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Title: A Baseline Assessment of the Policy and Regulatory Environment for HIV Self-testing in Malawi, Zimbabwe and Zambia

Background: Devices that allow individuals to conduct HIV selftesting (HIVST) are being rapidly scaled-up in Sub Saharan Africa to increase access to testing. Some countries are already regulating HIVST and have developed policies to support implementation, but in many there is no regulatory or policy framework. A baseline assessment of the policy and regulatory environment for HIVST was undertaken to inform development of a regulatory and policy framework to support implementation. This study was undertaken in Malawi, Zimbabwe and Zambia (countries in the STAR project, a large impact evaluation study of HIVST).

Methods: We combined a legal and policy review on HIVST with in-depth individual interviews with key informants (e.g. legal, pharmacy and regulatory bodies, Bureaus of Standards, national reference laboratories, Ministries of Health, implementing agencies and academics). We used a policy analysis triangle to better understand current status and capacity for policy and regulation, as well as to identify key gaps and concerns. A thematic framework approach was used for analysis. Results: We will present findings on close to 60 interviews in the three countries. Emerging themes to date indicate that policymakers need to have a clearer understanding of the role and mandate of their regulatory bodies for in-vitro diagnostics (IVDs). IVDs are not actively regulated in all three countries, but regulators are currently pursuing this. Regulators were often not included in policy level discussions, leading to disconnection between policy and regulation. Ministries of Health are keen to adopt HIVST into policy however the establishment of coordination bodies for HIVST appears to be in a very early stage of development in all three countries.

Conclusion: The policy environment is favorable for HIVST however both policy makers and regulators must be included in national coordination bodies to ensure the alignment of policy and regulation and the development of regulatory pathways.