Specialist Nurse-Led Clinics to Improve Control of Hypertension and Hyperlipidemia in Diabetes

Economic analysis of the SPLINT trial

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OBJECTIVE — To determine the cost-effectiveness of specialist nurse-led clinics provided to improve lipid and blood pressure control in diabetic patients receiving hospital-based care.

RESEARCH DESIGN AND METHODS — A policy of targeting improved care through specialist nurse-led clinics is evaluated using a novel method, linking the cost-effectiveness of antihypertensive and lipid-lowering treatments with the cost and level of behavioral change achieved by the specialist nurse-led clinics. Treatment cost-effectiveness is modeled from the U.K. Prospective Diabetes Study and Heart Protection Study treatment trials, whereas specialist nurse-led clinics are evaluated using the Specialist Nurse-Led Clinics to Improve Control of Hypertension and Hyperlipidemia in Diabetes (SPLINT) trial.

RESULTS — Good lipid and blood pressure control are cost-effective treatment goals for patients with diabetes. Modeling findings from treatment trials, blood pressure lowering is estimated to be cost saving and life prolonging (−$1,400/quality-adjusted life-year [QALY]), whereas lipid-lowering is estimated to be highly cost-effective ($8,230/QALY). Investing in nurse-led clinics to help achieve these benefits imposes an addition on treatment cost-effectiveness leading to higher estimates: $4,020/QALY and $19,950/QALY, respectively. For both clinics combined, the estimated cost-effectiveness is $9,070/QALY. Using an acceptability threshold of $50,000/QALY, the likelihood that blood pressure-lowering clinics are cost-effective is 77%, lipid clinics 99%, and combined clinics 83%.

CONCLUSIONS — A method is described for evaluating the cost-effectiveness of policies to change patient uptake of health care. Such policies are less attractive than treatment cost-effectiveness (which implies cost-less self-implementation). However, specialist nurse-led clinics, as an adjunct to hospital-based diabetic care, combining both lipid and blood pressure control, appear effective and likely to provide excellent value for money.

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though there is abundant evidence that patients with diabetes benefit from interventions to lower cholesterol and blood pressure (1–3), there is less evidence to demonstrate how these findings can be translated into routine clinical practice. Influencing the health care delivered by clinicians or taken up by patients is an increasingly important policy objective in the health systems of developed countries. Where suboptimal care is identified, policymakers normally have to commit resources to influence behavior if desirable changes are to be achieved. A method for analyzing the economics of behavioral change in clinicians was recently published (4). The approach differentiated between treatment cost-effectiveness (the net costs and benefits of a treatment when provided) and policy cost-effectiveness (which combines treatment cost-effectiveness with the cost and magnitude of change achieved by an implementation method). Some interventions that improve uptake of health care provision are targeted at the patient rather than the clinician: examples include patient education and organizational changes such as improved clinic times. This article assesses the cost-effectiveness of improved blood pressure and cholesterol control, achieved by using specialist nurse-led clinics (5) as an adjunct to hospital-based diabetic care.

RESEARCH DESIGN AND METHODS

Specialist nurse-led clinics

In England, about one-half of people with diabetes have their care managed in hospitals, and the other half are managed in primary care. Diabetic information systems, supporting structured diabetes care, have improved the quality of care provided (6). To further improve care and try to achieve the blood pressure targets achieved in the U.K. Prospective Diabetes Study (UKPDS) (1), a specialist nurse-led
intervention to treat and control hypertension and hyperlipidemia in patients with diabetes (SPLINT) was conducted and reported (5). In brief, SPLINT enrolled 1,407 subjects attending the diabetes center at Hope Hospital, Salford, U.K., for annual review with raised blood pressure (≥140/80 mmHg), raised total cholesterol (≥5.0 mmol/l), or both. Subjects were randomized to usual care or usual care with subsequent invitation to attend specialist nurse–led clinics. Patients with both raised blood pressure and hyperlipidemia were eligible for enrollment in either or both clinics. Because of the design of the study, a separate specialist nurse provided each intervention. In routine practice, it is anticipated that both interventions, along with glycemic control, would be provided by a single nurse providing holistic support for patients.

The two nurse specialists recruited for the study were registered nurses educated to degree level with ≥2 years previous clinical experience of the management of diabetes, hypertension and dyslipidemia, and patient education, and working as advisors to other health care professionals. They received additional training in the management of hypertension and dyslipidemia in patients with diabetes from the local clinicians (J.M.G. and J.P.N.) and pharmacists.

During an initial 45-min consultation, the specialist nurse discussed the reason for the visit, targets for their treatment, and reasons for these targets. Medications were reviewed and other key conditions likely to influence treatment were noted, such as poorly controlled diabetes. An accurate assessment of their presenting condition was made. For patients with hypertension, three measurements of blood pressure were taken using an Omron 705CP (Omron Health Care, Henfeld, U.K.), and the average of the latter two readings was recorded. Lifestyle factors were discussed, the patient’s willingness to adjust was assessed, and an individualized action plan was drawn up. At subsequent visits, lifestyle factors were reinforced and reviewed and medications were titrated according to response to the treatment and according to protocol.

The lipid specialist nurse–led clinic improved the proportion of patients achieving the cholesterol target (53.3 vs. 40.3%). The change in total cholesterol attributable to the intervention was −0.28 mmol/l (95% CI −0.44 to −0.13; P = 0.0004). The hypertension specialist nurse–led clinic improved the proportion of patients achieving the blood pressure target (26.6 vs. 24.1%), although the difference was not statistically significant: a reduction in mean arterial blood pressure of 1.2 mmHg (−1.7 to 4.0; P = 0.21).

Lipid and blood pressure lowering

The UKPDS research program enrolled 1.148 hypertensive patients (systolic/diastolic ≥160/≥90 mmHg) with newly diagnosed adult-onset diabetes to tight or routine blood pressure control (1,2). A significant reduction in mean arterial blood pressure was achieved by tight control after 1 year of 5.7 mmHg. Tight control achieved relative risk reductions in myocardial infarction (MI) of 21% (41 to −7%) and stroke of 44% (65 to 11%). Published economic analyses of intensive blood pressure control indicate that savings from reduced morbidity may completely or substantially offset costs of treatment and that intervention is highly cost-effective (7,8).

Published major trials of lipid lowering include patients both with and without diabetes. The recently published Heart Protection Study (HPS) found that statin treatment reduced mean total serum cholesterol by 1.7 mmol/l at 1 year. Statin use achieved relative risk reductions in MI of 27% (33 to 21%) and stroke of 25% (34 to 15%) (3). Several economic analyses have been conducted of the effect of lipid lowering in patients with diabetes (9,10), but their assumptions and findings are diverse.

Methods

There are a number of steps involved in evaluating a policy to influence patient uptake of health care (Fig. 1). Political, social, and organizational factors may also be important when research findings from different contexts are being applied locally. The technical data are used to address efficiency using a simple mathematical formula (Fig. 2). The formula links treatment and implementation through a surrogate outcome—in this instance, average reductions in blood pressure and lipid levels at 1 year (treatment trials: Δp; implementation trial: Δp′). Occasionally, the value of changed behavior is an instant measurable benefit, such as a life saved when an accident is prevented. Often behavioral change is targeted at the management of chronic diseases where the benefits of better care only become apparent over time. Implementation trials in these areas do not aim to replicate treatment trials in terms of numbers of patients and duration of follow-up, since this would normally be unethical and certainly inefficient. Consequently, implementation trials need to choose a surrogate outcome also found in the treatment trials. If part of the change in the surrogate outcome seen in treatment trials is achieved in an implementation study using the same treatment, then under certain assumptions, implementation will reasonably achieve a proportion of the long-term benefit.

Thus, the value of a policy of introducing specialist nurse–led clinics is determined by the cost-effectiveness of treatment to improve blood pressure and lipid levels and a loading factor (L_CE) de-
Policy cost-effectiveness

\[ \Delta CE_p = \Delta A \cdot N \cdot \Delta C_i + \Delta B \cdot N \cdot \Delta \delta_i \]

Where:

- \( N \) is the number of patients covered by the policy
- \( \Delta CE_i \) is the treatment cost-effectiveness
- \( \Delta \delta_i \) is the change in care divided by the net health gain
- \( \Delta A \) is the net cost divided by the reduction in blood pressure or lipids achieved

*If behavioral change is permanent then \( \Delta \delta_i \) is a one-off cost. If re-implementation is needed periodically to maintain change then a series of interventions are costed over time.

Policy model

- Net policy cost: \( \Delta C = N \cdot \Delta C_i + \Delta \delta_i \cdot N. \Delta \delta_i \)
- Net policy benefit: \( \Delta B = \frac{\Delta \delta_i}{N. \Delta \delta_i} \cdot N. \Delta \delta_i \)
- Policy cost-effectiveness: \( \Delta CE_p = \frac{\Delta A \cdot N. \Delta \delta_i}{\Delta \delta_i} \cdot N. \Delta \delta_i \)

Modeling economic estimates

To provide consistent estimates of lifetime treatment costs and benefits for blood pressure and lipid lowering, a simple lifetime Markov model was constructed and evaluated (Fig. 3). A Markov model begins with a cohort of healthy diabetic patients and follows them over time. Each year, patients may die or experience a nonfatal MI or stroke. The model moves forward in annual steps until the cohort of patients are dead, and their cumulative experience is used to calculate average life-expectancy, quality-adjusted survival, and health care costs. The model was evaluated with and without drugs that lower the likelihood of disease. The difference between model estimates was used to calculate net costs and survival gains from treatments.

Quality-adjusted survival was estimated by applying quality-of-life weights to “alive” states: healthy = 1, post-MI = 0.88, and post-stroke = 0.5, following previously published values (8). Estimates were produced with future costs and benefits discounted at 0, 3, and 5% per annum reflecting common conventions.

The model applies Framingham risk equations each year to patients in the healthy state to calculate the risk of sul-
A commonly reported cost-effectiveness threshold for U.S. health care is $50,000/QALY. The likelihood that a policy comes (from the SPLINT trial) were sampled from published ranges (19). The longer-term distributions for blood pressure and lipid lowering were taken from the UKPDS (1). National mortality statistics for England and Wales (15) were adjusted for age and sex-adjusted likelihood of dying each year for patients who have had a stroke or MI. Adjusted by age and sex, risk for cardiovascular death was used to calculate the risk of death each year. The treatment effect after stroke and MI were drawn as relative reductions in cardiovascular end points.

<table>
<thead>
<tr>
<th>Year</th>
<th>Male</th>
<th>Female</th>
<th>Both</th>
<th>Male</th>
<th>Female</th>
<th>Both</th>
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<td>2000</td>
<td>1,490</td>
<td>1,620</td>
<td>1,555</td>
<td>1,260</td>
<td>1,340</td>
<td>1,300</td>
</tr>
<tr>
<td>2005</td>
<td>1,570</td>
<td>1,690</td>
<td>1,630</td>
<td>1,720</td>
<td>1,820</td>
<td>1,770</td>
</tr>
<tr>
<td>2010</td>
<td>1,630</td>
<td>1,750</td>
<td>1,690</td>
<td>1,800</td>
<td>1,920</td>
<td>1,860</td>
</tr>
<tr>
<td>2015</td>
<td>1,690</td>
<td>1,810</td>
<td>1,770</td>
<td>1,880</td>
<td>2,000</td>
<td>1,940</td>
</tr>
<tr>
<td>2020</td>
<td>1,750</td>
<td>1,870</td>
<td>1,810</td>
<td>1,980</td>
<td>2,100</td>
<td>1,990</td>
</tr>
</tbody>
</table>

Table 1—The cost-effectiveness of blood pressure and lipid-lowering treatment in patients with diabetes.
Economic analysis of the SPLINT trial

Table 2—Cost-effectiveness of a policy of introducing specialist nurse–led clinics to improve the care of hospital-managed patients with diabetes

<table>
<thead>
<tr>
<th></th>
<th>Blood pressure control</th>
<th>Lipid control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist clinic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cost*</td>
<td>$306,400</td>
<td>$306,400</td>
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<tr>
<td>Caseload/year</td>
<td>506/year</td>
<td>345/year</td>
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<tr>
<td>Cost/patient</td>
<td>$605/patient</td>
<td>$888/patient</td>
</tr>
<tr>
<td>Change in surrogate outcome</td>
<td>1.2 mmHg</td>
<td>0.28 mmol/l</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost/QALY gained</td>
<td>−$1,400/QALY</td>
<td>$8,230/QALY</td>
</tr>
<tr>
<td>QALYs gained</td>
<td>0.53/patient</td>
<td>0.46/patient</td>
</tr>
<tr>
<td>Change in surrogate outcome</td>
<td>5.7 mmHg</td>
<td>1.7 mmol/l</td>
</tr>
<tr>
<td>Life expectancy</td>
<td>16.1 years</td>
<td>16.1 years</td>
</tr>
<tr>
<td>ΔCEp,BP</td>
<td>$0.53 \times 12 - 1,400</td>
<td>$0.46 \times 0.28 + 8,230</td>
</tr>
<tr>
<td>ΔCEp,lipid</td>
<td>$5.7 \times 605 - 1,400</td>
<td>$17 \times 888</td>
</tr>
<tr>
<td>Policy analysis*</td>
<td>$5,420/QALY</td>
<td>$19,950/QALY</td>
</tr>
</tbody>
</table>

*Clinics were run by a specialist nurse: salary, on-costs, clinic rental, and administration were costed and converted to U.S. prices: U.K. £0.65 = 1 US $ (see text). Clinic invitations are assumed to be repeated annually, future costs were discounted at 5% per annum. †Estimation using formula (Fig. 1), policy cost per life-year gained, and 95% CI shown in parentheses. Future costs and benefits were discounted at 5% per annum.

RESULTS

Cost-effectiveness of specialist nurse–led clinics

Clinics were staffed by experienced specialist nurses. One 0.5 full-time equivalent nurse was used for each intervention, to which the cost of clerical support and clinic time was added. With on-costs (National Insurance and Superannuation) and a 40% institutional overhead, each nurse cost $23,075 per year, half time. (Costs have been converted from £ sterling to U.S. dollar, applying a World Health Organization general goods and services purchasing power parity: 1 US$ = £0.65.) The institutional overhead covered administrative support and some clerical support costs; some clerical work contacting patients and arranging repeat appointments was conducted by the specialist nurses. The clinic room rental cost was estimated at $3,845 per clinic per annum (16). Thus, the total cost of each clinic was estimated at $26,920 per annum. It was conservatively assumed that these clinics would have to be repeated annually over the remaining lifetime of patients to maintain changes in blood pressure and lipid control. In an economic analysis, future benefits and costs are valued progressively less the further they occur in the future: commonly they are discounted at a rate of 5% per annum.

Discounted lifetime net treatment costs are measured at 0, 3, and 5%: both interventions are cost-effective at each of these rates. Findings were not particularly sensitive to the discount rate and reflected the distribution of both costs and benefits over time.

Policy model findings

Data from the treatment trials and SPLINT were combined to evaluate a policy of introducing specialist nurse–led clinics (Table 2). Introducing a specialist nurse–led clinic introduced loadings of $5,420/QALY and $11,720/QALY to blood pressure– and lipid-lowering treatment cost-effectiveness, respectively. Overall, the clinics remained good value for money, with cost-effectiveness estimated at $4,020/QALY and $19,950/QALY, respectively. The estimated cost-effectiveness of the combined clinic was $9,050/QALY. If the discount rate for future costs and benefits is lowered from 5 to 3% and 0%, the cost-effectiveness of the combined clinic reduces to $7,750/QALY and $5,420/QALY, respectively.

Uncertainty surrounding estimates is shown graphically in cost-effectiveness acceptability curves (Fig. 4). The effect of implementing the hypertension and lipid clinics is to place a loading or addition on treatment cost-effectiveness. For the hypertension clinic, this loading is less precisely known, reflecting the uncertainty in the SPLINT trial findings. Thus, although lipid-lowering treatment is less cost-effective than blood pressure–lowering treatment, the added value of the nurse clinic was estimated precisely in the SPLINT trial, leading to a steeply rising slope. For blood pressure lowering, the effect of the nurse clinic was measured imprecisely, leading to a much more shallow curve. Applying the threshold of $50,000/QALY, the likelihood that the blood pressure–lowering clinic is cost-

is more cost-effective than this threshold is reported and shown graphically.
The benefits of improved blood pressure and lipid control are such that investment in specialist nurse clinics appears good value for money. If specialist nurse clinics tackled both blood pressure and cholesterol control, as would be anticipated in clinical practice, then they might be cheaper to implement, although the success of the clinics may rest in part on their having a single objective. Further research with specialist nurse-led clinics seeking to improve the cardiovascular risk profile of hospital care-based diabetic patients through improved diet, blood pressure, lipids, and glycemic control would inform this issue.

Implications for policymakers
This study demonstrates that the provision of specialist nurse-led clinics are likely to be cost-effective as adjunctive care lowering blood pressure and cholesterol in hospital-based management of diabetes. As such, these clinics appear an important step in improving the quality of care of patients with diabetes. The impact of the specialist nurse clinic is similar to other “resourced” behavioral change studies targeted at clinicians and patients (22). Concurrently with the SPLINT trial, we evaluated the use of specialist nurses to provide educational outreach and support to practice nurses in primary care. This trial (educational outreach in diabetics to encourage practice nurses to use primary care hypertension and hyperlipidemia guidelines [EDEN]) found no impact on blood pressure or lipid levels in patients (23). Two of the reasons identified were lack of new resources for practice nurses to take on the additional work, and poor communication between practice nurses (who saw patients) and general practitioners (who had to approve medication changes). Transparently, worthwhile change is more likely to occur when new resources are provided (in SPLINT, this was the provision of new specialist nurses and additional clinics), and the new activity is supported by and integrated with routine care.

The findings of the implementation studies may have to be assumed transferable not just to different localities but to different treatments and diseases. The costs of outreach may be anticipated to vary with economies of scale and by locality and country. Implementation studies that report units of component resources, disaggregated from their unit costs, will help users to derive a valid local cost of implementation by applying local utilization patterns and prices.
Economic analysis of the SPLINT trial

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References