The price of emergency contraception in the United States: what is the cost-effectiveness of ulipristal acetate versus single-dose levonorgestrel?

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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
This study evaluated the cost-effectiveness of ulipristal acetate, for emergency contraception, within 120 hours of unprotected intercourse. The authors concluded that ulipristal acetate was more cost-effective than levonorgestrel, and its use should be promoted. The analyses and methods were reasonable, but poor reporting of all the data, particularly for effectiveness, means that it is difficult to assess the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study evaluated the cost-effectiveness of ulipristal acetate, for emergency contraception, within 120 hours of unprotected intercourse.

Interventions
Ulipristal acetate was compared with the other available emergency contraceptive, single-dose levonorgestrel. Ulipristal acetate (30mg pill) or levonorgestrel (1.5mg) was taken up to 120 hours after unprotected intercourse, each as one dose.

Location/setting
USA/out-patient.

Methods
Analytical approach:
A decision-tree model was developed to estimate the outcomes of unprotected intercourse, followed by emergency contraception, with ulipristal acetate or levonorgestrel. The outcomes were no pregnancy, or pregnancy followed by induced abortion, miscarriage, ectopic pregnancy, or delivery vaginally or by caesarean section. The authors stated that a societal perspective was adopted.

Effectiveness data:
The primary measure of effectiveness was unintended pregnancies averted. The model examined one episode of emergency contraception use, and assumed that pregnancies averted did not occur at a later date. The key effectiveness parameters were the failure rates of the two drugs, which were from a published meta-analysis (see Other Publications of Related Interest). The failure rates were for emergency contraception within 120 hours of unprotected intercourse, independent of the timing of the menstrual cycle. To extrapolate effectiveness to the US population, sales data for levonorgestrel, in 2010, were adjusted for its estimated annual use, based on the results of a published randomised controlled trial.

Monetary benefit and utility valuations:
The utility values were elicited using the time trade-off method. They were from a published study of the effects of unintended pregnancy on women’s quality of life. Quality-adjusted life-years (QALYs) were calculated by assuming that each woman lived for 55 years, after an averted pregnancy, with 0.992 QALYs per additional life-year.

Measure of benefit:
Two measures of benefit were used: unintended pregnancies averted, and QALYs gained from the aversion of these
unintended pregnancies. Life expectancy was discounted at an annual rate of 3%.

Cost data:
The costs included those of pregnancy and the drugs. Pregnancy costs were from a published study that used Medicaid payments. The costs of the drugs were their pharmacy prices per dose. The costs were reflated to 2011 US $, using the US consumer price index. They were discounted at 3% annually, and they were extrapolated to the US population, over the long-term, using the same methods as for the effectiveness data.

Analysis of uncertainty:
Univariate and multivariate sensitivity analyses were performed to test the model assumptions. Univariate analyses were performed, for all the model inputs, with each input varied from 50% to 200% of its initial value, to identify the threshold at which the conclusion changed. A probabilistic sensitivity analysis was performed to estimate the overall effect of uncertainty in the model. All model inputs were assigned probabilistic distributions and sampled for 10,000 trials, using Monte Carlo simulation. The results were displayed on a cost-effectiveness plane, and a cost-effectiveness acceptability curve.

Results
The model indicated that the routine use of ulipristal acetate, over levonorgestrel, resulted in 37,589 fewer unintended pregnancies per year, which gained 8,053 QALYs and saved $116.3 million. Ulipristal acetate was more effective and less expensive than levonorgestrel.

In the one-way sensitivity analyses, at the reported failure rate for ulipristal acetate (1.3%), it could cost up to $265 ($40 in the main analysis) and still be cost-effective, at a cost-effectiveness threshold of $100,000 per QALY gained. Ulipristal acetate was more cost-effective than levonorgestrel as long as the failure rate for ulipristal acetate was less than 2.17%, or the cost was under $265.

Probabilistic sensitivity analysis indicated that at a threshold of $50,000 per QALY gained, ulipristal acetate was the most cost-effective option in 95% of simulations. The cost-effectiveness plane showed that in most simulations ulipristal acetate was more effective and less costly.

Authors' conclusions
The authors concluded that ulipristal acetate was more cost-effective than levonorgestrel, for emergency contraception, and its use should be promoted.

CRD commentary
Interventions:
The interventions appear to have been appropriate. The comparator was levonorgestrel taken within 120 hours of unprotected intercourse, but the recommendation was that levonorgestrel, bought over the counter, should be used within 72 hours of unprotected intercourse. The authors acknowledged that copper-releasing intrauterine devices were the most effective emergency contraception, but these were not included in the model because they provided long-term contraception, and they required a trained provider for insertion in the uterus. This justification appears reasonable.

Effectiveness/benefits:
The authors indicated that the best available effectiveness data were chosen, but the methods of finding and selecting these data, and the methods for the meta-analyses were not given. It was not clear if the best available data were used. The authors acknowledged that the meta-analysis only combined data from two studies; the quality of these studies and potential differences between them were not reported. It was unclear whether they assessed levonorgestrel given within 72 or 120 hours of unprotected intercourse. The time trade-off method was used for the utilities, but it was not clear if the EQ-5D or a generic method was used. It was not clear who provided the utilities, and valued the model states. A utility value was only assigned for unplanned pregnancy, in general, and applied to the end result of the decision tree. The utility scores were not decreased over time to account for natural age-related utility decline, but this was the same for both interventions, so it should not affect the results. It was not clear if it was appropriate to apply the same utility decrement to every year of life remaining for the women.

Costs:
The costs appear to have reflected a mixed patient and payer perspective, which may influence the generalisability of the results to other settings. The methods used to select the costs were not reported. No unit costs were described, so it is not possible to assess how well they would apply to another setting. All costs were analysed for a one unprotected intercourse event, assuming that pregnancy did not occur at a later time. For some women pregnancy could be delayed, and costs would be incurred later. This was not considered. Repeat use of emergency contraception, and the effects of emergency contraception on the use of other contraception were not considered, and could affect the cost-effectiveness for a broader decision problem. The costs appear to have been derived from appropriate US sources. The limitations of the cost data were discussed, and extensive sensitivity analyses were undertaken on the costs.

Analysis and results:
The results of the model appear to have been robust to alternative parameter assumptions and overall parameter uncertainty, but the probabilistic distributions were not described. Widely varying alternative assumptions were tested in the one-way sensitivity analysis and there were few model parameters, so it is unlikely that the conclusion would change, unless the effectiveness data were not valid (the meta-analysis for effectiveness should be assessed). The results were clearly presented, demonstrating a high likelihood that ulipristal acetate was more effective and less costly than levonorgestrel. It is possible that factors not considered in the model, or different setting characteristics could affect the certainty in the results.

Concluding remarks:
The analyses and methods were reasonable, but poor reporting of all the data, particularly those for effectiveness, means that it is difficult to assess the validity of the authors' conclusions.

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