The effects of a pediatric unilateral inguinal hernia clinical pathway on quality and cost

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 clinical pathway (CP) for outpatient surgical repair of paediatric inguinal hernia. The CP was developed with the aim of minimising duplicative or unnecessary interventions.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised healthy infants with straightforward unilateral inguinal hernia, who were of greater than 50 weeks’ gestational age. Premature infants were not excluded from the study.

Setting
The setting was secondary care. The economic study was carried out in Norfolk (VA), USA.

Dates to which data relate
The effectiveness evidence and resource use data related to 1995 to 1997. The dates to which the price data related were not stated.

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

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. The costs were collected prospectively in the intervention group and retrospectively in the control group.

Study sample
The way in which the sample size was determined was unclear, as the authors mentioned the sample size in the abstract of the paper and referred to a power of 0.8. However, they did not elaborate on the methods used. The method of sample selection was unclear. The study sample consisted of 92 patients, 46 in each of the two groups (control and intervention). It was stated that the patients in the intervention group were selected randomly from 75 “pathway” patients who underwent surgical repair of inguinal hernia in the study hospital. The reason for not including 29 (69%) of the 75 patients identified was not given. The patients in the intervention group were recruited from November 1996 to April 1997. The matched control group was selected from February 1995 to October 1995. The mean age of the
patients in the study was 5.8 (standard deviation, SD=3.5) years in the control group and 5.7 (SD=3.2) years in the intervention group. Seventy-six per cent of patients in each group were male, and 63% of the control group were white versus 67% of the intervention group. The authors did not comment on how representative the study sample was of a more general population.

**Study design**
This was a single-centre study utilising a cross-sectional, retrospective cohort study. The method by which the intervention group was randomly selected was not stated. The length of follow-up appears to have been one month following the surgical intervention. There appears to have been no loss to follow-up. The study was not blinded.

**Analysis of effectiveness**
All of the patients included in the study were accounted for in the analysis. The primary health outcomes were wound infection rate, anaesthesia and procedure times, times in the post-anaesthesia care unit (PACU), and PACU step-down and readmissions. The groups were shown to have been comparable in terms of their age, gender and white origin.

**Effectiveness results**
In the control group, the mean times were 52 (SD=13) minutes for anaesthesia, 24 (SD=11) minutes for the procedure, 43 (SD=17) minutes in the PACU, and 54 (SD=19) minutes for PACU step-down. The overall time was 149 (SD=30) minutes.

In the intervention group, the mean times were 49 (SD=10) minutes for anaesthesia, 21 (SD=7) minutes for the procedure, 40 (SD=12) minutes in the PACU, and 49 (SD=21) minutes for PACU step-down. The overall time was 138 (SD=25) minutes.

The difference in overall time between the control and study groups was not statistically significant, (p=0.056).

There were no statistically significant differences in wound infection rate or readmissions between the treatment groups.

**Clinical conclusions**
The authors concluded that this study showed that the CP maintained the quality of care associated with standard practice.

**Measure of benefits used in the economic analysis**
No summary measure of health benefit was used in the economic analysis. Hence, a cost-consequences analysis was performed. The study also showed no difference in effectiveness between the two groups. Therefore, the results could also be viewed as a cost-minimisation analysis.

**Direct costs**
The resource quantities and the costs were not reported separately. The study recorded the direct hospital costs. These included supplies and laboratory testing, associated surgery, and hotel costs. Professional fees and the cost of follow-up visits were excluded from the analysis. The source of the cost data and the estimation of the price data were not described, and the date to which they related was not available. Discounting was not relevant as the costs were incurred during less than one year. The study reported the average costs.

**Statistical analysis of costs**
The mean costs and SDs, and p-values for the difference in mean cost between the groups were provided. The authors stated that analysis of variance and chi-squared tests were used to assess differences between the groups, although the
precise test to which the cost p-values related was not stated. The significance level used was 5%. No power calculations were performed for the cost analysis.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

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

**Cost results**
The mean total cost was $982 (SD=173) in the control group compared with $880 (SD=121) in the intervention group. The difference was statistically significant, (p=0.001). The costs of follow-up visits were excluded from the analysis.

**Synthesis of costs and benefits**
Not applicable.

**Authors’ conclusions**
The use of a clinical pathway (CP) was cost-saving. The CP also maintained the quality of care observed in standard practice.

**CRD COMMENTARY - Selection of comparators**
The study used current practice as of 1995 in the study hospital, in Virginia (USA), as the comparator. The observed practice was not described in detail. This would make it difficult for the reader to assess the relevance of the comparator to their setting or practice.

**Validity of estimate of measure of effectiveness**
The authors acknowledged that a randomised controlled trial would have been better in terms of generalising their results to other settings. They justified their use of historical controls on the grounds that, within their centre, it would have been difficult to prevent a concurrent control group benefiting from staff knowledge of the CP. The authors did not state whether the study sample was representative of the study population. The study groups were shown to have been comparable at analysis. However, the method by which the intervention group of 46 patients was selected from the potential group of 75 patients was unclear. Consequently, it is not possible to judge the extent or existence of selection bias in the intervention group.

**Validity of estimate of measure of benefit**
The health benefits and costs were not formally synthesised. As the study showed no statistically significant differences in health outcome between the groups, the cost analysis may be viewed as a cost-minimisation analysis.
Validity of estimate of costs
Although the authors reported that repeat admissions and wound infections were relevant outcomes, these do not appear to have been costed, even though they would be relevant from a hospital perspective. The study also omitted the costs of professional fees, including physician costs. It is not possible to assess whether the inclusion of these costs would have affected the authors’ conclusions. The costs and the quantities were not reported separately.

The resource use quantities were taken from a single study. The study used an historical control, so there is the possibility that differences in resource use between the control and intervention arms may have resulted from the procedures’ evolution over time. A statistical analysis of differences in average time in anaesthesia, procedure, PACU, PACU step-down and total time between the two groups was performed.

The authors did not provide the source of the price data, which limits the generalisability of the study findings. It also means that it is not possible to quality assess the use of price data.

Other issues
The authors did not compare their findings with those from other studies in the same area. They acknowledged that the generalisability of their findings was limited by the study design. They also acknowledged that different CPs must be developed for areas where standard practice differs. The authors did not present their results selectively and their conclusions reflected the scope of the analysis. The authors also mentioned that the small change in practice might have been due to the Hawthorne effect, rather than the CP itself. The Hawthorne effect occurs where workers increase their productivity simply because they know they are being studied. However, they went on to reject this hypothesis on the grounds that the difference in time between the two groups was clinically and statistically insignificant.

Implications of the study
The authors recommended that, as standard practice changes, the CP should be adjusted accordingly and the clinical and cost-effectiveness should be reassessed.

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