

OC 8713 MAXIMISING RESEARCH IMPACT TO STRENGTHEN PUBLIC HEALTHCARE

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Background Billions of dollars are spent on research globally every year, yet little is translated to public use through policy and/or commercialisation. For the few research findings that make it to policy, evidence in most LMICs shows they hardly see the light of implementation. Our EDCTP-funded TWENDE consortium used implementation of tuberculosis (TB) molecular diagnostics as a model to investigate the barriers, and opportunities to unlock them in order to maximise uptake of health research innovations into policy and practice. **Methods** Mixed methods approach including surveys, audits, in-depth interviews and focus group discussions (FGDs), policymaker dialogues to unravel the bottlenecks and how to overcome them.

Results 1119 respondents representing from Uganda, Kenya and Tanzania participated in the study. 19% were district/county health officers, 12% healthcare audits, 58% one-on-one interviews and FGDs with healthcare practitioners, community leaders, TB patients and survivors, and care givers, and 11% policymaker workshops. Barriers: government poverty, family/individual poverty, incompatibility of technologies to existing infrastructure, low awareness and socio-cultural beliefs in the community were found. Stigma at community and healthcare levels was rife. Consequently, TB diagnostics were underimplemented and underutilised. Xpert MTB/RIF test was fully utilised in ~10% of healthcare facilities (conducting 8 tests per day) whilst Line probe assay was implemented in less than 1% of the facilities.

Conclusion Based on our findings, we believe overcoming the barriers presents the opportunity to maximise research impact of public healthcare. This could be achieved through sustained public and practitioners' sensitisation to remove stigma to increase demand and utilisation of services; early interaction of researchers and policymakers to increase sense of ownership and acceptability of research innovations; early communication between developers and end-users to align the tools with the needs and existing infrastructure capacity; and increased affordability of innovations through socioeconomic empowerment programmes.

OC 8715 GOING FURTHER TOGETHER: THE ROLE OF THE EU IN SUPPORTING REGULATORY HARMONISATION OF HEALTH TOOLS IN AFRICA

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Background On May 20, 2018, African governments adopted the Treaty for the establishment of the African Medicines Agency (AMA) as a stepping stone in the strengthening and harmonising of medical products regulation on the continent.

Many countries in Africa lack robust and comprehensive regulatory systems supporting the research and registration of health products, hampering the translation of health research and innovation into public health impacts. The AMA could substantially improve the access to quality-assured, safe and effective health solutions and technologies in Africa and around the world. As the main trade partner and donor to Africa, the European Union (EU) has a key role to play in supporting this effort.

Method Desk research and case-study analyses of key initiatives to strengthen medicines regulation in Africa were conducted. Specifically, the EDCTP, the African Vaccine Regulatory Forum (AVAREF), the African Medicines Regulatory Harmonisation Programme (AMRH) and the Zazibona Process; to assess the gaps, needs and opportunities for EU collaboration using actual and reconfigured EU-Africa funding and policy cooperation mechanisms.

Results and conclusions This presentation will explore initiatives aimed at regulatory strengthening and harmonisation in Africa and propose policy recommendations on how to improve EU efforts in order to support these initiatives in a more systematic and synergetic manner. The recommendations fall into four categories: EU-Africa priority-setting, coordination, funding and capacity-building actions. Recommendations explore, for instance, advancing the national implementation of the African Union Model Law on Medical Products Regulation by all African countries, enlarging the scope of EDCTP regulatory strengthening actions to include Africa's Regional Centres of Regulatory Excellence (RCOREs) or improving the attractiveness and incentive system of the EMA's article 58 procedure for African governments, researchers and manufacturers.

OC 8716 ENHANCING RESEARCH ETHICS REVIEW CAPACITY IN SUDAN

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Background In Sudan, there is an increase in health research in a situation of scarce resources and limited counteractive quality assurance in research ethics. The aim of this project was to enhance the ethical review system in Sudan.

Methods Our framework for enhancing the ethical review capacity was based on the context of Sudan with emphasis on governance, coordination, feasibility, efficiency and sustainability. Activities conducted to achieve our goals included reviewing the guidelines that govern human subjects research, enhancing the governance of national authorities (National Health Research Ethics Committee and National Medicine and Poisons Board), improving coordination between the national authorities by developing a consensus clarifying their roles and functions, capacity building for the oversight bodies and institutional ethical review committees (RECs) as well as establishing a network of research ethics committees.

Results The guidelines that govern human subjects research in Sudan were reviewed and updated. In addition, a consensus document was endorsed to clarify the roles of the national regulatory authorities creating channels of coordination and cooperation between them and institutional RECs. Thirty-nine RECs from different parts of Sudan have been trained and the results of the pre/post test have shown an increase in the