

DOES RNA TESTING DETECT CLINICALLY SIGNIFICANT HPV INFECTION?

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Background: There is evidence to suggest that the detection of oncogenic transcripts: E6/E7 may be more accurate for the identification of clinically significant cervical HPV infection compared with DNA (L1) based assays. However more clinical data are needed to support this contention.

Objectives: To compare the clinical sensitivity and specificity of the APTIMA® HPV RNA based assay (AHPV, Gen-Probe Incorporated) with the Hybrid Capture 2 DNA based assay (HC2, Qiagen Ltd). Although our study is designed to be longitudinal (in order to assess prospective sensitivity and specificity) - we present the initial, cross-sectional data.

Methods: Women attending two NHS colposcopy clinics in two city hospitals in the UK were invited to participate. Liquid based cytology (LBC) samples were collected and tested via the 2 HPV assays described. Biopsies were taken where clinically indicated and clinical sensitivity and specificity of each assay for disease (defined as CIN2 or worse) were calculated.

Results and Conclusions: A total of 532 women have been recruited to the study so far. At time of abstract submission, 387 LBC samples (from 385 women) have been tested by both assays and have associated, confirmed pathology results – analyses are based on this subset.

Overall, concordance between the two tests was 91%; 95% for CIN2+ and 88% for CIN1 or less. Sensitivity and specificity of the AHPV for CIN2 or worse were 97% and 60% respectively. By comparison, sensitivity and specificity of the HC2 for CIN2 or worse were 95% and 52% respectively. These preliminary data suggest that APTIMA and HC2 assays show equivalent sensitivities for the detection of CIN2 or worse (in a high-prevalence population) with the APTIMA displaying slightly higher specificity. Further data and associated 95% CIs will be presented.