Outcome analysis of a pharmacist-managed anticoagulation service
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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
Prevention of complications, thromboembolic and haemorrhagic events, in patients receiving warfarin pharmacotherapy through monitoring by a pharmacist-managed anticoagulation service.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Family Practice Medical Group patients receiving warfarin therapy.

Setting
The study was carried out in a community based population served by the Family Practice Medical Group (FPMG) based at the University of Florida, USA.

Dates to which data relate
The effectiveness study was based on patients receiving therapy between October 1988 and December 1993. Resources were measured in the same period.

Source of effectiveness data
Derived from a single study.

Link between effectiveness and cost data
Costing was carried out on the same patient sample as the effectiveness data. Cost and effectiveness data were collected at the same time and were retrospective.

Study sample
All FPMG patients who received warfarin therapy between October 1988 and December 1993. All patients who received a prothrombin time test were included in the sample. The sample was divided into a control group who were receiving warfarin and whose progress was followed only by their physician and a study group consisting of patients monitored by the anticoagulation monitoring service (AMS). Follow up consisted of following records while patients were taking warfarin and therefore was of varying periods. Comparison was therefore based on person-years of treatment to see an event. The control group was followed over 28 person-years of treatment and the study group over 60 person-years of treatment. Patients who switched groups were evaluated only in the first group to which they
belonged and only for the amount of time they were in that group. One patient in the control group contributed a large proportion of outcome events due to serious noncompliance. Analysis was carried out both with and without this person.

**Study design**
Prospective cohort study and retrospective chart review.

**Analysis of effectiveness**

It was not stated whether the analysis is based on intention to treat.

The outcomes evaluated were based on the number of thromboembolic and haemorrhagic events. Major haemorrhagic events were defined as gross haematuria, major haematoma and upper gastrointestinal bleed. Minor haemorrhagic events were defined as increased bruising, bleeding gums, bleeding from minor trauma site and epistaxis. Thromboembolic events included cerebrovascular accident, pulmonary embolism and deep vein thrombosis. Events were evaluated by two physicians blinded as to the group. Those events not thought to be attributable to inadequate or excessive anticoagulation were excluded from the study.

Unplanned clinic visits, emergency room treatments and hospital admissions were also compared between groups. Groups were compared for age, gender, race, alcohol use and tobacco use: differences were not significant. Groups were also compared on 11 indications for warfarin therapy: differences were not significant.

**Effectiveness results**

Minor haemorrhagic events: There were 2 in each group. In the control group this was 14.1 (95%CI 3.9-116.1) person years per event and in the AMS group 29.9 (95%CI 8.3-246.7) person years per event but the difference is not significant (p=0.451).

Major haemorrhagic events: There were 5 in the control group and none in the AMS group. The control group produced 5.6 (95%CI 2.2-17.4) person years per event and the AMS group >60 (95%CI 20- ) person years per event, calculated by using an exact test for binomial proportions and computing the probability of observing zero events in the study group under the null hypothesis that the control and study groups have identical underlying event rates. Differences between groups were significant (p= 0.003).

Thromboembolic events: Ten events were recorded in the control group and none in the AMS group. Person years per event were 2.8 (95%CI 1.5-5.9) in the control group and >60 (95%CI 20- ), calculated as above, in the AMS group (p=<0.0001).

Differences between groups in unplanned clinic visits, emergency room visits and hospital admissions were all very highly significant (p=<0.0001).

**Clinical conclusions**

Monitoring by a pharmacist-managed anticoagulation service is highly effective in preventing complications due to warfarin therapy. The control group was 20 times more likely than the study group to experience any event (rate ratio 20, 95% CI 5-87).

**Measure of benefits used in the economic analysis**

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**Direct costs**
Costs and quantities were not reported separately. They included: costs of participation in the AMS service, costs of a physician office visit, the cost of a prothrombin time test. Costs resulting from adverse events during the study period were included, where available, from actual charges. Emergency room and hospital admission charges were obtained from the affiliated hospital billing department. They represent charges to the patient rather than prices of quantities of goods and services.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
Minor haemorrhagic events: There were 2 in each group. In the control group this was 14.1 (95%CI 3.9-116.1) person years per event and in the AMS group 29.9 (95%CI 8.3-246.7) person years per event but the difference is not significant (p=0.451).

Major haemorrhagic events: There were 5 in the control group and non in the AMS group. The control group produced 5.6 (95%CI 2.2-17.4) person years per event and the AMS group >60 (95%CI 20- ) person years per event, calculated by using an exact test for binomial proportions and computing the probability of observing zero events in the study group under the null hypothesis that the control and study groups have identical underlying event rates. Differences between groups were significant (p= 0.003).

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**Cost results**
The total cost for the control group for 28 person years was $119,074.95. Per person year this was a cost of $4252.68. The cost of participation in the AMS scheme was $15 per month, $180 per year or a total of $5040 for 28 person years which was the equivalent of the total for the control group. Actual total costs for the AMS group were not given. A potential cost avoidance from preventing hospital admissions due to AMS was given as $114,034.95 or $4072.68 per person year. This was the actual cost of hospital and other emergency treatment of events in the control group less the cost of the AMS participation ($119,074.95 - $5040) This was because no hospital admissions, emergency room visits or unplanned clinic visits were recorded in the AMS group. Because both groups are charged for prothrombin times and/or international normalised ratios at the same rate these were considered irrelevant costs and were not calculated.

**Synthesis of costs and benefits**
A synthesis was not undertaken by the authors since monitoring by AMS was the dominant strategy.

**Authors' conclusions**
The control group was 20 times more likely to experience a thromboembolic or haemorrhagic event than the AMS group. Pharmacist involvement in the care of patients receiving warfarin therapy can improve patient outcomes in a family medicine setting. This strategy also proved cheaper since no charges for hospital admissions, emergency room visits or unplanned clinic visits were incurred by the AMS group.

**CRD Commentary**
Although no synthesis of costs and benefits was needed because of the dominance of one strategy there were not enough costs and prices details to clearly compare the costs of the two strategies. No total costs were given for the AMS group. No discounting of costs was carried out although the study was done over 5 years and prices and charges probably varied over that time.

Costs given were charges made by a hospital and FPMG in Florida and these are difficult to generalise and compare with other locations or health care systems.

The numbers in the study were relatively small and the confidence intervals wide yet no sensitivity analysis was carried out.

**Bibliographic details**

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