Universität Basel

Research Project

Evidence-based Differentiated Care for HIV in South-Eastern Africa: Shaping the post 2020 agenda

Third-party funded project

Project title Evidence-based Differentiated Care for HIV in South-Eastern Africa: Shaping the post 2020 agenda
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Background and rationale:With the Public Health Approach, over the last decade, the World Health Organization promoted standardized and simplified HIV care allowing scale-up of antiretroviral therapy (ART) provision even in very under-resourced health systems. This approach succeeded in a massive increase of people receiving ART in Sub-Saharan Africa. However, despite substantial progress, HIV/AIDS remains a leading cause of morbidity and death in Sub-Saharan Africa. Further progress towards ending the AIDS epidemic is challenged by several factors: (i) scaling up ART provision among “hard-to-reach” populations, (ii) maintaining the rising numbers of patients on ART in under-resourced health care facilities while international funding support decreases, (iii) preventing and adapting to emerging resistance of HIV to current drugs, (iv) improving outcomes among children and adolescents taking ART. To meet the above-listed challenges, continuing the “one size fits all” approach will not be sufficient, and refining the public health approach through differentiated care models (DCM) will be required. “Differentiated care” is the term describing the adjustment of treatment programs to a patient’s individual needs and prognosis. DCMs have the potential to improve patient outcomes as well as cost-effectiveness through better allocation of resources. However, to date the data on DCMs at larger scale are scarce and generating evidence through randomized trials in differentiated care represents an urgent requirement. Aim of the Project:This project entails four randomized trials (RCT) aiming to test innovative new DCMs in real-life settings and assess relevant endpoints of clinical response/outcome, virological control as well as the cost-effectiveness of interventions. The DCMs tested all make use of new and innovative technologies and - if successful - have the potential to be integrated into future guidelines and policies. All RCTs will be conducted in Lesotho, Southern Africa. RCT-3 will additionally include research sites in South Africa and RCT-4 will include sites in Tanzania.Planned Studies:RCT-1: HOSENG trial: “Home-based testing plus self-testing to improve HIV diagnosis coverage in rural Lesotho” - an open-label cluster randomized trial. Including 100 clusters with >10’000 individuals, this trial assesses if combining home-based HIV testing with dispensing of oral self-test kits to household members absent during home-based HIV testing is an effective approach to reach high testing coverage in remote rural hard-to-reach settings.RCT-2: VIBRA trial: “Village-based refill of ART after same-day ART start vs a clinic-based ART provision to HIV-positive individuals not on ART after home-based HIV testing” - an open-label cluster randomized trial in rural Lesotho. This trial aims at improving linkage to care, initiation of and retention on ART to achieve viral suppression in individuals newly diagnosed with HIV during home-based testing in remote rural settings. It is the first trial to test a DCM using village-health-worker based ART-care right from diagnosis.RCT-3: VITA-LENA trial: “Viral load triggered ART care in Lesotho and KwaZulu Natal” - an open-label cluster-

randomized trial. The proposed DCM called “VITA” uses an innovative database that groups patients on ART automatically into different follow-up algorithms depending on their last viral load result, and informs patients automatically about their viral load results via SMS. Grading intensity of follow-up according to viral load result shall allow to optimize resource-allocation in HIV care and improve patient-outcomes. Sending results via SMS directly to patients shall promote treatment literacy.RCT-4: GIVES-MOVE trial: “Genotype-Informed Versus Empiric Management Of VirEmia” in children and adolescents: an open-label randomized trial. This will be the first trial to test if management informed by genotypic resistance testing improves outcomes of children and adolescents with treatment failure while taking ART, and if this will be cost-effective. It will be conducted simultaneously in Lesotho and Tanzania.POLE-project: In addition to the four RCTs, the “Point Of care Lamivudine Emtricitabine” (POLE) project aims at developing the first point-of-care test for measurement of lamivudine and emtricitabine concentration and to integrate this test into DCM.The studies listed above will be conducted in close collaboration with:-SolidarMed, Swiss Organization for Health in Africa (www.solidarmed.ch)-Ministry of Health of Lesotho-Molecular Virology of the Department of Biomedicine, Haus Petersplatz, University of Basel-Human Sciences Research Council of South Africa (RCT-3)-Department of Global Health, University of Washington, United States-Ifakara Health Institute, Tanzania (RCT-4)-Department of Infectious Diseases, University Hospital of Geneva, Switzerland-Laboratory Services, University Hospital of Lausanne, Switzerland

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