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From sequence data to patient result: A solution for HIV drug resistance genotyping with Hyrax Exatype, end to end software for DNA sequence analysis and patient result generation**Leonard Kingwara**

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Background: With rapid scale-up of Antiretroviral Therapy (ART), there is an ongoing concern on probable emergence and transmission of HIV Drug Resistance (HIVDR) mutations. This has led to a push for routine HIV DR testing to guide clinical decisions for selected populations (clinical failure, toxicity, non-suppressed, persistent low-level viremia and PMTCT) before regimen switch. Much of the wet laboratory processes currently have been standardized, though a slow, labor-intensive, data transfer and subjective manual sequence interpretation step is still required to finalize and release HIV DR patient results. This is likely to be a bottleneck for laboratories and programs scaling up HIV DR testing.

Method: We performed a laboratory-based validation of a new Hyrax biosciences owned software Hyrax Exatype, a sequence data to patient result fully automated sequence analysis software. HIV-1 drug resistance testing was performed on 135 clinical samples at National HIV Reference Laboratory (NHRL). ABI sequence data files were manually edited, then analyzed and result generated using the gold standard method (Recall software and Stanford University HIV DR database) and the same raw DNA sequence data were subsequently reanalyzed using Hyrax Exatype, without human intervention. We then assessed the performance characteristics of Hyrax bioscience Exatype against the standard method (Recall and Stanford database).

Result: In total, 126 out of 135 sequences were analyzed and the result generated by both standard and Hyrax software. Result production using Hyrax requires minimal hands-on time in comparison to the gold standard (6 hours using the gold standard method hours versus 1.5 Hyrax computation-hours). Concordance between the two systems was 99.8% for 311,227 bases compared. (99.7 %) of discordances were attributed from the nucleotide mixtures as a result of sequence editing of mixtures in Recall. Both methods identified similar (99.1%) of key antiretroviral resistance-associated mutations resulting in a 99.2% concordance of resistance susceptibility interpretations. Cohen's kappa (0.97 to 0.99) indicated almost perfect agreement among the two methods.

Conclusion: Hyrax Exatype HIV DR sequence analysis platform and result generation tool thus provides both standardizations of sequence analysis and efficiency in HIV DR data workflow and result generation

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