PAPNET-assisted rescreening of cervical smears: cost and accuracy compared with a 100% manual rescreening strategy


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
Computer assisted rescreening of cervical Papanicolaou smears using the PAPNET system.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
American active duty or retired military personnel and eligible wives and daughters receiving routine screening for cervical cancer.

Setting
Smears were taken at US Air Force clinics in the USA and Japan. Screening of the smears took place at the Armed Forces Institute of Pathology in the USA.

Dates to which data relate
Smears were obtained in 1994 and 1995. The period during which PAPNET-assisted rescreening took place was not stated. No resource or price dates were provided.

Source of effectiveness data
The source of effectiveness data was a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as the effectiveness study. The costing (collection of data relating to the need for manual rescreening of slides detected abnormal via computer-assisted rescreening) was part of the effectiveness study and was therefore collected prospectively.

Study sample
5,478 cases were studied which had been diagnosed in 1994 and 1995 as "within normal limits" or as possessing "benign cellular changes" on both primary manual screening and a 10% random manual rescreen. 82.93% of the smears were taken from women aged between 20 and 59; a full breakdown of the ages was given in the paper. No power calculations were performed.
Study design
The study was a non-randomised trial with historical controls. The PAPNET-assisted rescreening of the 5,478 smears took place at a single laboratory in the USA. Some follow-up data were provided although the period of time during which patients were foll owed-up was not stated and follow-up was incomplete. One of four individuals (3 cytotechnologists; 1 cytopathologist) reviewed the PAPNET images. If the smear was diagnosed as "atypical squamous/glandular cells of undetermined significance" or more abnor mal, it was further reviewed by a consensus panel of 3 pathologists and 3 cytotechnologists. Out of 6 cases in which squamous or atypical glandular cells were detected, no follow-up was available for 3.

Analysis of effectiveness
The study analysis was based on intention to treat. The primary health outcome was the detection of atypical squamous cells of undetermined significance (ASCUS), atypical glandular cells of undetermined significance (AGUS) and low-grade squamous intraepithelial neoplasia (LSIL). The manual rescreening and the PAPNET-assisted rescreening were carried out on the same sample but at different points in time.

Effectiveness results
Of 5,478 pap smears imaged using the PAPNET system, 1,614 (29%) required additional microscopic review. 448 (8%) of the total had possibly abnormal cells and ultimately 11 were found by the reviewer to possess potentially undiagnosed abnormal cells. The case was then reviewed by the consensus panel as described above. Of these 11 cases, five were classified as ASCUS and one as AGUS. After an undisclosed period of follow-up, it was reported that in the one case of AGUS, the patient had two subsequent pap smears demonstrating LSIL; two patients with smears demonstrating ASCUS had subsequent normal pap smears. No follow-up was available for the remaining 3 patients.

Clinical conclusions
The authors stated that the value of ASCUS and AGUS diagnoses in guiding patient treatment had not been established. Therefore on the basis of the results found here, the authors were not able to derive any clinical conclusions from using the PAPNET system for rescreening pap smears already rescreened manually.

Modelling
No modelling was carried out.

Measure of benefits used in the economic analysis
The benefit measures used were diagnosis of ASCUS, AGUS or LSIL. It was assumed that PAPNET-assisted rescreening would identify as abnormal those identified as abnormal by manual rescreening. The benefits of PAPNET-assisted rescreening can therefore be seen as the additional benefits (in this case diagnoses).

Direct costs
The following health service costs were measured: machine costs and cytotechnologist's time. The cytotechnologists' costs derived from a cost analysis undertaken at the laboratory, although no methodological details were given. The machine costs relate to PAPNET system charges. Price dates were not stated. Quantities and costs were presented separately with the quantities being based on data in this study. The cost-effectiveness analysis related the additional costs of using computer-assisted (rather than manual rescreening) to additional benefits, in terms of added diagnoses of abnormalities.

Statistical analysis of costs
Costs were not treated stochastically.
Indirect Costs
Indirect costs were not included in the study.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The economic analysis assumed that the PAPNET-assisted rescreening might have been expected to identify two additional cases of LSIL, which was not the case in this study but which, the authors argued, might have been expected on the basis of the 6 ASCUS diagnoses. PAPNET yields one more ASCUS or AGUS diagnosis for every 913 cases rescreened and might be expected to yield one more LSIL diagnosis for every 2,739 cases rescreened. This was compared with the routine rescreening programme used at the author’s laboratory which rescreens at-risk patients and a 10% random rescreening. During 1996 the routine rescreening of 4,970 cases identified 3 LSIL diagnoses, 3 AGUS diagnoses and 11 ASCUS diagnoses.

Cost results
The cost of manual rescreening was assumed to be equal to the cost of the cytotechnologist's time which was set at $3 per slide. The cost of PAPNET-assisted rescreening consists of the fees charged by the company running the machine for digitisation and analysis of studies, cost of the cytotechnologist's time for reviewing the PAPNET images and the cost of manually rescreening those slides deemed potentially abnormal which results in a total cost of $9.38 per slide. The marginal cost was therefore $6.38.

Synthesis of costs and benefits
PAPNET yields one more ASCUS or AGUS diagnosis than manual rescreening for every 913 cases rescreened, at a total additional cost of $5,825 and one more LSIL diagnosis per 2,739 cases rescreened at a total additional cost of $17,475. If the costs quoted in PAPNET advertisements of $40 per case are used, the additional cost of using PAPNET was reported to be $33,781 (ASCUS or AGUS) and $101,343 (LSIL). The routine rescreening programme, by comparison, produced an LSIL diagnosis at a cost per diagnosis of $4,970 and a cost per ASCUS/AGUS diagnosis of $1,065.

Authors’ conclusions
The authors concluded that PAPNET-assisted rescreening does generate more cases of ASCUS than manual rescreening but at a relatively high cost. The cost-effectiveness ratio will, however be higher for laboratories screening populations with a higher prevalence of cervical cancer and a higher false-negative rate at initial screening. But the authors suggested that there are more cost-effective means of reducing the incidence of cervical cancer, not least by trying to screen women who have not been screened before. Educational efforts aimed at promoting better sampling of the cervix may also be a better strategy than rescreening, either manual or automated.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of comparator is clear. The highly publicised false-negative rates associated with the cervical cancer screening programme make the issue and the choice of comparison (manual versus automated rescreening) relevant to the health service.

Validity of estimate of measure of benefit
A larger sample population may have provided firmer data on the yield of LSIL diagnoses associated with PAPNET-assisted rescreening; as it was the authors had to infer such a rate since this study did not produce any such diagnoses. When judging the results, the historical nature of the controls, which were manually rescreened some time in the past, should also be considered. Moreover, it should be noted that the analysis did not consider the cost of the subsequent investigations and interventions in those cases detected.

**Other issues**
The generalisability of these study results depends, as the authors themselves noted, very much on the setting. In particular the quality of the original pap smears, the rate of false-negative readings in the laboratory and the prevalence of cervical cancer among the population.

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**Other publications of related interest**

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