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Title **MAVARIC - A Comparison of Automation-Assisted and Manual Cervical Screening: A Randomized Controlled Trial**

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Aim

To compare automation-assisted reading of cervical cytology with manual reading using the histological endpoint of cervical intraepithelial neoplasia grade II (CIN2) or worse (CIN2+). Secondary objectives included assessing the slide ranking facility of the Becton Dickinson (BD) FocalPoint™ Slide Profiler, especially "No Further Review" (NFR), and automated versus manual in terms of productivity and cost effectiveness.

Conclusions and results

The proportion of abnormal cytology management results by grade were: borderline, 3.6%; mild dyskaryosis, 2.4%; and moderate and severe dyskaryosis combined, 1.22%. These were similar to England as a whole. Non-negative cytology amounted to 5.47% in the paired arm and 5.52% in the manual-only arm. In the paired arm, the proportion of discordant pairs on final result was 3.8% (1850/48 271); for 1.3% (625/48 271); the discordance was between inadequate and negative. Discordant pairs occurred in both directions with respect to manual and automated reading. There were 192 additional low-grade/HPV-positive abnormalities detected by manual reading only (manual positive/auto negative) and 47 additional high-grade abnormalities detected by manual reading only in the paired arm. The overall referral rate to colposcopy was 4.7%. The proportion with CIN2+ was 1.6% (398/24 566) and 1.5% (707/48 271) for the manual and paired arms respectively (p=0.10). The primary outcome of the relative sensitivity for CIN2+ of automated reading compared with manual reading in the paired arm was 0.92 (95% confidence interval [CI] 0.85 to 0.95). Relative specificity was 1.006 (95% CI 1.005 to 1.007). Productivity in terms of the number of slides read per day by primary screeners was estimated to be 60% to 80% higher for automated reading than for manual reading. The overall costs per case of CIN2+ detected were almost identical between automated and manual reading (2892 pounds sterling [GBP], 95% CI GBP 2720 to GBP 3098; and GBP 2838, 95% CI GBP 2676 to GBP 3030 respectively). The overall costs per case of cervical intraepithelial neoplasia grade III (CIN3) or worse (CIN3+) detected are also similar between automated and manual reading (GBP 4762, 95% CI GBP 4378 to GBP 5245; and GBP 4775, 95% CI GBP 4400 to GBP 5244 respectively). Hence, manual screening is slightly more expensive and effective, and could be considered cost effective compared to automated reading if decision makers were willing to pay at least GBP 5000 for each additional case of CIN2+ detected. NFR in the BD FocalPoint GS Imaging System was reported in 22% of slides and was a reliable indicator of the absence of underlying disease, with only 3.1% of detected CIN2+ being missed by NFR, and even more so if NFR was restricted to routine screening slides. When both savings in staff time to read slides and the additional equipment costs were taken into account, utilizing the NFR option generated cost savings.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1462.asp.

Methods

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Further research/reviews required

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