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POINT-OF CARE TESTING FOR HIV ANTIBODY AS A NEW MODEL OF CARE

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AIMS: Validate and implement the Abbott Determine assay for nurse-led delivery of point-of-care (POCT) HIV antibody testing.

METHODS: Validation: 210 sera tested by Determine and lab-based Vitros, including: (a) HIV-infected patients with subtype B (25) or non-B (25; A, C, D, F, G); (b) 84 patients seeking HIV testing; (c) 40 patients with hepatitis C or B; (d) 36 patients with equivocal Vitros reactivity but negative confirmatory tests, including patients seeking HIV testing, pregnant women and renal dialysis patients; (e) 27 samples taken from acute seroconverters over 28 days. Implementation: policy document, standard operative procedure, recorded training and certification, health and safety, risk management, and internal/ external quality control programmes set up to ensure compliance with clinical governance and accreditation requirements.

RESULTS: Validation (a) 25/25 B and 25/25 non-B patients positive by both assays; (b) 5/84 patients positive by both assays, confirmed HIV-positive; (c) 40/ 40 patients negative by both assays; (d) 36/36 samples negative by Determine. In acute seroconverters, Vitros and Determine became positive at days 7–23 and 14–28 after presentation, respectively. On average, Determine became positive 5–7 days later than Vitros. Implementation: the POCT service started in January 2006 to be run twice weekly and open to all patients seeking HIV testing. For reactive Determine results, service provision includes lab-based confirmatory antibody test (1 h turn-around), followed by two additional confirmatory antibody tests and viral load (48 h turn-around).

CONCLUSION: Determine showed excellent agreement with the lab-based assay. With quality assurance in place, implementation is feasible in routine clinical settings. Caution is required in the interpretation of negative Determine results in patients with symptoms suggestive of acute seroconversion.

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