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 a picture archiving and communication system (PACS) in the reporting of incidental findings outside the area of interest. The area of interest was lumbar spinal magnetic resonance imaging (MRI).

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with reports of lumbar spinal MRI examinations.

Setting
The setting was secondary care. The study was performed in Philadelphia (PA), USA.

Dates to which data relate
The effectiveness and resource use data were collected between 1995 and 2000. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data appear to have been collected retrospectively from the same sample population as that used in the effectiveness analysis.

Study sample
No power calculations, to assure a certain power, were performed in the planning phase of the study. A total of 500 consecutive reports of lumbar spinal MRI examinations from 5 consecutive years (between 1995 and 2000, and starting on January 1 of each year) were reviewed. Therefore, 2,500 patients comprised the study sample considered in the clinical analysis. There were 1,512 female patients and 988 male patients. The mean age was 52 years (age range: 9 - 92). The authors did not report any evidence that the study sample was representative of the study population.

Study design
This was a retrospective, comparative study with historical controls. Three intervention groups were considered at
analysis. These corresponded to the reports collected during the 3 years after the complete implementation of the PACS (post-PACS years 1, 2 and 3). These intervention groups were compared with the control group, in which the reports were collected during the year before the implementation of the PACS (pre-PACS year). An additional group was considered in which PACS and hard-copy images co-existed. This corresponding to the year in which PACS was implemented (PACS transition year). The study was performed at a single centre. The period of follow-up appears to have been until the results of the initial examinations were obtained, in cases where no incidental findings were found or, for those cases with an incidental finding, until the results of further examinations were obtained.

**Analysis of effectiveness**

The primary health outcomes considered at analysis were:

- the total incidental findings and the number of patients associated with them;
- the frequency and type of incidental finding per year;
- the number of follow-up studies recommended;
- the number of ultrasonography examinations required; and
- the number of malignancies and occult metastatic disease detected.

The groups were not shown to be comparable at analysis.

**Effectiveness results**

A total of 202 incidental findings among 183 patients were found throughout the whole study period, although only 83 had clinical charts available for review.

The numbers of incidental findings were 19 during the pre-PACS year, 31 during the PACS transition year, 53 during post-PACS year 1, 49 during post-PACS year 2, and 50 during post-PACS year 3.

The increase in the number of incidental findings was significant for each year after PACS implementation, (p<0.001), but not for the transition year, (p=0.055).

The most frequent incidental findings were renal, uterine, adnexal, hepatic, lymph node and pulmonary abnormalities.

When compared with the pre-PACS year (with 5 follow-up studies recommended), the total number of follow-up studies recommended increased significantly after the introduction of PACS. Fifteen studies were recommended during the transition year, (p=0.02), 32 during post-PACS year 1, (p<0.001), 22 during post-PACS year 2, (p=0.001), and 18 during post-PACS year 3, (p=0.005).

The number of ultrasonography examinations increased from 2 during the pre-PACS year to 11 during the transition year, 27 during post-PACT year 1, 17 during post-PACT year 2, and 14 during post-PACT year 3.

The number of occult malignancies detected were zero in the pre-PACS year, one during the transition year, one during post-PACS year 1, and two during post-PACS year 2.

A case of metastatic disease was detected during post-PACS year 3.

**Clinical conclusions**

The number of incidental findings reported increased considerably after the introduction of the PACS. Considerable increases were also observed in the number of follow-up studies recommended, the number of follow-up ultrasonography examinations, and the number of occult malignance diseases detected.
Measure of benefits used in the economic analysis
The summary measure of benefit used was the number of occult malignancies identified with the PACS. This was obtained directly from the effectiveness analysis.

Direct costs
Some resource quantities were reported, but not all, and no unit prices were reported. The authors reported that the direct costs considered in the analysis were those of the health service. Only the costs related to follow-up examinations generated by the incidental findings were finally included. Some relevant costs for the perspective adopted, such as the costs of obtaining either PACS or hard-copy images, or the costs of additional physician visits or laboratory tests, were not included. The direct costs were derived from Medicare reimbursements. The costs appear to have been estimated on the basis of actual data. Discounting was not carried out, but it was unnecessary since the patients were followed up for less than 2 years. The price year was 2000. The direct costs reported were the total costs per year and the total costs associated with the incidental findings after the implementation of the PACS.

Statistical analysis of costs
No statistical analyses of the costs were reported.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were reported.

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

Cost results
The costs per year (i.e. per 500 cases) were:

$2,110 during the pre-PACS year,
$4,653 during the transition PACS year,
$6,713 during post-PACS year 1,
$5,279 during post-PACS year 2, and
$4,126 during post-PACS year 3.

Therefore, the total costs associated with the incidental findings found with the PACS were $22,882.

Synthesis of costs and benefits
A cost-effectiveness ratio was calculated as the cost per occult malignancy identified during both the pre-PACS and PACS periods combined. This cost-effectiveness ratio was $5,721 per occult malignancy identified.
Authors' conclusions
The introduction of a picture archiving and communication system (PACS) for lumbar spinal magnetic resonance imaging (MRI) appears to have been associated with an increase in the number of incidental findings (most commonly, renal, gynaecologic and hepatic abnormalities) and follow-up studies recommended. Although costs may increase as a result of additional examinations, there is the advantage that some cases of occult malignant disease would be identified.

CRD COMMENTARY - Selection of comparators
The use of hard-copy images was considered to be the comparator because it was the current practice in the authors' setting before the PACS was implemented. You should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
This was a retrospective comparative study with historical controls. It may have been appropriate given the data available to perform the study, but it is subject to considerable bias, such as patient selection bias (it could not assure that the patients' characteristics were similar across groups) or environmental differences due to differences across time. As the authors stated, reports instead of images were reviewed, which may have resulted in less incidental findings being identified. In addition, the follow-up results for incidental findings were not available for all of the patients. There may have been variability, both in the interpretation of the incidental findings (several radiologists interpreted the images) and in medical practice (the requirement for further follow-up procedures). The study sample may not have been representative of the study population since patients from only one institution were considered for the effectiveness analysis. Therefore, the clinical study may lack both internal and external validity.

Validity of estimate of measure of benefit
The summary measure of benefit used in the economic analysis (i.e. the total number of cases of occult malignancies identified with PACS outside the area of interest) was obtained directly from the effectiveness analysis. The implicit justification appears to have been that the use of PACS images allows the interpretation of incidental findings outside the region of interest. Other measures of benefit (e.g. the number of quality-adjusted life-years gained) would allow the results to compared with those from different interventions, although they would be difficult to estimate in this study.

Validity of estimate of costs
Not all the costs relevant to the perspective adopted were considered in the economic analysis. This exclusion is likely to have affected the authors' conclusions. The authors stated that the costs associated with the PACS may have been underestimated. No statistical or sensitivity analyses of the costs were reported. Some resource quantities were given separately, but not the associated unit costs. Therefore, there is considerably uncertainty surrounding the cost estimation. In addition, it would be difficult to perform appropriate relation exercises in other settings. The price year was given. Discounting was not performed since the follow-up period appears to have been less than 2 years.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. These consistently showed that the productivity of the radiology department may increase by using a PACS because of the reduction in the time required for examination, an improvement in detection of findings, and a potential increase in cost-effectiveness. The fact that patients from a single institution were considered for the effectiveness analysis may, as the authors acknowledged, limit the generalisability of the results to other settings. The cost-effectiveness ratio calculated was meaningless for decision-making purposes, as it divided the combined costs from both intervention periods by the combined effects from both periods. The appropriate analysis would have been to divide the difference in costs between the interventions by the difference in effects between the interventions.

Implications of the study
The authors recommended further research to guarantee that the effect of the PACS on the identification of incidental findings can be generalised to other institutions, and to measure this effect on non-lumbar spinal examinations.

Caution should be exercised when interpreting the study findings because of the caveats highlighted. It will be necessary to conduct further research to assess the costs associated with the PACS appropriately, and to perform accurate comparisons with the comparator chosen at analysis.

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