Diagnostic value and cost-effectiveness of on-site evaluation of fine-needle aspiration specimens: review of 5,688 cases

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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.

Health technology
The use of on-site fine-needle aspiration (FNA) as a diagnostic technique for cytopathology.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who underwent on-site FNA for diagnosis of cytopathology. No further inclusion or exclusion criteria were stated.

Setting
The setting of the study was secondary care. The economic study was conducted in the USA.

Dates to which data relate
The effectiveness data for the intervention were collected during 5 years, between 1 January 1996 and 31 December 2000. The resource use data related to the same dates. The year to which the prices referred was not stated. Data derived from a review of the literature were based on studies published from 1981 to 1993.

Source of effectiveness data
The effectiveness data were derived from a single, non-comparative study. Subsequently, the data were compared with respective data derived from a review of published studies.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
The study sample consisted of all FNA cases from a medical centre in Pennsylvania, over a 5-year period, on which on-site interpretation of the specimens was performed. In order to form the study sample, the pathology files of the institution were searched. A total of 5,688 cases were identified retrospectively.

Study design
The study was a historical case series, conducted on cases from one hospital. There was no control group. The effectiveness results of the study, in terms of on-site FNA, were compared with the results for non-on-site FNA, as derived from a review of the literature (see 'Review' sections of this abstract).

**Analysis of effectiveness**
The effectiveness was measured in terms of the diagnostic accuracy of on-site FNA. On-site FNA diagnostic results were compared with the final FNA diagnosis. However, the primary effectiveness measure used in the analysis was the "nondiagnostic rate" of on-site FNA observed in the study sample, which required a subsequent FNA re-examination. The baseline characteristics of the study sample, such as age, sex, or other details (e.g. the organs examined for cytopathology), were not reported. In addition, the comparability of this group of patients and the patient population for the non-on-site FNA data (from the review of studies) was not discussed.

**Effectiveness results**
Comparison of on-site immediate and final FNA diagnosis revealed agreement in 85% of cases (4,829 out of 5,688), disagreement in 2.7% of cases (163 out of 5,688), and deferment to the final diagnosis in 12% of cases (696 out of 5,688).

The overall nondiagnostic rate due to inadequate cellularity was 0.98%.

The authors provided separate results for specimens taken from different sites. However, they provided no statistical analysis of the data reported.

**Clinical conclusions**
The authors concluded that on-site immediate FNA and final FNA diagnostic results revealed high concordance. In terms of the nondiagnostic rate, this was lower for the on-site FNA than for the non-on-site FNA (as derived from the review).

**Outcomes assessed in the review**
The outcome assessed in the literature review was the average nondiagnostic rate of FNA when on-site evaluation was not utilised.

**Study designs and other criteria for inclusion in the review**
Not stated.

**Sources searched to identify primary studies**
Not stated.

**Criteria used to ensure the validity of primary studies**
Not stated.

**Methods used to judge relevance and validity, and for extracting data**
Not stated.

**Number of primary studies included**
Approximately 9 primary studies were included in the review.
Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The average nondiagnostic rate of FNA when on-site evaluation was not utilised was 20%.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic study. In effect, this was a cost-consequences analysis.

Direct costs
The study perspective was not explicitly stated. However, the costs consisted of hospital costs only, in relation to FNA and additional services required for the diagnosis. These costs involved the basic laboratory fee for an FNA, including technical and professional charges, an additional on-site fee, costs of ancillary laboratory studies (special stains, immunocytochemistry and flow cytometry), and guidance procedures (ultrasound, endoscopy, computed tomography scan, bronchoscopy, fluoroscopy and magnetic resonance imaging). The quantities and the costs were not reported separately. The costs were estimated using actual data derived from the records of one hospital. The unit costs reflected the costs and fees charged in this hospital. Discounting was not carried out, which was appropriate as all costs were incurred during a short time (less than one year). The quantity of resources used was measured between 1 January 1996 and 31 December 2000. The price year was not reported.

Statistical analysis of costs
Although the estimated costs involved a patient sample, they were not treated stochastically. No statistical tests were carried out for the cost analysis.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The estimated total costs of non on-site FNAs performed on 5,688 patients were $3,522,009.6. These hypothetical costs comprised only the costs of additional non on-site FNAs on nondiagnosed cases (20%). The basic costs of 5,688 initial non on-site FNAs were omitted.

The estimated total costs of on-site FNAs on the same patient sample were $1,499,382.97. These costs consisted of the
additional on-site FNA costs of cases initially nondiagnosed (0.98%), and also the on-site fee for the first FNA applied to all 5,688 cases. As before, the basic costs of initial FNAs were omitted. The cost-savings of performing on-site FNA on 5,688 patients during a 5-year period, compared with non on-site FNA on these patients, were $2,022,626.63. These were also expressed as savings of $404,525.33 per year. The results reflected the use of on-site FNA on a specific number of patients, in a specific hospital institution.

Synthesis of costs and benefits
Not relevant as a cost-consequences study was carried out.

Authors' conclusions
On-site cytopathologic evaluation of fine-needle aspiration specimens was accurate and efficient, and it improved patient care in the study institution.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was not explicitly justified. However, the intervention (on-site FNA) was described as an enhanced form of the basic diagnostic technique (FNA), which, presumably, reflected current practice. You should decide whether (and which of) the alternatives reflect current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study and a review of the literature. Data from these two sources were then compared. The single study was a historical case series and evidence referred to a single group of patients without an explicit control group. No details about the study sample were provided, so the degree to which it was representative of the patient population cannot be objectively assessed. The methodology and conduct of the review of the literature were not described, so the quality of the results cannot be judged. The patient population and the precise health technology to which these results referred were not reported. Thus, the single study and the review did not necessarily refer to the same study population. Neither did they refer to the same years, which might also have introduced bias when interpreting the results. Statistical analyses to show a significant difference between the results derived from the two sources, or to ensure that potential bias or confounders (e.g. case-mix) did not affect the single study results, were not undertaken.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

Validity of estimate of costs
Although the study perspective was not explicitly stated, the costs included hospital costs only. Basic costs of FNA, applied to all patients initially, were omitted from the estimation of the total costs of both on-site and non on-site FNA techniques, so that the final result was not affected. The costs and the quantities were not reported separately. The resources used (guidance procedures and ancillary laboratory tests) were derived from the single study. The same kind of resource use was assumed when estimating the costs for both alternatives. No statistical analysis of the costs was undertaken. The unit costs were taken from one hospital and, in many cases, reflected charges and not resources used. No sensitivity analysis was undertaken to examine the robustness of the results to changes in these values. Discounting was not carried out, which was appropriate since the costs were incurred in less than one year. The price year was not reported.

Other issues
The authors made appropriate comparisons of their effectiveness results with those from other studies. The issue of the generalisability of the results to other settings was addressed. It was suggested that, although the final results of the study were based on charges and specimen volumes of one hospital, the formula used for calculating these results had
high applicability and validity, and could be used for estimating the cost-savings in any other hospital institution. A limitation of the study, as reported, was that it did consider the indirect costs. In general, the results of the study were adequately reported. The results referred to a specific number of cases examined, and hence, were not generalisable to other settings and patient volumes. It might have been more meaningful to have presented the results as cost-savings per case examined. However, since the authors acknowledged that their results referred to a specific institution and specimen volume, and suggested that only the general formula for calculating cost-savings be used in other studies, their general conclusions reflected the scope of the analysis.

**Implications of the study**
The authors stated that a high accuracy rate of on-site FNA diagnosis is often critical for appropriate patient management. Thus, they suggested that the presence of an experienced cytopathologist on-site is essential.

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None stated.

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