

# 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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**Abbreviations:** HPS, Heart Protection Study; MI, myocardial infarction; QALY, quality-adjusted life-year; SPLINT, Specialist Nurse-Led Clinics to Improve Control of Hypertension and Hyperlipidemia in Diabetes; UKPDS, U.K. Prospective Diabetes Study.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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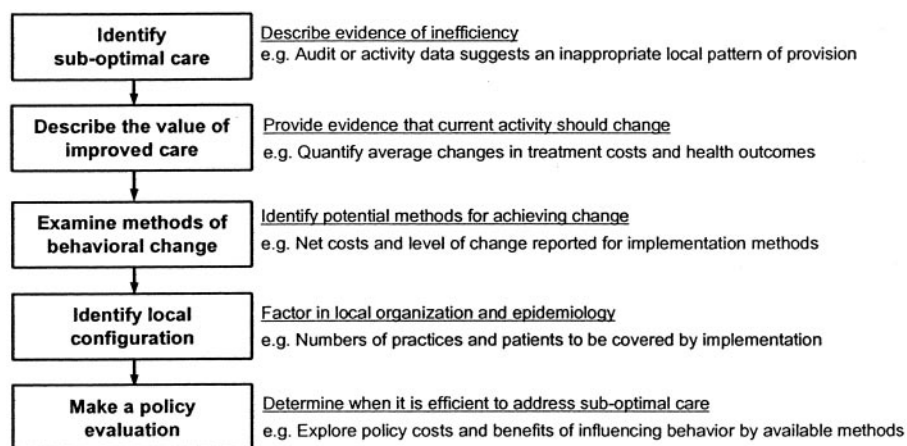
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Although there is abundant evidence that patients with diabetes benefit from interventions to lower cholesterol and blood pressure (1–3), there is less evidence to demonstrate how these findings can be translated into routine clinical practice. Influencing 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



**Figure 1**—Assessing the value of a policy of behavioral change.

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 ( $\geq 140/80$  mmHg), raised total cholesterol ( $\geq 5.0$  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  $\geq 2$  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  $\geq 160/\geq 90$  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 sav-

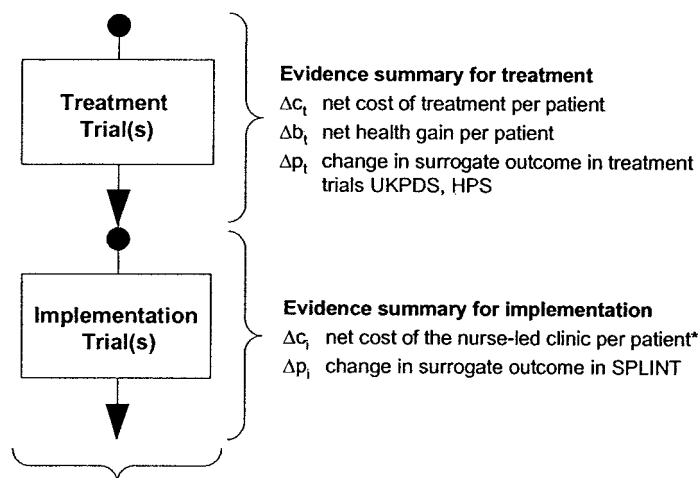
ings from reduced morbidity may completely or substantially offset costs of treatment and that intervention is highly cost-effective (7,8).

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:  $\Delta p_i$ ; implementation trial:  $\Delta p_i$ ). 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 Model**

Net policy cost:  $\Delta C \approx N \cdot \Delta c_t + \frac{\Delta p_i}{\Delta p_t} \cdot N \cdot \Delta c_i$

Net policy benefit:  $\Delta B \approx \frac{\Delta p_i}{\Delta p_t} \cdot N \cdot \Delta b_t$

Policy cost-effectiveness:  $\Delta CE_p = \frac{\Delta C_p}{\Delta B_p} \approx \frac{N \cdot \Delta c_t + \frac{\Delta p_i}{\Delta p_t} \cdot N \cdot \Delta c_i}{\frac{\Delta p_i}{\Delta p_t} \cdot N \cdot \Delta b_t}$

$\Delta CE_p \approx \frac{\Delta p_i}{\Delta b_t} \cdot \Delta CE_t + \Delta CE_i \approx L_{CE} + \Delta CE_i$

Where:

N is the number of patients covered by the policy

$\Delta CE_t$  is the treatment cost-effectiveness

( $\Delta c_t / \Delta b_t$ : the change in cost of care divided by the net health gain).

$\Delta CE_i$  is cost-effectiveness of implementation

( $\Delta c_i / \Delta p_i$ : the net cost divided by the reduction in blood pressure or lipids achieved).

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

**Figure 2**—Policy assessment of the value of introducing a call center to improve glycemic control in patients with type 2 diabetes.

terminated by the cost and impact of the call center.

Policy cost-effectiveness:  $\Delta CE_p =$

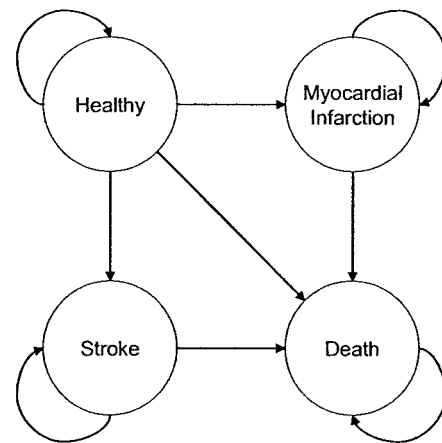
$$\frac{\Delta p_i}{\Delta b_t} \cdot \frac{\Delta c_t}{\Delta p_t} + \Delta CE_t = L_{CE} + \Delta CE_i \tag{1}$$

where  $\Delta CE_t$  is the treatment cost-effectiveness of improved blood pressure or lipid control modeled from the UKPDS and HPS trials. The loading term is composed of two ratios: the nurse-led clinic net cost per patient ( $\Delta c_i$ ) per change in surrogate outcome ( $\Delta p_i$ ) and the (inverted) treatment net health gain ( $\Delta b_t$ ) per change in surrogate outcome ( $\Delta p_t$ ).

If an implementation method is cost-

less ( $\Delta c_i = 0$ ), then policy and treatment cost-effectiveness are the same. If the same level of change is achieved in implementation and treatment trials, then (because  $\Delta p_i / \Delta p_t = 1$ ) the policy cost-effectiveness becomes  $\Delta c_t + \Delta c_i$  divided by  $\Delta b_t$ , a simple cost loading on treatment cost-effectiveness. Otherwise, there is a weighting on the health benefit achieved ( $\Delta b_t$ ) determined by proportion of change in the surrogate outcome ( $\Delta p_i / \Delta p_t$ ).

The policy model involves a number of assumptions, for example, that patient populations and treatment are similar in implementation and treatment trials. Additionally, the persistence of behavioral change after 1 year has to be explored and modeled appropriately. If the implementation method needs to be reapplied peri-



**Figure 3**—Transition state diagram for a model of cardiovascular disease.

odically to maintain change, then a series of interventions need to be costed over time. This approach allows the discounting of future costs to be applied consistently for treatment and implementation. These issues are illustrated through the worked example of the specialist nurse-led clinic.

**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 suf-

Table 1—Cost-effectiveness of blood pressure- and lipid-lowering treatment in patients with diabetes

	Tight blood pressure control			Lipid control		
	Male	Female	Both	Male	Female	Both
Net cost ( $r = 5\%$ )*	-606	-888	-747	3,590	3,980	3,780
Life expectancy†	14.5	16.9	15.7	14.5	16.9	15.7
Years of life gained‡	0.78 (0.18–1.46)	0.99 (0.34–1.70)	0.88 (0.26–1.58)	0.78 (0.62–0.95)	0.89 (0.70–1.07)	0.84 (0.66–1.01)
Cost/life-year gained	-1,690	-2,080	-1,910	9,940	10,200	10,100
( $r = 5\%$ )§	(-19,200 to 16,300)	(-18,800 to 14,100)	(-18,900 to 15,100)	(-2,000 to 22,900)	(-2,610 to 24,800)	(-2,540 to 23,600)
Cost/QALY ( $r = 0\%$ )	-1,620	-1,750	-1,690	5,660	5,550	5,600
Cost/QALY ( $r = 3\%$ )	-1,490	-1,630	-1,570	7,200	7,040	7,110
Cost/QALY ( $r = 5\%$ )	-1,260	-1,520	-1,400	8,380	8,100	8,230
	(-13,400 to 10,000)	(-13,400 to 8,200)	(-13,400 to 8,590)	(-1,720 to 18,800)	(-2,520 to 18,900)	(-2,280 to 18,900)

\*Costs shown are in U.S. dollars (originally in U.K. pounds sterling and 2003 prices and converted using U.K. £0.65 = \$1 U.S.). The cost of additional hypertensive therapy was estimated to be \$154/year and, for statin therapy, \$571/year. The cost of drug treatment was assumed to continue until death. Other costs included acute and chronic management after MI and stroke. Future costs were discounted at 5% per annum. Costs are shown to three significant figures. †Model prediction of life expectancy for untreated patients from age 60 years. This compares with population average estimates for men and women of 19 and 23 years. Subjects modeled have diabetes and are nonsmokers of 60 years of age with total cholesterol (TDL)/LDL 5.8/1.3 mmol/L, BP 160/80 mmHg. Of the subjects, 14% were modeled as having left ventricular hypertrophy (LVH) as a proxy for existing cardiovascular disease. ‡Model prediction of life-years (LY) gained and 95% CI shown in parentheses. Modeling details are found in RESEARCH DESIGN AND METHODS. §Cost per life-year gained and 95% CI shown in parentheses; future costs and benefits discounted at 5% per annum. Cost-effectiveness ratios are shown to three significant figures. ||Cost per QALY gained and 95% CI shown in parentheses; future costs and benefits discounted at 0, 3, and 5% per annum. Cost-effectiveness ratios are shown to three significant figures.

fering a stroke or MI according to their age, sex, and cardiovascular risk factors (11–13). Framingham 30-year mortality data were used to calculate the risk of death each year for patients who have had a stroke or MI, adjusted by age and sex (14). National mortality statistics for England and Wales (15) were adjusted for diabetes (14) and provided the age- and sex-adjusted likelihood of dying each year from noncardiovascular causes.

To evaluate the effects of drugs, the predicted incidence of stroke and MI was reduced applying reported risk ratios and their CIs modeled as log-normal distributions. The risk ratio for blood pressure lowering was taken from the UKPDS (1) and for lipid lowering from the HPS (3). These two trials were chosen as most closely relevant to the SPLINT trial population. We did not attempt meta-analyses of trials because of the need to summarize the surrogate end point (not consistently reported across trials) as well as relative reductions in cardiovascular end points.

Costs of drugs, and acute and chronic treatment after stroke and MI were drawn from published sources (16–18). These costs were conservative, not reflecting broader costs of care borne by society or loss of earnings. Gamma distributions were fitted to treatment costs reflecting published ranges (19). The longer-term benefits and costs of treatment are unknown and have not been varied. The assumption is that treatment continues having the same relative benefit and costs year-on-year.

Uncertainty surrounding estimates from the treatment and policy models was explored using cost-effectiveness acceptability curves, generated from Monte Carlo analyses making 10,000 evaluations of each model. In the treatment model, parameters were sampled randomly from distributions for costs of acute and chronic stroke and MI, and risk ratios for blood pressure and lipid lowering. In the policy model, modeled distributions for net costs and benefits of treatment and changes in surrogate outcomes (from the SPLINT trial) were sampled randomly.

A commonly reported cost-effectiveness threshold for U.S. health care is \$50,000/quality-adjusted life-year (QALY) (20): the likelihood that a policy of introducing specialist nurse-led clinics

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

	Blood pressure control	Lipid control
Specialist clinic		
Total cost*	\$306,400	\$306,400
Caseload/year	506/year	345/year
Cost/patient	\$605/patient	\$888/patient
Change in surrogate outcome	1.2 mmHg	0.28 mmol/l
Treatment		
Cost/QALY gained	−\$1,400/QALY	\$8,230/QALY
QALYs gained	0.53/patient	0.46/patient
Change in surrogate outcome	5.7 mmHg	1.7 mmol/l
Life expectancy	16.1 years	16.1 years
Policy analysis†	$\Delta CE_{p,BP} = \frac{5.7 \times 605}{0.53 \times 1.2} - 1,400$ $= 5,420 - 1,400$ $= \text{£}4,020/\text{QALY}$	$\Delta CE_{p,lipid} = \frac{1.7 \times 888}{0.46 \times 0.28} + 8,230$ $= 11,720 + 8,230$ $= \text{£}19,950/\text{QALY}$

\*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.

is more cost-effective than this threshold is reported and shown graphically.

## 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. If a cohort of patients lives on average 16 years, the cost of the clinic in the first year is \$26,920, in the second year the cost is \$26,920/1.05 or \$25,640, and in the 16th year the cost is \$26,920/(1.05)<sup>16</sup> or \$12,330. Hence, the discounted future cost of providing the clinic for the cohort was estimated at just over \$300,000 (Table 1). The discounted cost per patient (cost of the clinic divided by the patient caseload) was \$888 for the lipid clinic and \$605 for the blood pressure clinic.

### Cost-effectiveness of lipid- and blood pressure-lowering treatment

The modeled patient population was at high risk for cardiovascular disease, with a predicted 10-year risk of cardiovascular disease of ~30%.

Estimated lifetime cost-effectiveness values for treatments are shown in Table 2. Blood pressure lowering predicted net cost savings and survival gains; patients were predicted to live an average of 11 months longer (95% CI 3–19 months). Discounted lifetime net treatment costs for diabetic patients aged 60 years receiving antihypertensive therapy were estimated to be −\$750 (a saving), although the 95% CI stretched from −\$3,580 to \$2,600. The model predicted the likeli-

hood that antihypertensive therapy was cost neutral or saving in this patient group to be 62%.

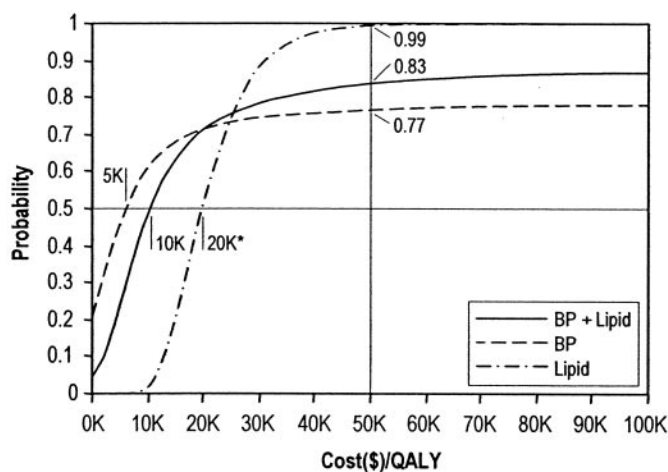
Lipid lowering was predicted to extend life average by 10 months (95% CI 8–12). Discounted lifetime net treatment costs for diabetic patients aged 60 years receiving lipid-lowering therapy were estimated to be \$3,780 (−\$1,310 to \$8,880).

The cost-effectiveness of blood pressure- and lipid-lowering treatment is reported as the cost per QALY gained and shown with future costs and benefits discounted 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 \$7,560/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-



**Figure 4**—Cost-effectiveness acceptability curve for specialist nurse-led clinics. BP, blood pressure. \*Median values ( $P = 0.5$ ) shown may vary slightly from tabulated mean values.

effective is 77%, lipid clinic 99%, and combined clinic 83%. The sampled median cost-effectiveness values shown in the figure are similar, but not identical, to the tabulated precise mean values, which are calculated differently.

**CONCLUSIONS**— Health policymakers are aware of apparent inefficiencies in their health care systems due to suboptimal uptake of health care. Examples include overuse of new but borderline cost-effective health technologies and underuse of established cheap and effective but unfashionable treatments. Whether a policy should be enacted to change patient behavior depends on an interplay of factors. Policy cost-effectiveness is most likely to be attractive in those treatments that are highly cost-effective (as is the case in this article) and most likely to be unattractive when cost-effectiveness of treatment is borderline at the outset. All things being equal, cheaper implementation methods achieving greater levels of change or in pursuit of larger health gains all reduce the loading. A cost-effective treatment may not be worth pursuing as a policy goal when the implementation loading factor is large.

### Using the framework

The virtue of the policy model is it allows the value of behavioral change methods to be determined using efficient study designs: implementation findings can be combined with the long-term effect of improved treatment for chronic diseases. However, important assumptions have to be made when applying the model to a local setting.

First, it is assumed that the emerging benefits of treatment over time in the implementation trials and treatment trials are linearly proportionate (through the ratio  $\Delta p_i/\Delta p_t$ ). Second, it must be assumed that implementation and treatment cohorts use similar profiles of treatment with similar costs. The persistence of behavioral change and the need for periodic reimplementations needs careful analysis: our analysis used the conservative cost assumption that the specialist nurse clinic will need to be re-used fully by patients on an annual basis. An even more conservative scenario would be that patients fully reutilized the clinic, but it became progressively less effective at achieving change: this seems unlikely. A more optimistic scenario would be that after the first year, patients would need less clinic time. In support of our assumption, an evaluation of a computer-based clinical decision support system to prevent venous thromboembolism demonstrated the need for continuing implementation of the system to achieve continuing behavioral change (21).

If published estimates of treatment cost-effectiveness are used, then the similarity between local and trial-enrolled patients needs to be explored. However, our analysis provided bespoke treatment cost-effectiveness estimates for the Salford hospital care population.

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 local-

ity 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.

### 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 diabetes 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 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.

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**References**

1. UK Prospective Diabetes Study Group: Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. *BMJ* 317:703–713, 1998
2. UK Prospective Diabetes Study Group: Efficacy of atenolol and captopril in reducing risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 39. *BMJ* 317:713–720, 1998
3. Heart Protection Study Collaborative Group: MRC/BHF Heart Protection Study of antioxidant vitamin supplementation in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet* 360:23–33, 2002
4. Mason J, Freemantle N, Nazareth I, Eccles M, Haines A, Drummond M: When is it cost-effective to change the behaviour of health professionals? *J Am Med Assoc* 286: 2988–2992, 2001
5. New JP, Mason JM, Freemantle N, Teasdale S, Wong L, Burns JA, Gibson JM: Specialist nurse-led intervention to treat and control hypertension and hyperlipidaemia in diabetes (SPLINT): a randomised controlled trial. *Diabetes Care* 26: 2250–2255, 2003
6. New JP, Hollis S, Campbell F, McDowell D, Burns E, Dornan TL, Young RJ: Measuring clinical performance and outcomes from diabetes information systems: an observational study. *Diabetologia* 43:836–843, 2000
7. UK Prospective Diabetes Study Group: Cost effectiveness analysis of improved blood pressure control in hypertensive patients with type 2 diabetes: UKPDS 40. *BMJ* 317:720–726, 1998
8. CDC Diabetes Cost-Effectiveness Group: Cost-effectiveness of intensive glycaemic control, intensified hypertension control, and serum cholesterol level reduction for type 2 diabetes. *JAMA* 287:2542–2551, 2002
9. Grover SA, Coupal L, Zowall H, Dorais M: Cost-effectiveness of treating hyperlipidemia in the presence of diabetes: who should be treated? *Circulation* 102:722–727, 2000
10. CDC Diabetes Cost-Effectiveness Group: Cost-effectiveness of intensive glycaemic control, intensified hypertension control, and serum cholesterol level reduction for type 2 diabetes. *JAMA* 287:2542–2551, 2002
11. Wilson PWF, D'Agostino RBD, Levy D, Belanger AM, Silbershaltz H, Kannel WB: Prediction of coronary heart disease using risk factor categories. *Circulation* 97: 1837–1847, 1998
12. Wolf PA, D'Agostino RB, Belanger AJ, Kannel WB: Probability of stroke: a risk profile from the Framingham Study. *Stroke* 22:312–318, 1991
13. Anderson KM, Odell PM, Wilson PW, Kannel WB: Cardiovascular disease risk profiles. *Am Heart J* 121:293–298, 1991
14. Kannel WB, Wolf PA, Garrison RJ (Eds.): Survival following initial cardiovascular events: 30 year follow-up. In *The Framingham Study: An Epidemiological Investigation of Cardiovascular Disease*. Springfield, IL, U.S. Department of Commerce, National Technical Information Service, 1988
15. Office for National Statistics: *Mortality Statistics Cause Review of the Registrar General on Deaths by Cause, Sex and Age, in England & Wales 2000*. London, National Statistics, Series DH2, no. 27, 2001
16. Netten A, Curtis L: *Unit Costs of Health and Social Care 2002*. Personal Social Services Research Unit, University of Kent at Canterbury. <http://www.ukc.ac.uk/PSSRU>
17. Department of Health: *Prescription Cost Analysis: England 2002*. <http://www.doh.gov.uk/stats/pca2002.htm>
18. Department of Health: *Reference Costs: England 2001*. <http://www.doh.gov.uk/nhsexec/refcosts2001.htm>
19. Briggs AH, Goeree R, Blackhouse G, O'Brien BJ: Probabilistic analysis of cost-effectiveness models: choosing between treatment strategies for gastroesophageal reflux disease. *Medical Decision Making* 22:290–308, 2002
20. Owens DK: Interpretation of cost-effectiveness analysis. *J Gen Intern Med* 13: 716–717, 1998
21. Durieux P, Nizard R, Ravaud P, Mounier N, Lepage E: A clinical decision support system for prevention of venous thromboembolism: effect on physician behavior. *JAMA* 283:2816–2821, 2000
22. Hulscher MEJL, Wensing M, van der Weijden T, Grol R: Interventions to implement prevention in primary care (Cochrane Review). In *The Cochrane Library*. Issue 3. Oxford, U.K., Update Software, 2003
23. New JP, Mason JM, Freemantle N, Teasdale S, Wong L, Bruce NJ, Burns JA, Gibson JM: Educational outreach in diabetes to encourage practice nurses to use primary care hypertension and hyperlipidaemia guidelines (EDEN): a randomised controlled trial. *Diabet Med* 21:599–603, 2004