²Eusibios Maro, ³Pythia T Nieuwkerk, ⁴Rob E Aarnoutse, ^{1,2}Blandina T Mmbaga, ^{1,5}Marion Sumari-De Boer. ¹Kilimanjaro Clinical Research Institute, Moshi, Tanzania; ²Kilimanjaro Christian Medical Center, Moshi, Tanzania; ³Department of Medical Psychology, Academic Medical Center, Amsterdam, the Netherlands; ⁴Department of Pharmacy and with the Radboud Institute for Health Sciences, Radboud UMC, Nijmegen, the Netherlands; ⁵Department of International Health, Radboud UMC, Nijmegen, the Netherlands

10.1136/bmjgh-2019-EDC.114

Background Pregnant women living with HIV have difficulties in reaching adequate levels of adherence to treatment. One way to intervene is sending reminder cues using short message service (SMS) texts. We conducted a pilot study on the use of SMS among pregnant and breastfeeding women living with HIV in Kilimanjaro, Tanzania. One objective was to investigate technical feasibility of sending SMS reminders.

Methods We enrolled adult (age 18–45) pregnant or breastfeeding women living with HIV from Kilimanjaro region, Tanzania. Women received a reminder SMS 30 min before usual time of intake. One hour after usual time of intake, they received an SMS asking whether she took medication. The women had to reply with ‘Yes’ or ‘No’. SMSes were sent less-than-daily and randomly distributed over the week. We did