Potential economic benefits of lower-extremity amputation prevention strategies in diabetes

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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
Lower-extremity amputation prevention strategies among individuals with diabetes.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
A hypothetical cohort of 10,000 individuals with diabetes, based on population-based prevalence data.

Setting
Multi-disciplinary practice settings. The study was conducted in the United States.

Dates to which data relate
The main effectiveness data were taken from published studies dated 1975-1995. Resource and cost data were mainly derived from 1995 sources. The price year was 1996.

Source of effectiveness data
Estimates of the percentage of people with a history of foot ulcer, the annual incidence of first lower-extremity amputation, risk reduction by prevention for each selected strategy and cost of lower-extremity amputation were derived from previously completed studies.

Modelling
A decision analytic model was used to estimate the incidence of associated costs of lower-extremity amputation. The time frame used in the analysis was 3 years.

Outcomes assessed in the review
The outcomes assessed in the review were the age distribution, mortality rates, percentage of people with a history of foot ulcer, annual incidence of first lower-extremity amputation and the risk reduction for amputation for each selected strategy.

Study designs and other criteria for inclusion in the review
No specific study designs were stipulated by the authors as inclusion/exclusion criteria.
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
The authors reviewed 18 studies in total but a sub-total of 13 were used as the sources of effectiveness data.

Methods of combining primary studies
The risk reduction for each strategy was taken as the mid-point of the range reported in the literature.

Investigation of differences between primary studies
Not stated.

Results of the review
The age distribution was estimated to be:

- 10% in the age range 0-39;
- 9.2% in the age range 40-49;
- 18.9% in the age range 50-59;
- 18.9% in the age range 60-69;
- 26.3% in the age range 70-79
- 16.7% in the 80+ age group.

The mortality rates and history of foot ulcer were:

- age range 0-39, 1% and 0%;
- age range 40-49, 1% and 4%;
- age range 50-59, 2.8% and 2.9%;
- age range 60-69, 2.8% and 6%;
- age range 70-79, 5.8% and 8.8%;
- 80+ age group, 13.6% and 14%.

The annual incidence of first lower-extremity amputation was 4.8%. The risk reduction by prevention was estimated to be 72%, for patient/provider education, 47% for multidisciplinary clinic and 53.5% for therapeutic shoe coverage.
Measure of benefits used in the economic analysis
The benefit measure was cases of first lower-extremity amputation averted.

Direct costs
Costs of lower-extremity amputation were included in the analysis. Quantities were not analysed separately from costs (averages per patient were determined). The quantity/cost boundary adopted was the managed care organization. The source of cost data was a previously published study. A discount rate of 5% was applied. The price year was 1996.

Statistical analysis of costs
Not relevant.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were carried out to examine the robustness of estimates of economic benefits in relation to changes in the risk of lower-extremity amputation among individuals with a history of diabetic ulcer, the cost of lower-extremity amputation and the risk of lower-extremity amputation.

Estimated benefits used in the economic analysis
The number of individuals with a history of foot ulcer who would be expected to undergo a first lower-extremity amputation each year was estimated to be 679. The number of cases of lower-extremity amputation estimated to occur in the absence of intervention was estimated to be 91 (32.7, 30.3 and 28.1 for year 1, 2 and 3, respectively). The number of cases averted through educational interventions were estimated to be 66 (23.6, 21.8 and 20.2 for year 1, 2 and 3, respectively), 43 (15.4, 14.2 and 13.2 for year 1, 2 and 3, respectively) for multi-disciplinary clinics and 49 (17.5, 16.2 and 15.2 for year 1, 2 and 3) for insurance coverage for therapeutic shoes.

Cost results
The cost of lower-extremity amputation (per case) was $48.152. The potential discounted savings over the 3-year period were estimated to be nearly $3.0 million for educational interventions, $2.0 million for multi-disciplinary clinics and $2.2 million for insurance coverage for therapeutic shoes.

Synthesis of costs and benefits
No synthesis of costs and benefits was provided. The 3 year potential discounted savings were estimated to range from $2,900 to $4,442 per person with a history of foot ulcer. Results were fairly sensitive to the assumed changes. When the rate of risk of reduction was reduced by half, potential economic benefits still ranged from $1 to $1.5 million.

Authors' conclusions
Strategies to reduce the risk of lower-extremity amputation may generate substantial economic benefits and should be a standard component of routine diabetes care. Benefits may best be achieved through a partnership of government, private payers, health care service providers and producer, and individuals with diabetes.
CRD COMMENTARY - Selection of comparators
The reason for the choice of the selected strategies to reduce the incidence of lower-extremity amputation among individuals with diabetes is clear. Literature-derived effectiveness data about such strategies have reported reductions in the risk of lower-extremity amputation. You, as a user of this database, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
The estimates of measure of benefit used in the economic analysis need to be treated with a degree of caution since the published evidence of effectiveness of strategies is limited: most of the studies cited were uncontrolled, non-randomized and/or retrospective. Additionally, individuals were assumed to be served by each strategy when in reality, as recognised by the authors, participation rates for some interventions may be minimal. As the model focuses only on the risk of first amputation from large groups and estimates of the risk of lower-extremity amputation, the associated benefits of prevention might be conservative.

Validity of estimate of costs
The study considers only costs incurred over 3 years. Additionally, the costs of the intervention were not included in the analysis and the authors did not consider variations in provider types and practice settings.

Other issues
The limitations of the data were partially addressed in the sensitivity analyses undertaken. The issue of generalisability to other settings or countries was not addressed in that, as stated by the authors, different populations, countries and practice settings were not considered. Comparisons with other studies were not made.

Implications of the study
Further analysis is required to evaluate these strategies across multiple populations and practice settings.

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