Cost-effectiveness of a fourth-generation combination immunoassay for human immunodeficiency virus (HIV) antibody and p24 antigen for the detection of HIV infections in the United States

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The objective of the study was to evaluate the cost-effectiveness of the fourth-generation assay when compared to a third-generation assay test in screening for HIV infections. The authors concluded that screening using fourth-generation assay might have been cost-effective for HIV detection in appropriate US settings, particularly in higher incidence populations. The methods, analyses, and results were mostly clear and comprehensive, but some model inputs were uncertain making it hard to assess the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to evaluate the cost-effectiveness of the fourth-generation assay when compared with a third-generation assay in screening for HIV infections.

Interventions
The fourth-generation HIV test was ARCHITECT HIV Ag/Ab Combo for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV type 1 (HIV-1 Group M and Group O) and/or type 2 (HIV-2) in human serum and plasma. This was compared with a representative third-generation HIV antibody test, Genetic systems HIV-1/HIV-2 Plus O EIA.

Location/setting
USA/out-patient care.

Methods
Analytical approach:
A decision-analytic individual time-to-event micro-simulation model was developed to assess the health outcomes and costs associated with the two HIV screening interventions in a hypothetical population of 1.5 million patients aged 13 to 64 years. The time horizon was the lifetime of the patient. The authors stated that both a US third-party payer (direct costs only) and a public health (HIV transmissions prevented) perspective were adopted.

Effectiveness data:
Clinical and effectiveness data were from published and unpublished studies. The main measures of effectiveness used in the model were the sensitivity and specificity of the two screening tests. Sensitivity estimates, which varied according to patient seroconversion status, were from a published study. Specificity estimates were unpublished data from a head-to-head clinical trial carried out by the manufacturer of the fourth-generation test.

Monetary benefit and utility valuations:
Utility estimates were from a published study.

Measure of benefit:
Quality-adjusted life-years (QALYs) gained were the measure of benefit.
Cost data:
The direct costs included those related to: the initial screening tests; confirmatory testing; physician counselling; and HIV and AIDS treatment. Costs were from laboratory fee schedules, physician fee schedules, and published studies. The only exception was for the costs of the fourth-generation test, which were assumed to be $3. All costs were reported in US $.

Analysis of uncertainty:
One-way sensitivity analyses were conducted to evaluate the robustness of the model. Parameters varied included: prevalence of undetected acute HIV; frequency of routine HIV screening; test sensitivity; specificity; cluster of differentiation 4 cell count at time of screening; costs and utilities.

Results
The total QALYs gained were 173,405 with the fourth-generation test and 173,011 with the third-generation test; an incremental gain of 395 QALYs.

The total costs incurred were: $6,947,999,665 with the fourth-generation test and $6,914,379,956 with the third-generation test, an incremental cost of $33,619,708.

Compared with the third-generation test, the fourth-generation test was associated with an incremental cost-utility ratio of $85,206 per QALY gained.

The authors reported that the model was most sensitive to variations in the cluster of differentiation 4 cell counts for initiation of antiretroviral treatment.

Authors’ conclusions
The authors concluded that screening using the fourth-generation assay might have been cost-effective for HIV detection in appropriate US settings, particularly in higher incidence populations.

CRD commentary
Interventions:
The interventions were well described. The comparator was appropriate as it appeared to have reflected usual care in the study setting.

Effectiveness/benefits:
Clinical and effectiveness data were from published and unpublished studies. The authors did not report whether a systematic review of the literature was undertaken, so it was not possible to determine whether all relevant information was included in the model. QALYs were a valid benefit measure, as HIV has an impact both on quality of life and survival. They also allow comparisons with other disease areas. Limited information was provided on the estimation of the utility values, but the sources of references were reported. The authors did not report if future QALYs were discounted, which appeared to have been relevant given the lifetime horizon of the analysis.

Costs:
The perspectives were explicitly reported to have been that of the health care payer and public health. For these perspectives it appears that all major relevant costs were included in the analysis. The sources for these costs were adequately reported and were for the US setting. The time horizon was the lifetime of the patient, the authors did not state whether future costs were discounted. The price year was not reported, which would hamper future inflationary exercises.

Analysis and results:
An appropriate incremental approach was used to synthesise the costs and benefits of the alternative testing strategies. Uncertainty was investigated using a determinist approach, which focused on variations in individual inputs, but a probabilistic sensitivity analysis would have captured the full impact of parameter uncertainty on the results. As a main limitation to the study, the authors reported that reimbursement for the fourth-generation assay was not widely established, so its cost had to be assumed.
Concluding remarks:
The methods, analyses, and results were mostly clear and comprehensive, but some model inputs were uncertain making it hard to assess the authors' conclusions.

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