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Assessing the acceptability of N-of-1 trials/tests and their implementation: Getting ready for piloting N-of-1 trials in Ethiopia

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Due to lack of bioequivalence-data, additional assurance tests are needed to build trust in cheaper locally made drugs in Ethiopia. N-of-1 therapeutic equivalence trials can improve the quality of care provided to patients by improving healthcare providers practice in ways most beneficial to patients under the prevailing circumstances. By establishing bioequivalence information on local drugs, N-of-1 trials have the potential to promote patient-centred, quality use of medicine. The objective of this study is to assess whether it is acceptable to use N-of-1 tests to evaluate local-drugs in a resource-limited clinical practice setting. A descriptive qualitative study, using focus group discussions and key informant interviews, was conducted. Five key informant interviews (two senior regulatory authority members and 3 institutional review board members), as well as 4 focus group discussions (2 with physicians and 2 with patients), were held. The interviews were audiotaped and transcribed verbatim. Data were analyzed using an inductive, thematic process. Five major themes were identified in this study; (1) Opinions about using N-of-1 tests to test the therapeutic equivalence of local drugs, (2) N-of-1 therapeutic equivalence tests: clinical care vs research, (3) Ethical and regulatory requirements, (4) Barriers to imp mention the study and (5) Possible solutions to address challenges. Overall, this qualitative study showed that N-of-1 tests are acceptable as a strategy to assess therapeutic interchangeability of local generics in Ethiopia. However, key informants of the regulatory authority didn't support additional tests on local drugs. Regarding ethical requirements, while the IRB members believed that IRB approval sufficed to conduct N-of-1 tests, the regulatory members reported that N-of-1 tests require approval at the regulatory level. Not only access but quality should be a top priority in health and this requires the development of policies and regulations on evidence-based, patient-centered clinical care.

Biography

Chalachew Alemayehu is a PhD candidate in Medical Science in School of Medicine, University of Queensland, Australia. His PhD is on the role of N-of-1 Trials in the Clinical Care of Developing Countries. He is a primary care medical practitioner in Ethiopia. He has published more than 10 research papers and is a peer reviewer of International Journal for Equity in Health.

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