

Management of diabetes

A clinical and resource impact assessment

May 2010

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Executive summary

The Scottish Intercollegiate Guidelines Network (SIGN) is publishing this report as part of its commitment to support the implementation of its clinical guidelines. The objective is to provide business planners, organisational development managers and clinical leads with estimates of the resources required and associated costs to implement key recommendations in SIGN Guideline 116 'Management of Diabetes' (the 'Guideline'). This report should be read in conjunction with the Guideline.

The recommendations in the Guideline were prioritised according to their likely effect on both patient outcomes and NHSScotland. Those identified as potentially having a major benefit for patients and a material impact on the level or form of service provision are replicated below. The numbers refer to the sections in the Guideline.

Education

Recommendations 3.2.1, 3.2.2 and 3.2.3 refer to structured education programmes in adults and children with types 1 and 2 diabetes:

- Adults with type 1 diabetes experiencing problems with hypoglycaemia or who fail to achieve glycaemic targets should have access to structured education programmes based upon adult learning theories. Grade A
- Children and adolescents [with type 1 diabetes] should have access to programmes of structured education which have a basis in enhancing problem solving skills. Grade B
- Adults with type 2 diabetes should have access to structured education programmes based upon adult learning theories. Grade A

Section 5.3.2 contains a related best practice point:

- Pump therapy should be available from a local multidisciplinary pump clinic for patients who have undertaken structured education.

Lifestyle

Recommendation in section 3.6:

- Obese adults with type 2 diabetes should be offered individualised interventions to encourage weight loss (including lifestyle, pharmacological or surgical interventions) in order to improve metabolic control. Grade A

Note: no estimated resources or costs have been provided for this recommendation because NHS Quality Improvement Scotland is reviewing the cost-effectiveness of weight management programmes and bariatric surgery for adults with obesity. Two Evidence Notes on these topics will be published in June 2010.

Psychological intervention

Recommendation in section 4.3.3:

- Children and adults with type 1 and type 2 diabetes should be offered psychological interventions (including motivational interviewing, goal setting, skills and CBT [cognitive behavioural therapy]) to improve glycaemic control in the short and medium term. Grade A

Management of diabetes

Recommendations on insulin regimens in section 5.3.2:

- An intensified treatment regimen for adults with type 1 diabetes should include either human or rapid-acting insulin analogues. Grade B
- Children and adolescents [with type 1 diabetes] may use either insulin analogues (rapid-acting and basal), regular human insulin and NPH [Neutral Protamine Hagedorn, a synthetic mixture of insulin and protamine] preparations or an appropriate combination of these. Grade B
- Soluble human insulin or rapid-acting insulin analogues can be used when intensifying insulin regimens to improve or maintain glycaemic control [with type 2 diabetes]. Grade A

Section 5.3 of the Guideline also contains recommendations on continuous subcutaneous insulin infusion (CSII) therapy:

- CSII therapy is associated with modest improvements in glycaemic control and should be considered for patients unable to achieve their glycaemic targets. Grade A
- CSII therapy should be considered in patients who experience recurring episodes of severe hypoglycaemia. Grade B

Gestational diabetes

Recommendations in section 7.8:

- A suitable programme to detect and treat gestational diabetes should be offered to all women in pregnancy. Grade A
- Pregnant women with GDM (gestational diabetes mellitus) should be offered dietary advice and blood glucose monitoring and be treated with glucose-lowering therapy depending on target values for fasting and postprandial targets. Grade A
- Metformin or glibenclamide may be considered as initial pharmacological, glucose-lowering treatment in women with gestational diabetes. Grade B

Statins

Recommendation in section 8.4.7:

- Intensive lipid-lowering therapy with atorvastatin 80 mg should be considered for patients with diabetes and acute coronary syndromes, objective evidence of coronary heart disease or following coronary procedures. Grade A

Stents

Recommendation in section 8.6.4:

- In patients with diabetes, drug-eluting stents (DES) are recommended as opposed to bare metal stents (BMS) in stable coronary heart disease or non-ST elevation myocardial infarction to reduce in-stent re-stenosis and target lesion revascularisation. Grade A

Additional resources required

The major additional resource required is staff time. Four interventions require material additional staff support:

- more structured education
- psychological support
- insulin pumps; and
- the detection and management of pregnant women with gestational diabetes.

The requisite hours for the first and subsequent years are estimated in Table 1-1. The first year requires the greatest resources as staff are trained to undertake new roles in providing structured education and deliver mild psychological interventions.

Table 1-1 Additional staff hours required by recommendation

	Additional staff hours	
	Year 1	Year 2 onwards
Structured education	21,499	19,038
Psychological support	10,281	8,097
Insulin pumps	8,273	8,273
Gestational diabetes	7,349	7,349
Total	47,402	42,758

Over 75% of the additional hours are assumed to be provided by specialist diabetes nurses. These hours are equivalent to about 23 more full-time nurses. However, the number of nursing staff impacted will be considerably higher. The analyses assume NHS boards will train existing nurses to deliver the educational programmes and the psychological therapies. The objectives for such staff would thus be altered so that these activities can be conducted within the nurses' working week.

Additional dietician support to deliver components of the structured education courses will also be required. The balance of staff needed will be a range of allied health professionals to deliver the psychological therapies, psychologists to mentor these staff and about 430 hours of additional consultant time associated with increasing the use of pump therapies.

No additional staff input is required for insulin therapies or stents. Additional outpatient appointments for an estimated 1,675 patients could also be needed in the first year to titrate people with diabetes and acute coronary syndromes to more efficacious statins.

Additional costs required

Annual operating costs excluding value added tax (VAT) and depreciation

Table 1-2 provides an estimate of the annual operating costs for year 1 and in subsequent years for each recommendation. These are estimated at £2.5 million in the first year, rising to about £3.8 million by year 5. The annual cost increases reflect the higher number of insulin pumps in use each year. The NHS incurs additional annual operating costs of about £950 for each pump user, compared with multiple daily injections. The operating costs thus increase over years 2 to 5, in line with the increasing investment in pumps.

In the first year, 36% of the costs are associated with providing more structured education and 26% with providing insulin pumps. By year 5, pumps account for over 65% of the annual expenditure.

The recommendation on using a greater proportion of human insulin therapies is anticipated to be cost saving.

Table 1-2 Estimated annual costs and savings (excluding VAT) of implementing key recommendations by guideline

	Additional operating costs		% of total operating costs	
	Year 1 costs	Year 2 onwards	Year 1 costs	Year 2 onwards
Structured education	£904,270	£783,567	36%	21%
Psychological support	£283,484	£174,391	11%	5%
Insulin therapies	-£150,000	-£150,000	-6%	-4%
Insulin pumps	£744,291	£2,522,771 (year 5)	30%	66%
Gestational diabetes	£362,086	£362,086	14%	9%
Lipid-lowering therapies	£281,193	£38,168	11%	1%
Drug-eluting stents	£73,185	£73,185	3%	2%
Total	£2,498,509	£3,804,168	100%	100%

The year 1 costs are higher than subsequent years for:

- structured education and psychological support, reflecting the initial cost to train staff to deliver these interventions; and
- lipid-lowering therapies because in the initial year some patients will attend an outpatient clinic for titration to atorvastatin 80 mg.

These costs exclude depreciation of £0.19 million in year 1, rising to £0.96 million in year 5. This is associated with the capital costs of the insulin pumps. More detailed analyses of the additional resources and costs required to implement these recommendations are presented in this report, with a separate section dedicated to each.

Annual operating costs including VAT

Most NHS boards cannot recover the VAT they pay on VAT-rated goods and services. Such goods encompass drugs and devices including insulin pumps. The estimated annual operating costs including VAT are £2.6 million in year 1, rising to £4.2 million in year 5. These are shown, by recommendation, in Table 1-3.

Table 1-3 Estimated annual costs and savings (including VAT) of implementing key recommendations by guideline

	Additional costs	
	Year 1 costs	Year 2 onwards
Structured education	£904,270	£783,567
Psychological support	£283,484	£174,391
Insulin human analogues	-£150,000	-£176,250
Insulin pumps	£822,100	£2,911,800 (year 5)
Gestational diabetes	£396,778	£396,778
Lipid-lowering therapy	£296,692	£44,848
Drug-eluting stents	£85,992	£85,992
Total	£2,639,316	£4,221,126

Capital costs

The only capital cost item is the purchase of pumps. For each of the first five years the estimated additional annual capital expenditure is £963,500, excluding VAT, rising to £1,132,115 with VAT. The cumulative additional capital expenditure over the five years is estimated at £4,817,500 excluding VAT, rising to £5,660,565 with VAT.

Costing templates

An Excel costing report and associated templates are available on the SIGN website (www.sign.ac.uk) to aid implementation of the recommendations.

These templates are workbooks that contain the assumptions and results for the base case parameters. The workbooks are designed to be flexible and enable users to change the assumptions to reflect local epidemiology, resource use and costs. The figures in one or two of the spreadsheets differ very slightly from the figures reported in this document because of rounding. For example, this report may round 2,004 people to 2,000 and allocate these to boards; the worksheet calculations used the 2,004 figure.

1 Introduction

1.1 Objectives of this report and associated templates

As part of its commitment to support the implementation of its guidelines, SIGN has developed this report with the objective of facilitating more rapid implementation of key recommendations in the Guideline 116 Management of Diabetes; available from url: <http://www.sign.ac.uk/guidelines/fulltext/116/index.html>ⁱ.

It is anticipated that providing resource and cost information to decision makers, primarily in the NHS boards and the Scottish Government Health Directorates (SGHD), will assist them to develop business cases at the local, regional and national level and introduce changes in line with the Guideline. Improving implementation should enhance patient care and enable more equitable patient access throughout Scotland.

The evidence base to support this objective comes mainly from developments in England. Since January 2005, the National Institute for Health and Clinical Excellence (NICE) has provided costing reports and templates providing the cost of implementing 'significant resource impact recommendations'ⁱⁱ in its clinical guidelines and technology appraisals. In October 2005, the Audit Commissionⁱⁱⁱ reported that the absence of an awareness of costs was one of the biggest difficulties in developing plans to implement guidelines. It added that the most useful implementation tool was the provision of robust cost information, noting that boards adopting the tool were more likely to implement a guideline.

For each key recommendation in the Guideline the report presents estimates of:

- the number of individuals in Scotland who may have better health outcomes following its implementation
- the additional resources required to implement the recommendation; and
- the associated costs.

No estimate of the associated clinical benefits has been provided.

The cost and resource assessments are estimates, based on a number of assumptions. They provide an indication of the possible impact of the key recommendations based on assessment of current baseline practice; however local practice may vary from this. An Excel costing template accompanies this report, for use by planners to estimate the local impact of each key recommendation (www.sign.ac.uk).

No cost-effectiveness analyses are presented within this report. Instead, the Guideline included a review of the cost effectiveness of certain clinical procedures, as part of the standard SIGN guideline methodology.

1.2 Management of diabetes guideline process

SIGN guidelines are based on systematic review of the clinical and cost-effectiveness evidence. A detailed description of the SIGN methodology is available at <http://www.sign.ac.uk/methodology/index.html>.

The previous diabetes guideline was published in 2001. This has been updated to incorporate new evidence in the following areas: type 1 diabetes, cardiovascular disease, drug therapy for type 2 diabetes, foot disease, lifestyle, pregnancy, renal disease and retinopathy.

SIGN acknowledges that its recommendations are not resource neutral. Since 2002, it has included a section entitled 'Resource implications of implementing the guideline' in its guidelines. This section is developed in discussion with the Guideline Development Group, considering current resource use across Scotland and identifying those recommendations most likely to have significant resource implications. It does not, however, always express the costs of implementation, primarily because of differing levels of baseline resource use by each NHS board.

The SIGN methodology is set out in 'A Guideline Developer's Handbook' <http://www.sign.ac.uk/guidelines/fulltext/50/index.html>. The Diabetes Guideline followed this methodology. Thus a Development Group was formed, comprising multidisciplinary, nationally-representative members. The members agreed the clinical areas for review and undertook systematic review of the evidence, with support from the SIGN Executive. They developed recommendations that were explicitly linked to the supporting evidence and subject to consultation and peer review before final publication. The recommendations were then reviewed to establish which were most likely to have significant resource implications.

Estimated resource use and costs were informed by the available Scottish epidemiology and cost data and through consultation with independent healthcare professionals, members of the Guideline Development Group and peer review.

1.3 Other initiatives to support implementation

In 2009, SIGN Council supported a shift in emphasis from developing leading evidence-based clinical guidelines to supporting the implementation of existing guidelines and to put them into practice. The related tools supporting the implementation of the Diabetes Guideline will be posted on the SIGN website at <http://www.sign.ac.uk/guidelines/implementation.htm>.

Implementation of this Guideline will also be supported by the Scottish Diabetes Group. This is a national steering group, formed in 2002, to take forward the implementation of the Scottish Diabetes Framework and the subsequent Action Plan. It aims to promote Scotland-wide collaboration, peer support and dissemination of best practice. It also provides expert advice to the SGHD and will be co-ordinating and evaluating many of the key recommendations in the SIGN Diabetes Guideline. Further information is available at <http://www.diabetesinscotland.org.uk/Groups.aspx>.

1.4 Statement of intent

This report is intended to provide an indication of the resources required and costs involved to implement key recommendations within the SIGN Diabetes Guideline. However the baseline practice assumed throughout Scotland will vary between NHS boards, and therefore the resource requirements outlined in this report may not reflect the actual requirements. Differences in epidemiology were identified using the Scottish Diabetes Survey 2009.

The aim is to provide as detailed and comprehensive information as possible, quoting sources and assumptions so that users can adapt the information for their own purposes. The relevant resource use and costs will vary depending on the context and purpose of the decision maker, thus users should adapt the estimated values to suit their needs. The report, of necessity, has had to omit some of the detail underpinning the estimates. If users require further information or advice on using the data, they should contact Ms Lisa Wilson, Health Economist, NHS Quality Improvement Scotland by email at lisa.wilson3@nhs.net. Any comments on this work would also be appreciated and should be sent to the same addressee.

1.5 Document overview

Section 2 discusses the methodology used to estimate the resources required and costs to implement each key recommendation. Section 3 provides estimates of the total additional staff and costs required to deliver these recommendations for each NHS board and at the aggregate Scotland level. The background to each of the seven themes, the relevant patient groups, the additional resources and costs to support their implementation, and associated sensitivity analyses, are provided in sections 4 to 10. Acknowledgements and references are then provided.

2 Methodology

2.1 Scope

This report estimates the additional resources and associated costs required to implement the key recommendations within the Guideline. The estimates are based on assumptions regarding current baseline practice and predicted changes following implementation of each recommendation. The assumptions are informed by available information and consultation with healthcare professionals. In general, current standard practice—rather than best practice—has been used as a baseline.

The SIGN Programme Managers advised which of the draft Guideline recommendations were likely to require a significant change in current practice. The recommendations and their respective grades from the 7 key themes that emerged are now provided. The grade relates to the strength of the supporting evidence.

Education

Recommendations 3.2.1, 3.2.2 and 3.2.3 refer to structured education programmes in adults and children with types 1 and 2 diabetes:

- Adults with type 1 diabetes experiencing problems with hypoglycaemia or who fail to achieve glycaemic targets should have access to structured education programmes. Grade A
- Children and adolescents should have access to programmes of structured education which have a basis in enhancing problem solving skills. Grade B
- Adults with type 2 diabetes should have access to structured education programmes based upon adult learning theories. Grade A

Section 5.3.2 contains a related best practice point:

- Pump therapy should be available from a local multidisciplinary pump clinic for patients who have undertaken structured education.

Lifestyle

The recommendation in section 3.6 relates to weight management in type 2 diabetes:

- Obese adults with type 2 diabetes should be offered individualised interventions to encourage weight loss (including lifestyle, pharmacological or surgical interventions) in order to improve metabolic control. Grade A

Note: no estimated resources or costs have been provided for this recommendation because NHS Quality Improvement Scotland is reviewing the cost-effectiveness of weight management programmes and bariatric surgery for adults with obesity. Two Evidence Notes on these topics will be published in June 2010.

Psychological intervention

Recommendation 4.3.3:

- Children and adults with type 1 and type 2 diabetes should be offered psychological interventions (including motivational interviewing, goal setting, skills and CBT [cognitive behavioural therapy]) to improve glycaemic control in the short and medium term. Grade A

Management of diabetes

Recommendations in section 5.3.2 and 6.10.4 regarding insulin regimens:

- An intensified treatment regimen for adults with type 1 diabetes should include either human or rapid-acting insulin analogues. Grade B
- Children and adolescents may use either insulin analogues (rapid-acting and basal), regular human insulin and NPH [Neutral Protamine Hagedorn, a synthetic mixture of insulin and protamine] preparations or an appropriate combination of these. Grade B
- Soluble human insulin or rapid-acting insulin analogues can be used when intensifying insulin regimens to improve or maintain glycaemic control [for adults with type 2 diabetes] . Grade A

Recommendations in section 5.3.2 regarding continuous subcutaneous insulin infusion (CSII) therapy:

- CSII therapy is associated with modest improvements in glycaemic control and should be considered for patients unable to achieve their glycaemic targets. Grade A
- CSII therapy should be considered in patients who experience recurring episodes of severe hypoglycaemia. Grade B

Gestational diabetes

Recommendations in section 7.8 on gestational diabetes:

- A suitable programme to detect and treat gestational diabetes should be offered to all women in pregnancy. Grade A
- Pregnant women with GDM (gestational diabetes mellitus) should be offered dietary advice and blood glucose monitoring and be treated with glucose-lowering therapy depending on target values for fasting and postprandial targets. Grade A

- Metformin or glibenclamide may be considered as initial pharmacological, glucose-lowering treatment in women with gestational diabetes. Grade B

Statins

Recommendation in section 8.4.7 on lipid-lowering:

- Intensive lipid-lowering therapy with atorvastatin 80 mg should be considered for patients with diabetes and acute coronary syndromes, objective evidence of coronary heart disease or following coronary procedures. Grade A

Stents

Recommendation in section 8.6.4 on drug-eluting stents:

- In patients with diabetes, drug-eluting stents (DES) are recommended as opposed to bare metal stents (BMS) in stable coronary heart disease or non-ST elevation myocardial infarction to reduce in-stent re-stenosis and target lesion revascularisation. Grade A

2.2 Processes

Methodology to estimate resource use and associated costs

To estimate the resources and assess the cost impact of the recommendations, a structured approach was adopted as described in Appendix 1. Once the key recommendations had been identified, draft patient pathways, showing the changes required and associated costs to implement each key recommendation, were developed. Relevant Guideline Development Group members were asked to comment on the assumptions. These statements were then revised and re-issued for further comment and revision. Where possible, published epidemiology from the Scottish Diabetes Survey 2009 (<http://www.diabetesinscotland.org.uk/Publications.aspx?catId=3>) and costs from Information Services Division (ISD) Scotland (<http://www.isdscotland.org>) were used. These were supplemented by other published data as appropriate. Occasionally unpublished sources were used and these are referenced.

While it is recognised that implementing some of these recommendations may impact on other organisations, this report only considers the cost and resource implications for the NHS in Scotland.

Costing principles and approach

Where no published costs were available, a 'bottom-up' approach has been used whereby the unit costs and number of resources required at each stage in the pathway have been identified.

Costs excluding and including VAT at 17.5% are detailed. VAT is payable on drugs and other goods purchased by NHS boards and is usually not recoverable by these organisations.

Overheads have been added to cover employers' national insurance, superannuation contributions, training and indirect expenditure. If appropriate, capital overheads based on the accommodation requirements for NHS staff facilities, reflecting shared use of space and including recreational and changing facilities, have been added.

Capital expenditure is reported in two ways, firstly as a lump sum in the year incurred and secondly as an annual depreciation charge. The latter assumes relevant asset lives, for example five years for an insulin pump.

All costs are expressed in 2009/10 price levels and assumed to remain constant in real terms.

2.3 Limitations

This exercise is subject to several limitations including:

- uncertainty as to what comprises best and current clinical practice. The main methods used to address this uncertainty, were to undertake a literature search for relevant pathways and combine these with information from Guideline members
- some significant cost categories have been excluded, particularly the cost of service re-design and associated training and recruitment costs
- the analyses implicitly assume that staff and facilities can be shared efficiently across an NHS board
- accommodation costs assume an existing site is available for expansion, which is not always the case; and
- the exclusion of information on the Lifestyle weight management recommendations; this will be taken forward by NHS Quality Improvement Scotland through the publication of Evidence Notes in June 2010.

3 Total resource and cost impact of implementing key recommendations

3.1 Background

This section summarises the estimated aggregate resources and costs required to implement the key recommendations. No estimated resources or costs were provided for the interventions to manage obesity. NHS Quality Improvement Scotland is reviewing the cost effectiveness of a number of such interventions and will publish the related evidence later in 2010.

3.2 Aggregate additional resources required

The major additional resource required is staff time. Four interventions require material additional staff support:

- more structured education
- psychological support
- insulin pumps; and
- the detection and management of pregnant women with gestational diabetes.

The requisite hours for the first and subsequent years for each NHS board, for each recommendation, are estimated in Tables 3-1 and 3-2. The first year requires the greatest resources as staff are trained to undertake new roles in providing structured education and deliver mild psychological interventions. The number of whole time equivalents is about 30.

Over 75% of the additional hours are assumed to be provided by specialist diabetes nurses. These hours are equivalent to about 23 more full-time nurses. However, the number of nursing staff impacted will be considerably higher. The analyses assume NHS boards will train existing nurses to deliver the educational programmes and the psychological therapies. The objectives for such staff would thus be altered so that these activities can be conducted within the nurses' working week.

Additional dietician support to deliver components of the structured education courses will also be required. The balance of staff needed will be a range of allied health professionals to deliver the psychological therapies, psychologists to mentor these staff and about 430 hours of additional consultant time associated with increasing the use of pump therapies.

No additional staff input is required for insulin therapies or stents. Additional outpatient appointments for an estimated 1,675 patients could also be needed in the first year to titrate people with diabetes and acute coronary syndromes to more efficacious statins.

NHS Borders was assumed to contract with NHS Lothian to provide the structured education courses required for its population. This assumption was made because the number of courses required by NHS Borders was not judged sufficient to warrant the board incurring the high fixed costs required to train staff to deliver these programmes. The additional staff and other costs and resources are presented as a

charge to NHS Lothian. However, one may anticipate these will be charged out to NHS Borders.

Table 3-1 Estimated staff hours required annually for first year 1 for each key recommendation by NHS board

NHS board	Structured education (includes initial year staff training)	Psychological support (includes initial year staff training)	CSII	Gestational diabetes	Total	Whole time equivalents (assuming 42 weeks, 37.5 hours a week)
Ayrshire & Arran	1,926	804	807	487	4,024	2.2
Borders	0	426	140	144	710	0.3
Dumfries & Galloway	789	507	281	188	1,765	0.9
Fife	1,730	777	406	515	3,428	1.9
Forth Valley	1,500	669	493	416	3,078	1.6
Grampian	2,051	939	900	801	4,691	2.8
Greater Glasgow & Clyde	4,470	2,094	2,020	1,744	10,328	6.2
Highland	1,500	669	562	397	3,128	1.7
Lanarkshire	2,415	1,074	1,148	818	5,455	3.3
Lothian	3,372	1,473	1,005	1,210	7,060	4.1
Orkney	0	15	33	25	73	0.0
Shetland	0	15	33	34	82	0.1
Tayside	1,746	804	371	542	3,463	1.9
Western Isles	0	15	74	28	117	0.1
Total	21,498	10,281	8,274	7,349	47,402	27.1

Table 3-2 Estimated staff hours required annually for years 2 to 5 for each key recommendation by NHS board

NHS board	Structured education (excludes initial year staff training)	Psychological support (excludes initial year staff training)	CSII	Gestational diabetes	Total	Whole time equivalents (assuming 42 weeks, 37.5 hours a week)
Ayrshire & Arran	1,581	636	807	487	3,511	2.6
Borders	0	258	140	144	542	0.5
Dumfries & Galloway	684	339	281	188	1,492	1.1
Fife	1,385	609	406	515	2,915	2.2
Forth Valley	1,155	501	493	416	2,565	2.0
Grampian	1,946	771	900	801	4,418	3.0
Greater Glasgow & Clyde	4,260	1,758	2,020	1,744	9,782	6.6
Highland	1,155	501	562	397	2,615	2.0
Lanarkshire	2,310	906	1,148	818	5,182	3.5
Lothian	3,162	1,137	1,005	1,210	6,514	4.5
Orkney	0	15	33	25	73	0.0
Shetland	0	15	33	34	82	0.1
Tayside	1,401	636	371	542	2,950	2.2
Western Isles	0	15	74	28	117	0.1
Total	19,038	8,097	8,274	7,349	42,758	30.1

3.3 Aggregate additional costs required

Table 3-3 sets out the estimated additional operating costs (excluding VAT and depreciation) to implement each recommendation in the first year, by NHS board. Table 3-4 presents the estimated additional operating costs (excluding VAT and depreciation) to implement the recommendations in year 5, by recommendation and by NHS board.

Table 3-3 Additional operating costs for year 1 for each key recommendation by NHS board

NHS board	Structured education	Psychological support	Human insulin (savings)	CSII pumps	Gestational diabetes	Statins	Stents	Total (excluding VAT)
Ayrshire & Arran	£85,081	£21,890	(£11,886)	£72,759	£24,002	£21,589	£5,617	£219,052
Borders	£0	£14,952	(£3,380)	£12,656	£7,095	£6,200	£1,613	£39,136
Dumfries & Galloway	£34,571	£16,438	(£4,834)	£25,312	£9,241	£7,417	£1,926	£90,071
Fife	£77,763	£21,395	(£11,025)	£36,467	£25,357	£19,122	£4,973	£174,052
Forth Valley	£68,965	£19,412	(£8,622)	£44,344	£20,512	£16,176	£4,210	£164,997
Grampian	£82,230	£24,369	(£14,790)	£80,843	£39,449	£27,259	£7,093	£246,453
Greater Glasgow & Clyde	£178,688	£52,702	(£34,607)	£181,960	£85,944	£67,812	£17,657	£550,156
Highland	£68,965	£19,412	(£8,714)	£50,634	£19,556	£15,478	£4,026	£169,357
Lanarkshire	£95,974	£26,847	(£17,335)	£103,084	£40,320	£33,677	£8,768	£291,335
Lothian	£124,214	£41,303	(£20,936)	£90,317	£59,600	£38,520	£10,024	£343,047
Orkney	£3,028	£895	(£588)	£3,098	£1,220	£1,014	£264	£8,931
Shetland	£2,620	£895	(£600)	£3,110	£1,674	£688	£178	£8,565
Tayside	£78,452	£21,890	(£11,945)	£33,310	£26,724	£24,896	£6,486	£179,813
Western Isles	£3,713	£1,084	(£737)	£6,396	£1,392	£1,344	£350	£13,542
Total	£904,270	£283,484	(£150,000)	£744,291	£362,086	£281,193	£73,185	£2,498,508

Table 3-4 Additional annual operating costs (excluding depreciation) for year 5 for each key recommendation by NHS board

NHS board	Structured education	Psychological support	Human insulin (savings)	CSII pumps (year 5)	Gestational diabetes	Statins	Stents	Total (excluding VAT)
Ayrshire & Arran	£66,387	£13,499	(£11,886)	£246,823	£24,002	£2,930	£5,617	£347,372
Borders (a)	£0	£6,560	(£3,380)	£42,928	£7,095	£842	£1,613	£55,658
Dumfries & Galloway	£29,073	£8,047	(£4,834)	£85,856	£9,241	£1,007	£1,926	£130,316
Fife	£59,069	£13,003	(£11,025)	£123,499	£25,357	£2,596	£4,973	£217,472
Forth Valley	£50,271	£11,020	(£8,622)	£150,296	£20,512	£2,196	£4,210	£229,883
Grampian	£80,132	£15,977	(£14,790)	£273,827	£39,449	£3,700	£7,093	£405,388
Greater Glasgow & Clyde	£169,987	£35,918	(£34,607)	£617,120	£85,944	£9,204	£17,657	£901,223
Highland	£50,271	£11,020	(£8,714)	£171,722	£19,556	£2,101	£4,026	£249,982
Lanarkshire	£90,476	£18,455	(£17,335)	£349,044	£40,320	£4,571	£8,768	£494,299
Lothian	£118,783	£24,519	(£20,936)	£306,005	£59,600	£5,228	£10,024	£503,223
Orkney	£3,028	£895	(£588)	£10,666	£1,220	£138	£264	£15,623
Shetland	£2,620	£895	(£600)	£10,678	£1,674	£93	£178	£15,538
Tayside	£59,758	£13,499	(£11,945)	£112,774	£26,724	£3,379	£6,486	£210,675
Western Isles	£3,712	£1,084	(£737)	£21,532	£1,392	£182	£350	£27,515
Total	£783,567	£174,391	(£150,000)	£2,522,771	£362,086	£38,168	£73,185	£3,804,167

4 Structured education programmes

4.1 Background

Section 3.2 of the Guideline provided evidence that structured education programmes based on the principles of adult learning can improve the quality of life of people with type 1 diabetes. The text noted the results from two programmes, DAFNE (Dose Adjusted For Normal Eating) and Bournemouth type 1 Intensive Education (BERTIE), included improved glycaemic control. There was also evidence to indicate that developing the problem solving skills of children and adolescents with type 1 diabetes can improve their glycaemic levels.

The Guideline noted that similar improvements in quality of life and glycaemic control has been reported for some structured education programmes delivered to people with type 2 diabetes. The Guideline noted a recent cost-effectiveness analysis had compared several such programmes and concluded many were likely to be cost effective at the generally accepted thresholds of £20,000 to £30,000 per quality adjusted life year (QALY).

This evidence led the Guideline Development Group to recommend that:

- Adults with type 1 diabetes experiencing problems with hypoglycaemia or who fail to achieve glycaemic targets should have access to structured education programmes. Grade A
- Children and adolescents should have access to programmes of structured education which have a basis in enhancing problem solving skills. Grade B
- Adults with type 2 diabetes should have access to structured education programmes based upon adult learning theories. Grade A

Moreover, the provision of pump therapy was linked to education through the following best practice point:

- Pump therapy should be available from a local multidisciplinary pump clinic for patients who have undertaken structured education.

Section 3.2 of the Guideline explained that any structured education programme in use in Scotland should meet the criteria set out by the Diabetes Educational Advisory Group to the Scottish Diabetes Group.

The Better Diabetes Care consultation document issued by the SGHD (<http://www.scotland.gov.uk/Publications/2009/05/28085904/1>) noted that 12 of the 14 NHS boards in Scotland had well established systems in place to support people newly diagnosed with diabetes. This was confirmed by discussions with the SIGN Guideline Development Group members and the Chair of the Scottish Diabetes Group (meeting on 23 February 2010). These discussions concluded that the unmet need was for a range of programmes to be available, of different intensities to follow on from the initial courses. Such courses could be prioritised to those who do not achieve good day-to-day control of their condition and focus on improving self management by providing a greater understanding of the condition and knowledge on how to treat it.

4.2 Patient group

The relevant patient group was assumed to be people in Scotland with diabetes and poor glycaemic control. Tables 18 and 19 of the Diabetes Survey 2009 provided the numbers of patients with type 1 and 2 diabetes and an HbA1c >9, by NHS board. The groups were divided into those under and over 16 years of age by applying the age group analysis shown in Table 6 of the Survey. There were almost 9,100 people with type 1 diabetes and a HbA1c >9, of whom about 730 were estimated to be under 16 years old and over 24,200 with type 2 diabetes and a HbA1c >9.

Some of these people will have received a structured education programme. In 2006, the Healthcare Commission surveyed people with diabetes in England and reported that 11% of respondents had participated in an education course (http://www.cqc.org.uk/db/documents/Diabetes_survey_2006_summary.pdf). On this evidence, 10% of this poorly-controlled group of people with diabetes were assumed to have had some form of further education and so were excluded. It was further assumed that the interventions will be provided over five years and 70 out of 100 people offered a structured education programme will attend.

Type 1 diabetes children and adolescents

The figures from the Survey suggest each year about 92 young people under the age of 16 years with type 1 diabetes may attend a structured education programme. However, this group may also benefit from insulin pump therapy. Section 7 of this report explains that 63 of the group are assumed to be offered an insulin pump each year, with the balance of 29 undertaking a structured education programme. The pump pathway includes intensive education which commences after the consultant has referred the young person for a pump. The costs to educate young people receiving pump therapy are included in section 7 rather than this section of the report.

Type 1 diabetes adults

These assumptions suggest that annually about 1,050 adults with type 1 diabetes may benefit from a structured education programme. If 67% are assessed for a lower intensity, tier 2 intervention and 33% for the higher intensity tier 3 then 700 and 350 will attend tier 2 and 3 programmes, respectively.

Type 2 diabetes adults

These assumptions suggest that annually about 3,050 adults with type 2 diabetes may benefit from a structured education programme. There are estimated to be less than 40 young people under 16 years old with type 2 diabetes and none are assumed to fall into this priority category for education.

Table 4-1 summarises the numbers of people in each sub-group who may take up structured education programmes.

Table 4-1 Assessment of people with diabetes taking up structured education annually for 5 years

	HbA1c>9	If 10% already received training	Manage over 5 years	70% assessed & attend education	Tier 2	Tier 3 or pump
Type 1 under 16 years	732	659	132	92	29	63 (pumps)
Adults	8,364	7,528	1,506	1,054	700	350
Type 1 total	9,096	8,186	1,637	1,146	729	413
Type 2 (16 years or over)	24,234	21,811	4,362	3,053	3,050	

(Numbers may not add due to rounding)

4.3 Additional resources required

The resources included in this report are limited to the cost of training existing diabetes staff to deliver structured education programmes and running the requisite number of courses. Three programmes have been considered:

1. The resources required to deliver a tier 2 structured education programme to 700 adults and 29 young people with type 1 diabetes have been modelled on the BERTIE course (<http://213.105.192.75/bdec2/education/bertie.html>). This comprises 24 hours of education for 6 hours a day over 4 weeks, delivered to groups of about eight people. The course is delivered by a multidisciplinary team comprising a consultant physician, specialist diabetes nurse and dietician. The course has not been accredited for children.
2. The resources required to deliver a tier 3 structured education programme to 350 adults with type 1 diabetes have been modelled on the DAFNE course (<http://www.dafne.uk.com/>). This comprises 37.5 hours of education for 1 week and is delivered to a maximum of eight people per course. The course is delivered by a multidisciplinary team similar to BERTIE. The course has not been accredited for children.
3. The resources required to deliver a tier 2 structured education programme to 3,050 adults with type 2 diabetes have been modelled on the X-PERT course. <http://www.xperthealth.org.uk/>. This course is delivered over six weekly sessions, each of about 2 hours of face to face time, with 18 people able to attend each course.

BERTIE

BERTIE, or a course of similar intensity, is assumed to be delivered to 729 people with type 1 diabetes who have been assessed as likely to benefit from a tier 2 programme. It is assumed that the course will be delivered by a dietician (30% input) and a diabetes nurse (70% input); a consultant physician may have a marginal input of say 1 hour per course but this is not costed. The approach used by BERTIE is social learning theory. It is assumed that the nurse and dietician are trained in that discipline. Each board is assumed to train two staff, other than NHS Greater

Glasgow and Clyde and NHS Lothian who each train four staff. In some NHS boards, particularly NHS Grampian and NHS Lanarkshire, the trained diabetes nurse will spend much of his or her working year delivering courses.

Training professional staff to deliver BERTIE is undertaken in Bournemouth. Each staff member must complete a 2-day course. A further 2 days of travel time is assumed to be required.

The course duration is usually 9:15 am to 3:00 pm on a week day for 4 weeks. People with diabetes will often require time off work to attend and this may reduce uptake. The staff input is assumed to be 7.5 hours per day, with the additional 1.5 hours (25%), beyond the teaching time, providing time for quality assurance (QA), audit, preparation and travel.

Administration is assumed to be by an individual whose pay scale is agenda for change (AfC) band 3 for 2 days per course.

It is assumed that NHS Borders will make a contract with NHS Lothian to deliver the two courses required in its area and the NHS island boards will make a contract with a third party to provide a service at the same unit cost per member as incurred by the rest of Scotland. This could be delivered by an internet-based course or a general practitioner (GP) with a specialist interest. For example, there is an online learning programme based on part of the BERTIE programme (<http://213.105.192.75/bdec2/bertie.shtml>).

Table 4-2 shows the number of people requiring this intervention, the number of courses assuming a maximum of eight people per course, the number of staff to be trained plus associated hours for training, and delivering and administering the course, for each NHS board. Thus in the first year, 4,950 hours of specialist nurse and dietician time could be required. In future years the resource requirement is estimated to fall by 720 hours to 4,230 hours; this however assumes no further training is necessary. This is likely to understate the resources required because staff turnover will necessitate further training.

Table 4-2 Resources to deliver BERTIE for adults with type 1 diabetes by NHS board

NHS board	Number of participants	Number of courses required	Number of staff to train	Training and travel hours	Course delivery hours	Admin hours	Total hours in year 1
Ayrshire & Arran	60	8	2	60	240	120	420
Borders	16	2	0	0	0	0	0
Dumfries & Galloway	23	3	2	60	90	45	195
Fife	51	7	2	60	210	105	375
Forth Valley	41	6	2	60	180	90	330
Grampian	79	10	2	60	300	150	510
Greater Glasgow & Clyde	158	20	4	120	600	300	1,020
Highland	45	6	2	60	180	90	330
Lanarkshire	92	12	2	60	360	180	600
Lothian	107	14	4	120	480	240	840
Orkney	3	0	0	0	0	0	0
Shetland	3	0	0	0	0	0	0
Tayside	47	6	2	60	180	90	330
Western Isles	5	0	0	0	0	0	0
Total	729	94	24	720	2,820	1,410	4,950

DAFNE

DAFNE, or a course of similar intensity, is assumed to be delivered to 350 people with type 1 diabetes who have been assessed as requiring a tier 3 programme. It is assumed that the course will be delivered by a dietician (30% input) and a diabetes nurse (70% input); a consultant physician may have a marginal input of say 1 hour per course but this is not costed (Personal communication DAFNE staff at Diabetes Launch March 23 2010). DAFNE factsheets explain the training package and related costs http://www.dafne.uk.com/pubs_fact_sheets.php.

NHS Dumfries and Galloway, NHS Grampian, NHS Greater Glasgow & Clyde, NHS Lanarkshire and NHS Lothian already operate DAFNE courses; no further training is assumed to be required at these boards. At the other boards, two staff are assumed to be trained to deliver DAFNE. Training professional staff to deliver DAFNE is assumed to take 120 hours per person (being 105 training hours plus travel of 15 hours [see http://www.dafne.uk.com/pubs_fact_sheets.php]).

The DAFNE worksheets advise the course requires 10 days to deliver, of which 5 days are face to face contact; the remaining days are for QA, audit, preparation and travel.

Administration by an individual whose payscale is AfC band 3 for 2 days per course is also assumed.

Similar assumptions to those previously described for the BERTIE programme are made about NHS Borders contracting with NHS Lothian and the NHS island boards contracting with a third party.

The number of people requiring this intervention, the number of courses assuming a maximum of eight people per course and the number of staff requiring to be trained plus associated hours for training and then delivering the course, for each NHS board, are set out Table 4-3. In future years the resource requirement is estimated to fall by 1,200 hours from 5,430 to 4,230 hours; this however assumes no further training is necessary. This is likely to understate the resource required because staff turnover will necessitate further training.

Table 4-3 Resources to deliver DAFNE for adults with type 1 diabetes by NHS board

NHS board	Number of participants	Number of courses delivered	Number of staff to train	Training and travel hours	Course delivery hours	Admin hours	Total hours in year 1
Ayrshire & Arran	29	4	2	240	300	60	600
Borders	8	0	0	0	0	0	0
Dumfries & Galloway	11	2	0	0	150	30	180
Fife	24	3	2	240	225	45	510
Forth Valley	20	3	2	240	225	45	510
Grampian	38	5	0	0	375	75	450
Greater Glasgow & Clyde	76	10	0	0	750	150	900
Highland	22	3	2	240	225	45	510
Lanarkshire	44	6	0	0	450	90	540
Lothian	51	8	0	0	600	120	720
Orkney	2	0	0	0	0	0	0
Shetland	1	0	0	0	0	0	0
Tayside	23	3	2	240	225	45	510
Western Isles	2	0	0	0	0	0	0
Total	350	47	10	1,200	3,525	705	5,430

X-PERT

X-PERT, or a course of similar intensity, is assumed to be delivered to 3,050 people with type 2 diabetes who have been assessed as requiring a structured education programme. With up to 18 people attending each course, 172 courses could be provided across Scotland.

It is assumed that the course will be delivered by a dietician (30% input) and a diabetes nurse (70% input), with an administrator whose payscale is AfC band 3 also in attendance.

Each board is assumed to train two staff, other than NHS Greater Glasgow and Clyde and NHS Lothian who are each assumed to train four staff. The nurse and dietitian are assumed to attend a 2-day training course run by X-PERT and require a further 1 day of travel time.

The course duration is usually 2 hours on a week day for 6 weeks. The staff input is assumed to be 3.5 hours per session for the trainer and 3 hours for the administrator. The administrator is also assumed to spend 3 days arranging each course.

It is assumed that NHS Borders will make a contract with NHS Lothian to deliver the four courses required in its area and the NHS island boards will make a contract with a third party to provide a service at the same unit cost per member as incurred by the rest of Scotland. This could be delivered by an internet-based course or a GP with a specialist interest. For example, there is an online learning programme based on the X-PERT programme (<http://www.expertpatients.co.uk/course-participants/courses/online-course>).

Table 4-4 shows the number of people requiring this intervention, the number of courses assuming a maximum of 18 people per course, the number of staff to be trained plus associated hours for training, and delivering and administering the course, for each NHS board. In future years the resource requirement could remain at this level because X-PERT advises trainers should refresh their skills annually.

Table 4-4 Resources to deliver X-PERT for adults with type 2 diabetes by NHS board

NHS board	Number of participants	Number of courses delivered	Number of staff to train	Training and travel hours	Course delivery hours	Admin hours	Total hours in year 1
Ayrshire & Arran	241	14	2	45	294	567	906
Borders	69	0	0	0	0	0	0
Dumfries & Galloway	99	6	2	45	126	243	414
Fife	225	13	2	45	273	527	845
Forth Valley	177	10	2	45	210	405	660
Grampian	296	17	2	45	357	689	1,091
Greater Glasgow & Clyde	709	40	4	90	840	1,620	2,550
Highland	176	10	2	45	210	405	660
Lanarkshire	349	20	2	45	420	810	1,275
Lothian	421	28	4	90	588	1,134	1,812
Orkney	12	0	0	0	0	0	0
Shetland	12	0	0	0	0	0	0
Tayside	249	14	2	45	294	567	906
Western Isles	14	0	0	0	0	0	0
Total	3,050	172	24	540	3,612	6,966	11,118

Table 4-5 shows the number of staff hours required in the first year to deliver structured education programmes across Scotland and analyses these by discipline. The total hours of 21,498 comprise 2,460 hours to train staff and 19,038 hours to deliver the courses. In subsequent years the initial staff training is reduced such that the total resource input is about 20,000 hours. No whole time equivalents are provided; rather two staff from each board (four in Greater Glasgow and Clyde and Lothian) are assumed to be trained for each programme and will change their job content to be a mix of training with their other existing activities. The additional hours indicate the extent of back fill required for initial staff training only.

Table 4-5 Additional staff hours to set up and deliver structured education programmes by NHS boards in year 1

NHS board	BERTIE	DAFNE	X-PERT	Total	Nurse	Dietician	Admin
Ayrshire & Arran	420	600	906	1,926	825	300	747
Borders	0	0	0	0	0	0	0
Dumfries & Galloway	195	180	414	789	330	117	318
Fife	375	510	845	1,730	737	272	677
Forth Valley	330	510	660	1,500	672	248	540
Grampian	510	450	1,091	2,051	796	274	914
Greater Glasgow & Clyde	1,020	900	2,550	4,470	1,680	585	2,070
Highland	330	510	660	1,500	672	248	540
Lanarkshire	600	540	1,275	2,415	935	320	1,080
Lothian	840	720	1,812	3,372	1,315	455	1,494
Orkney	0	0	0	0	0	0	0
Shetland	0	0	0	0	0	0	0
Tayside	330	510	906	1,746	731	273	702
Western Isles	0	0	0	0	0	0	0
Total	4,950	5,430	<u>11,118</u>	21,498	8,692	3,091	9,081

4.4 Additional costs required

Table 4-6 sets out the costs common to each programme for certain resources.

Table 4-6 Unit costs for staff and consumables

Resource	Cost	Description
Specialist diabetic nurse	£34.16 per hour	Mid point band 7 £34,410 +23% on costs and 1,239 hours with patients per year (41.3 weeks a year, 37.5 hours a week of which 80% client related) Source http://www.pssru.ac.uk/pdf/uc/uc2009/uc2009.pdf .
Specialist diabetic dietician	£28.61 per hour	Mid point band 6 £28,816 +23% on costs and 1,239 hours with patients per year (41.3 weeks a year, 37.5 hours a week of which 80% client related) Source http://www.pssru.ac.uk/pdf/uc/uc2009/uc2009.pdf
Administrator	£13.04 per hour	Mid point band 3 £16,700 +23% on costs and 1,575 hours with patients per year (42 weeks a year, 37.5 hours a week)
Course materials	£4	Estimate based on the three courses
Meal costs	£5 per day DAFNE ; 50p per visit for others	Meal essential for DAFNE: drinks only for others
Travel costs per person	£10 per visit	Estimate; travel costs are assumed to be paid to encourage uptake

Costs to run BERTIE programmes

The BERTIE website (http://213.105.192.75/bdec2/health_professionals.shtml) states the cost of training is £250 per course per person. In addition return train travel of £140 per person and subsistence costs of 3 nights at £ 90 per night have been assumed.

The total set-up costs are £3,203 and comprise:

- backfill for two staff for 4 days £1,883
- course fees for two staff £500
- travel for two at £140 each £280
- subsistence 3 nights @ £90 £540.

The costs per course are estimated at £1,682, equivalent to £215 per attendee and comprise:

- trainers time being four sessions of 7.5 hours each for diabetes nurse (70% input) and dietician (30% input) £975
- administration time of 2 days for AfC band 3 £196
- course materials £32
- food: lunch for eight people for 4 days at £5 £160

each day

- travel for eight people for 5 days at £10 each £320.

The total costs to deliver 94 courses by NHS board are shown in Table 4-7. The initial training costs are £3,200 for every two staff members trained and are estimated to be about £38,400 in the first year. Running the courses will cost a further £175,000 for each of the 5 years.

NHS Orkney, Shetland and the Western Isles NHS boards were assumed to provide funding equal to £215 per person for three, three, and five people, respectively.

Table 4-7 Cost to deliver 94 Bertie courses by NHS board

NHS board	Number of courses	Training the trainer costs (year 1)	Deliver training course costs	Total year 1	Total year 2
Ayrshire & Arran	8	£3,203	£13,460	£16,663	£13,460
Borders	2	£0	£0	£0	£0
Dumfries and Galloway	3	£3,203	£5,047	£8,250	£5,047
Fife	7	£3,203	£11,777	£14,980	£11,777
Forth Valley	6	£3,203	£10,095	£13,298	£10,095
Grampian	10	£3,203	£16,824	£20,027	£16,824
Greater Glasgow & Clyde	20	£6,406	£33,649	£40,055	£33,649
Highland	6	£3,203	£10,095	£13,298	£10,095
Lanarkshire	12	£3,203	£20,189	£23,392	£20,189
Lothian	14	£6,406	£26,919	£33,325	£26,919
Orkney	0	£0	£631	£631	£631
Shetland	0	£0	£631	£631	£631
Tayside	6	£3,203	£10,095	£13,298	£10,095
Western Isles	0	£0	£1,052	£1,052	£1,052
Total	94	£38,436	£160,464	£198,900	£160,464

Costs to run DAFNE programmes

The costs of setting up a DAFNE site are estimated to be almost £16,600 and comprise:

- backfill for 120 hours to train a specialist diabetes nurse and dietician to deliver DAFNE at each site . £7,532
- travel and subsistence of 13 days at £90 for 70% of staff plus travel of £30 per person £1,698
- training course fees to DAFNE for two trainers . £2,700

- central administration fee (payable annually) £3,400
- course set-up fee (first year only) £1,266.

Only the boards with no established DAFNE courses are assumed to incur these costs (NHS Ayrshire and Arran, NHS Fife, NHS Forth Valley, NHS Highland and NHS Tayside).

The costs of running a course are estimated at about £3,265, equivalent to £408 per attendee. The components are:

- trainers' time: 10 days diabetes nurse (70% input) and dietician (30% input) £2,437
- administration time of 2 days for AfC band 3 £196
- course materials £32
- food: lunch for eight people for 5 days at £5 each day £200
- travel for eight people for 5 days at £10 each £400.

NHS Orkney, NHS Shetland and NHS Western Isles were assumed to provide funding equal to £408 per person for two, one and two people, respectively.

The costs in year 2 are simply the number of courses multiplied by the cost per course for boards which already incur the annual central administration charge of £3,400. The remaining boards operating DAFNE will also incur this charge.

Table 4-8 presents the total costs by NHS board. These are about £83,000 to train staff in NHS boards which currently do not operate DAFNE, and £152,000 to deliver the additional 47 courses. In subsequent years the costs are estimated at about £175,000.

Table 4-8 Cost to deliver 47 DAFNE courses by NHS board

NHS board	Number of courses	Site set-up costs (year 1)	Deliver training course costs	Total year 1	Total year 2
Ayrshire & Arran	4	£16,596	£13,059	£29,655	£16,459
Borders	0	£0	£0	£0	£0
Dumfries & Galloway	2	£0	£6,529	£6,529	£6,529
Fife	3	£16,596	£9,794	£26,390	£13,194
Forth Valley	3	£16,596	£9,794	£26,390	£13,194
Grampian	5	£0	£16,323	£16,323	£19,723
Greater Glasgow & Clyde	10	£0	£32,647	£32,647	£32,647
Highland	3	£16,596	£9,794	£26,390	£13,194
Lanarkshire	6	£0	£19,588	£19,588	£19,588
Lothian	8	£0	£22,853	£22,853	£26,117
Orkney	0	£0	£816	£816	£816
Shetland	0	£0	£408	£408	£408
Tayside	3	£16,596	£9,794	£26,390	£13,194
Western Isles	0	£0	£816	£816	£816
Total	47	£82,980	£152,216	£235,196	£175,880

Costs to run X-Pert programmes

The costs of setting up an X-PERT site are estimated to be about £5,560 and comprise:

- training course fees for two staff £1,100
- backfill for a diabetes nurse and dietician 2.5 days £1,177
- travel and subsistence (train £65 and subsistence for 2 nights) £490
- X-PERT pack per site £2,795.

The costs to run a course for 18 people are £2,370 (about £132 each) and comprise:

- training staff six sessions of 3.5 hours each for diabetes nurse (70% input) and dietician (30% input) £682
- administration per course (3 days set up and six sessions 3 hours each) £528
- handbooks £72

- refreshments £9
- travel six journeys (£10 each for 18 people) £1,080

In year 2, costs will be similar; staff can attend an annual update course at the same charge; there should be a small reduction because the X-PERT pack is updated at a cost of £500 rather than a purchase price of £2,795.

Table 4-9 presents the total costs of almost £480,000 to train 3,050 people with type 2 diabetes at tier 2 level.

Table 4-9 Cost to deliver 172 X-PERT courses by NHS board

NHS board	Number of courses	Site set-up costs (year 1)	Deliver training course costs	Total year 1	Total year 2
Ayrshire & Arran	14	£5,562	£33,202	£38,764	£36,469
Borders	4	£0	£9,486	£9,486	£7,191
Dumfries & Galloway	6	£5,562	£14,229	£19,791	£17,496
Fife	13	£5,562	£30,830	£36,392	£34,097
Forth Valley	10	£5,562	£23,716	£29,278	£26,983
Grampian	17	£5,562	£40,317	£45,879	£43,584
Greater Glasgow & Clyde	40	£11,124	£94,863	£105,987	£103,692
Highland	10	£5,562	£23,716	£29,278	£26,983
Lanarkshire	20	£5,562	£47,431	£52,993	£50,698
Lothian	24	£11,124	£56,918	£68,041	£65,746
Orkney	0		£1,581	£1,581	£1,581
Shetland	0		£1,581	£1,581	£1,581
Tayside	14	£5,562	£33,202	£38,764	£36,469
Western Isles	0		£1,845	£1,845	£1,845
Total	172	£66,743	£412,917	£479,660	£454,415

Table 4-10 provides the total costs for each of these programmes in the first year, which includes training costs, and for subsequent years. The total costs in the first year are £904,260, of which £188,159 are training related. These could fall to between £780,000 and £800,000 a year. The minimum figure is unlikely to be achieved should there be some staff turnover, thereby requiring further training.

Table 4-10 Total annual costs to deliver structured education by NHS board

NHS board	Set-up costs year 1	Deliver training costs year 1	Deliver training costs year 2
Ayrshire & Arran	£25,361	£59,720	£66,387
Borders	£0	£0	£0
Dumfries & Galloway	£8,765	£25,806	£29,073
Fife	£25,361	£52,402	£59,069
Forth Valley	£25,361	£43,604	£50,271
Grampian	£8,765	£73,465	£80,132
Greater Glasgow & Clyde	£17,530	£161,159	£169,987
Highland	£25,361	£43,604	£50,271
Lanarkshire	£8,765	£87,209	£90,476
Lothian	£17,530	£106,690	£118,783
Orkney	£0	£3,028	£3,028
Shetland	£0	£2,620	£2,620
Tayside	£25,361	£53,091	£59,758
Western Isles	£0	£3,712	£3,712
Total	£188,159	£716,110	£783,567

VAT

Inputs are mainly related to staff costs or education materials and so virtually all have no VAT payable. Therefore no separate costs inclusive of VAT are provided.

4.5 Sensitivity analyses

The key sensitivity analyses are on the number of people offered and undertaking structured education training. No higher option is provided because the base case presents sufficient challenge to the NHS boards. However, if only 50% undertake the training rather than the 70% assumed then the course-related costs would fall from £725,596 to about £520,000 in year one and to £580,000 in year 2.

5 Psychological support

5.1 Background

Section 4.3 of the Guideline provided evidence that psychological therapies can improve glycaemic control in the short and long term, in adults and young people with type 1 and type 2 diabetes. No single form of therapy was found to be the most effective and the sub-groups of patients most likely to benefit were not clear. The evidence led the Guideline Development Group to recommend that:

- Children and adults with type 1 and type 2 diabetes should be offered psychological interventions (including motivational interviewing, goal setting, skills and CBT [cognitive behavioural therapy]) to improve glycaemic control in the short and medium term. Grade A

In terms of service provision, in January 2006, the Psychology Working Group for the Scottish Diabetes Group reported that the provision of psychology input into the adults' diabetes services was limited to six to ten sessions, with eight and a half sessions provided to children's diabetes services^{iv}. These services seemed to be located in secondary care.

Subsequently, funding has been acquired for a pilot project to employ five part-time psychologists in diabetes services across Scotland. These psychologists should become integral members of the diabetes multidisciplinary team.

5.2 Patient group

The relevant patient group was assumed to be people in Scotland with diabetes and poor glycaemic control, and thus similar to the group eligible for structured education. The Diabetes Survey 2009 reported that almost 32,600 people with diabetes had a glycated haemoglobin recording of over 9 HbA1c. Of these, 20,650 were assumed to receive a form of structured education. The majority of the remaining individuals, some 2,000 a year for five years, were assumed to receive a psychological intervention to improve control.

5.3 Additional resources required

Most of the assumptions for the resource requirements were guided by Dr Andy Keen, Health Psychologist, and Grampian NHS board, who is also a member of the Psychology Working Group. The key assumptions were that:

1. A proportion of diabetes staff would be trained in delivering CBT and, with robust supervision from qualified psychologists, could deliver effective CBT interventions. The course providers are assumed to be a mix of AfC grades 20/30/50 of band 5,6 and 7 respectively.
2. Those selected to deliver these courses are assumed to attend an accredited course. For this purpose the course is assumed to be the South of Scotland Cognitive Behavioural Therapy (CBT) Certificate. This has been developed by a collaboration of NHS Lothian, NHS Glasgow and QMU School of Health Sciences. For each person, backfill will be required for 140 hours (the sum of taught time, tutorials and clinical supervision). The last element will also

require 28 hours input from a psychologist. Self-directed learning of over 400 hours is assumed to be conducted by the trainee outside the workplace. Full details of the course are available at

<http://www.nhslothian.scot.nhs.uk/ourservices/soscog/> .

3. Further on-the-job coaching and supervision of these trained staff is a core requirement for psychologists working in the diabetes service.
4. Each trained staff member receives 4 hours per month supervision from a psychologist, ideally one working within the diabetes service so that there is a shared understanding of the clinical needs of people with diabetes and of the treatment regimes. Over time this input may reduce.
5. Each trained staff member is assumed to deliver no more than 250 hours of CBT a year.
6. The CBT interventions are delivered as group interventions to a maximum of eight per group and comprise six 1-hour sessions plus a further 1 hour for preparation and set-up/close-down time per session for the trainer.
7. People who would benefit from referral are identified at diabetes clinics, possibly through the use of a Hospital Anxiety and Depression Scale (HADS) screening tool, administered in the clinic setting. No additional costs are assumed for the introduction and use of this tool; rather it is assumed clinic leads will be trained in its use once the additional part-time psychologists are in place.
8. Administration for the CBT groups is provided by an individual on the AfC payscale band 3, taking 2 days per group.
9. It is assumed the service providers in the islands will spend the equivalent cost per course (excluding travel time) to meet the needs of their population but will not train staff directly. Administrative support equivalent to 2 days per eight clients is assumed to be required.
10. It is assumed no additional resources will be required to deliver the training; for example fully serviced training rooms can be made available from within existing properties.
11. No travel costs are assumed to be paid. A sensitivity analysis assuming a cost of £10 per person per day is also provided.

Table 5-1 shows the number of interventions (2,000), number of groups (255) and the number of newly trained staff (13) estimated to be required across Scotland.

Table 5-1 Number of groups and staff delivering CBT by NHS board

NHS board	Number of interventions	Number of groups	Number of staff to train
Ayrshire & Arran	159	20	1
Borders	45	6	1
Dumfries & Galloway	65	9	1
Fife	146	19	1
Forth Valley	115	15	1
Grampian	199	25	1
Greater Glasgow & Clyde	459	58	2
Highland	117	15	1
Lanarkshire	234	30	1
Lothian	280	35	2
Orkney	8	1	0
Shetland	8	1	0
Tayside	157	20	1
Western Isles	10	1	0
Total	2,000	255	13

The total hours required for the initial training are set out in Table 5-2. Table 5-3 estimates the annual hours required to deliver the courses and provide the 4 hours psychologist support each month. The total hourly requirement in the first year is estimated to be about 10,270 hours of which 2,184 hours are related to providing diabetes staff with training in CBT and almost 8,100 to deliver the courses. Once trained, the CBT providers will require to devote around 3,650 hours annually to delivering courses and working with a psychologist (3,024 plus 624 hours of supervision with a psychologist) to deliver the 252 courses (i.e. excluding the islands). This represents just over 1.8 hours per client. In addition 624 hours are estimated to be required from the supervising psychologists, whilst administration will require a further 3,825 hours.

Table 5-2 Additional staff hours to train staff to deliver CBT by NHS board

NHS board	Trainer training (140 hours backfill each)	Psychologist supervision during training (28 hours per provider)	Total hours
Ayrshire & Arran	140	28	168
Borders	140	28	168
Dumfries & Galloway	140	28	168
Fife	140	28	168
Forth Valley	140	28	168
Grampian	140	28	168
Greater Glasgow & Clyde	280	56	336
Highland	140	28	168
Lanarkshire	140	28	168
Lothian	280	56	336
Orkney	0	0	0
Shetland	0	0	0
Tayside	140	28	168
Western Isles	0	0	0
Total	1,820	364	2,184

Table 5-3 Additional staff hours to deliver CBT by NHS board

NHS board	Deliver courses (6 x 2 hours each)	On-going psychologist Supervision 4 hours a month with each trainer	Admin hours 15 hours per course	Total hours
Ayrshire & Arran	240	96	300	636
Borders	72	96	90	258
Dumfries & Galloway	108	96	135	339
Fife	228	96	285	609
Forth Valley	180	96	225	501
Grampian	300	96	375	771
Greater Glasgow & Clyde	696	192	870	1,758
Highland	180	96	225	501
Lanarkshire	360	96	450	906
Lothian	420	192	525	1,137
Orkney	0	0	15	15
Shetland	0	0	15	15
Tayside	240	96	300	636
Western Isles	0	0	15	15
Total	3,024	1,248	3,825	8,097

5.4 Additional costs required

The relevant unit costs are the staff costs and course fees. Staff costs were estimated at £25 per hour for the diabetes staff delivering the courses. This assumed the mean cost per staff member was about £33,500, the midpoint in a range from the top of AfC band 5 scale to the top of the band 7 scale. Twenty three percent for national insurance and superannuation costs were added to give a total staff cost of £41,250. Assuming a mean number of hours worked of 1,650 per annum gave a cost per hour of £25.

Supervisor time from a psychologist was estimated to cost £50 an hour. This assumed it was provided by an AfC grade 8 c or d grade plus 23% for national insurance and superannuation and the supervisor worked 1,650 working hours a year.

The course fees were assumed to be £3,500, which is the cost of the Post Graduate Certificate <http://www.nhslothian.scot.nhs.uk/ourservices/soscoq/fees.asp>.

Table 5-4 provides the estimates additional costs to train staff by NHS board, whilst Table 5-5 provides the additional annual cost of providing the CBT courses to 2,000 people annually. The cost of delivering interventions on the islands is assumed to be £87 per client, the equivalent of the mainland cost per client. Training costs are estimated to be almost £110,000 across Scotland, with annual costs of delivering the interventions of almost £175,000.

Table 5-4 Estimate of the additional costs to train staff by NHS board

NHS board	Training the provider (140 hours backfill per person at £25 an hour)	Psychologist supervision during training (28 hours per deliverer at £50 an hour)	Course fees £3,500 per provider	Total costs
Ayrshire & Arran	£3,500	£1,392	£3,500	£8,392
Borders	£3,500	£1,392	£3,500	£8,392
Dumfries & Galloway	£3,500	£1,392	£3,500	£8,392
Fife	£3,500	£1,392	£3,500	£8,392
Forth Valley	£3,500	£1,392	£3,500	£8,392
Grampian	£3,500	£1,392	£3,500	£8,392
Greater Glasgow & Clyde	£7,000	£2,784	£7,000	£16,784
Highland	£3,500	£1,392	£3,500	£8,392
Lanarkshire	£3,500	£1,392	£3,500	£8,392
Lothian	£7,000	£2,784	£7,000	£16,784
Orkney	£0	£0	£0	£0
Shetland	£0	£0	£0	£0
Tayside	£3,500	£1,392	£3,500	£8,392
Western Isles	£0	£0	£0	£0
Total	£45,500	£18,094	£45,500	£109,094

Table 5-5 Estimate of the additional annual costs to deliver CBT by NHS board

NHS board	Delivery of course	Supervision cost provider & psychologist	Administration	Total costs
Ayrshire & Arran	£6,000	£3,586	£3,913	£13,499
Borders	£1,800	£3,586	£1,174	£6,560
Dumfries & Galloway	£2,700	£3,586	£1,761	£8,047
Fife	£5,700	£3,586	£3,717	£13,003
Forth Valley	£4,500	£3,586	£2,934	£11,020
Grampian	£7,500	£3,586	£4,891	£15,977
Greater Glasgow & Clyde	£17,400	£7,172	£11,346	£35,918
Highland	£4,500	£3,586	£2,934	£11,020
Lanarkshire	£9,000	£3,586	£5,869	£18,455
Lothian	£10,500	£7,172	£6,847	£24,519
Orkney	£700	£0	£196	£895
Shetland	£700	£0	£196	£895
Tayside	£6,000	£3,586	£3,913	£13,499
Western Isles	£888	£0	£196	£1,084
Total	£77,888	£46,618	£49,885	£174,391

VAT

No VAT will be payable on either the staff costs or course fees. Thus no separate VAT cost estimate is provided.

5.5 Sensitivity analyses

If travel costs of £10 per person per day are paid by the NHS boards then the annual costs would increase by £60 per person, equivalent to £120,000 a year to a total cost of almost £300,000 a year.

Note these costings assume NHS boards staff undertake the South of Scotland Cognitive Behavioural Therapy (CBT) Programme run by the QMU (Queen Margaret University) School of Health Sciences. An alternative approach would be for National Education Scotland (NES) to design, commission and quality assure a similar course. This work would be in conjunction with the psychologists and others within the diabetes teams in the NHS boards. If this approach was able to deliver targeted training, in a shorter period, then more staff in each board could be trained and thus enhance the capacity of the existing diabetes services to deliver these intervention.

6 Insulin analogues

6.1 Background

Sections 5.3.2 and 6.10.5 of the Guideline provided evidence indicating that short-acting insulin analogues and human insulin have a similar clinical efficacy over the longer term, for the management of adults with types 1 and 2 diabetes. The evidence in children similarly showed no clinical differences between the use of rapid-acting insulin analogues and regular human insulin.

The evidence led the Group to recommend that:

- An intensified treatment regimen for adults with type 1 diabetes should include either human or rapid-acting insulin analogues. Grade B
- Children and adolescents may use either insulin analogues (rapid-acting and basal), regular human insulin and NPH [Neutral Protamine Hagedorn, a synthetic mixture of insulin and protamine] preparations or an appropriate combination of these. Grade B
- Soluble human insulin or rapid-acting insulin analogues can be used when intensifying insulin regimens to improve or maintain glycaemic control [with type 2 diabetes]. Grade A

ISD prescribing data (http://www.isd.scot.nhs.uk/isd/information-and-statistics.jsp?pContentID=2241&p_applic=CCC&p_service=Content.show&) report that, measured in sales terms, insulin analogues have over 90% of the short-acting insulin market with human insulin having the remaining market share.

6.2 Patient group

The relevant patient groups are adults and children with types 1 and 2 diabetes, totalling 228,004 (source 2009 Diabetes Survey). The number of prescriptions for the three insulin analogues Novorapid[®], Apidra[®] and Humalog[®] was 146,100 compared with 14,644 for human insulin, mainly Humulin[®].

6.3 Additional resources required

The only implication of implementing this recommendation is a cost saving; some additional staff time will be required to explain to patients the choices of analogues available and encourage more to adopt human forms. This has not been measured.

6.4 Savings

The total expenditure on short-acting analogues was £7.48 million in the year to 31 March 2009 of which 91%, equivalent to £6.84 million, was spent on insulin analogues. The price of insulin analogues was about 6% higher per 10 mg vial and 9% higher per five 3 ml cartridges than the equivalent human insulin products. Assuming cartridges have about 80% of the market, as indicated by the prescribing data, then £0.53 million, could be saved if all current analogue use was switched to human insulin. This is equivalent to a reduction of 7.8% in the £6.84 million currently incurred purchasing insulin analogues.

A member of the Guideline Development Group advised that, with implementation support, it may be possible to increase the human insulin market share by 20–30% to 30–40%. This should be the aim for clinicians when intensifying insulin therapy for the first time. However, clinicians may find it difficult to switch patients from their existing regimen to a human insulin in order to reduce costs. If the market share of human insulin reached 35% then the savings could be about £150,000 a year across all boards. Table 3.3 allocates this sum across NHS boards in proportion to the number of people with diabetes in each board.

VAT

Any drug cost savings would also reduce VAT payments from the NHS board. Thus savings of £150,000 would be the equivalent of £176,250 including VAT.

6.5 Sensitivity analyses

If human insulin re-gains a 10% market share, the potential savings are about £58,000 across all NHS boards.

7 Continuous subcutaneous insulin infusion

7.1 Background

Section 5.3 of the Guideline noted that the use of continuous subcutaneous insulin infusion (CSII) or 'insulin pump' therapy had been evaluated in a number of meta-analyses, systematic reviews and randomised controlled trials for the management of type 1 diabetes. These showed that the therapy was associated with improved glycaemic control, with falls in the level of glycated haemoglobin, compared with multiple daily injections.

On the strength of the evidence, the Guideline recommended:

- CSII therapy is associated with modest improvements in glycaemic control and should be considered for patients unable to achieve their glycaemic targets. Grade A
- CSII therapy should be considered in patients who experience recurring episodes of severe hypoglycaemia. Grade B

Related good practice points included:

- Pump therapy should be available from a multidisciplinary pump clinic for patients who have undertaken structured education.
- An insulin pump is recommended for those with very low basal insulin requirements (such as infants and very young children), for whom even small doses of basal insulin analogue may result in hypoglycaemia.

These recommendations are similar to those made by NICE in (Multiple) Technology Appraisal Guidance No 151 – Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. The web reference for the appraisal and the related costing report and template documents is <http://www.nice.org.uk/guidance/TA151>. NHS Quality Improvement Scotland noted that there were no important differences between England and Scotland in this therapy and advised that the recommendations were valid for Scotland (http://www.nhshealthquality.org/nhsqis/controller?p_service=Content.show&p_applc=CCC&pContentID=4480).

This costing work draws on the NICE costing template and report.

7.2 Patient groups

The SIGN recommendations focus on two patient groups; children and patients with type 1 diabetes who are unable to achieve their glycaemic targets. Children were assumed to be those under 12 years old, consistent with the definition used by NICE.

Table 6 of the Scottish Diabetes Survey 2009 analysed the age, in five yearly groupings, for all 27,367 people with type 1 diabetes. These data were used to estimate that, in 2009, there were 1,083 children under 12 years of age with type 1 diabetes. This assumed the numbers in age group 10–14 years were evenly divided

over each of the 5 years. The number of people with type 1 diabetes aged 12 years or over was thus 26,284.

This report assumes 25% of these children (274) and 10% of adults (2,628) would be judged by clinical experts to be suitable for a pump; giving 2,902 in total. These usage rates of 25% and 10% are consistent with the NICE central case.

In 2009, 553 people already had insulin pumps (Table 22 Diabetes Survey 2009). This suggests an additional 2,350 insulin pumps may be required to meet the SIGN guideline recommendations. These are assumed to be introduced over 5 years at a rate of 470 per year. All 470 are assumed to be additional to the low level of historic implementation. Of these, 44 are assumed for use in children under 12 years old.

Table 7-1 provides the estimated additional annual demand for pumps by age group and by NHS board.

Table 7-1 Annual additional pump demand by age group and by NHS board

NHS board	Demand for pumps for under 12 years	Demand for pumps 12 years and over	Total pump demand
Ayrshire & Arran	4	41	46
Borders	1	7	8
Dumfries & Galloway	1	15	16
Fife	2	21	23
Forth Valley	3	25	28
Grampian	5	46	51
Greater Glasgow & Clyde	11	104	115
Highland	3	29	32
Lanarkshire	6	59	65
Lothian	5	52	57
Orkney	0	2	2
Shetland	0	2	2
Tayside	2	19	21
Western Isles	1	3	4
Total	44	426	470

(Rounding accounts for differences in absolute totals and calculated totals)

7.3 Additional resources required

The increased uptake of pumps will have implications for staff providing services for:

- structured education for children (adults services are addressed in Section 4);
- the assessment of potential patients for pump use at multidisciplinary clinics; and
- intensive support when the user receives a first pump.

The use of the pump is not assumed to change the numbers of regular clinic visits required. This is conservative; if glycaemic control is improved then the frequency of monitoring should reduce.

The key assumptions for each stage in the pathway are presented below. The sources of these assumptions are not referenced. These were informed by the many comments received from the SIGN Development Group members on an earlier draft of this work and from some work on the NICE website around implementing pumps in England.

<http://www.nice.org.uk/usingguidance/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=268>

Adults are assumed to have undertaken a structured education programme prior to assessment for a pump (see Section 4), with further intensive support when each starts on a pump. The pathway for children assumes the intensive education takes place after the identification of a child as a suitable pump user, together with intensive support when the pump is fitted.

Structured education programme and support: children

The Guideline Development Group members advised that the available adult education programmes for people with type 1 diabetes were not appropriate to use to cost the provision of pumps for children (Personal Communication Dr I Craigie, Yorkhill Diabetes Service Greater Glasgow & Clyde, January 2010). Two pathways were provided. The pathway supported by the Managed Clinical Network for Diabetes in NHS Greater Glasgow & Clyde included training in the school setting and intensive support, particularly during the first week of pump use. The NHS Lothian pathway has been implemented into clinical practice and is somewhat less intensive than that of NHS Greater Glasgow & Clyde. Table 7-2 describes the steps in the Lothian pathway and this has been used for the central case.

Table 7-2 Lothian guidance for CSII therapy for children with type 1 diabetes

Intervention	Diabetes nurse specialist hours	Specialist dietician hours	Consultant hours	Total hours
First visit	2.0			2.0
Second visit	0.5			0.5
Third visit	0.5			0.5
Pump start to week 4	15.0			15.0
At 4 weeks	1.0	0.5	0.5	2.0
Total (hours)	19.0	0.5	0.5	20.0

The description of the NHS Greater Glasgow & Clyde service noted administration support would be required but that was excluded from their estimates. An estimate of 1 hour per patient has been included in this analysis.

The number of children under 12 years receiving pump therapy is assumed to be 44. In addition, 18 adolescents under 16 years old are assumed to follow this pathway. Table 7-3 presents the estimated additional resource use required at each NHS board to provide a package of education and support for children under 16 years of age.

Table 7-3 Additional hours to deliver education and support to those under 16 years old by NHS board

NHS board	Number of people under 16 years fitted for pumps	Diabetes nurse	Dietician	Consultant	Admin	Total
Ayrshire & Arran	6	114	3	3	6	126
Borders	1	19	1	1	1	21
Dumfries & Galloway	2	38	1	1	2	42
Fife	3	57	2	2	3	63
Forth Valley	4	76	2	2	4	84
Grampian	7	133	4	4	7	147
Greater Glasgow & Clyde	15	285	8	8	15	315
Highland	4	76	2	2	4	84
Lanarkshire	9	171	5	5	9	189
Lothian	8	152	4	4	8	168
Tayside	3	57	2	2	3	63
Islands	1	19	1	1	1	21
Total	63	1,197	32	32	63	1,323

Multidisciplinary clinics: resources to assess potential patients for CSII

This analysis assumed:

- a multidisciplinary team comprising a consultant, a specialist diabetic nurse (AfC band 7) and a specialist diabetic dietitian (AfC band 6) assess the suitability of potential patients for CSII at review meetings
- five people are assessed to identify three successful patients for pumps, requiring 783 (470 multiplied by 5/3) cases to be reviewed annually
- each review meeting considers five potential clients for a pump
- only four cases are concluded at each meeting, with one case requiring further data.

Thus 196 (783/4) additional meetings were assumed to be required. The mean hours to prepare for and attend the assessment meeting were assumed to be 2 hours for a diabetes nurse and 1 hour each for the consultant and dietician. After the meeting the nurse was assumed to incur a further 1 hour for each successful client in communications with others and ordering a pump. Table 7-4 provides estimates of the total additional hours required by function and Table 7-5 provides the estimated additional hours for each NHS board, to assess patients suitable for pumps.

Table 7-4 Multidisciplinary team assessment and immediate follow up

Specialty and grade	Mean hours per meeting (including pre- and post-clinic)	Total hours
Consultant	1	196
Specialist diabetic nurse (AfC 7)	2+1 hour per successful patient	862
Specialist diabetic dietitian (AfC 6)	1	196
Total	5	1,254

Table 7-5 Estimate additional assessment hours by grade by NHS board

NHS board	Consultant	Specialist diabetic nurse	Specialist diabetic dietician	Total
Ayrshire & Arran	19	83	19	121
Borders	3	15	3	21
Dumfries & Galloway	7	29	7	43
Fife	10	43	10	63
Forth Valley	11	50	11	73
Grampian	21	94	21	137
Greater Glasgow & Clyde	48	210	48	305
Highland	13	59	13	86
Lanarkshire	27	121	27	175
Lothian	24	104	24	151
Orkney	1	3	1	5
Shetland	1	4	1	5
Tayside	9	39	9	56
Western Isles	2	7	2	10
Total	196	862	196	1,254

Support for new adult pump users

Follow up from day 1 for adults commencing pump therapy is assumed to follow the Greater Glasgow & Clyde adult pathway, excluding the component relating to carbohydrate counting. This aspect will have been covered in the structured education programme. This pathway requires the resources shown in Table 7-6. The additional resources required to follow up 407 adults over 16 years of age, starting on pump therapy and following this pathway is provided in Table 7-7.

Table 7-6 Additional hours to support a new adult user on a CSII

Intervention	Nurse	Dietician	Consultant	Total
Day 1	4			4
Day 2	0.5			0.5
Day 3	2			2
During 1 week	0			0
Week 1–2	2			2
Week 4	2			2
Week 8–12	2			2
Pump clinic	0.5	0.5	0.5	1.5
Total	13.0	0.5	0.5	14.0

Table 7-7 Additional hours required to support new adult users on CSII by NHS board

NHS board	Number of adults (> 16 years) fitted for pumps	Consultant	Specialist diabetic Nurse	Specialist diabetic dietician	Total
Ayrshire & Arran	40	20	520	20	560
Borders	7	4	91	4	98
Dumfries & Galloway	14	7	182	7	196
Fife	20	10	260	10	280
Forth Valley	24	12	312	12	336
Grampian	44	22	572	22	616
Greater Glasgow & Clyde	100	50	1,300	50	1,400
Highland	28	14	364	14	392
Lanarkshire	56	28	728	28	784
Lothian	49	25	637	25	686
Orkney	2	1	26	1	28
Shetland	2	1	26	1	28
Tayside	18	9	234	9	252
Western Isles	3	2	39	2	42
Total	407	204	5,291	204	5,698

The total resources required for assessment and support, including structured education for under 16 year olds by NHS board is provided in Table 7-8.

Table 7-8 Additional hours required by NHS boards to implement CSII by NHS board

NHS board	Diabetes nurse	Dietician	Consultant	Clerical	Total
Ayrshire & Arran	717	42	42	6	807
Borders	125	7	7	1	140
Dumfries & Galloway	249	15	15	2	281
Fife	360	21	21	3	406
Forth Valley	438	25	25	4	493
Grampian	799	47	47	7	900
Greater Glasgow & Clyde	1,795	105	105	15	2,020
Highland	499	29	29	4	562
Lanarkshire	1,020	60	60	9	1,148
Lothian	893	52	52	8	1,005
Orkney	29	2	2	0	33
Shetland	30	2	2	0	33
Tayside	330	19	19	3	371
Western Isles	65	4	4	1	74
Total	7,350	431	431	63	8,274

7.4 Additional costs required

Estimated capital and consumable cost for pumps

The main cost elements are the pumps and related consumables. National Procurement has a national purchasing agreement in place with several manufacturers, each offering a volume-related price. Assuming the majority of pumps are sourced from the cheapest manufacturer then the mean capital cost is estimated at £2,050^{iv}. The annual cost of buying 470 pumps is £963,500. The total cost of buying 2,350 pumps over 5 years is £4.8 million.

In addition, consumables cost of about £1,500 per pump will be incurred^{iv}. This will be partly offset by savings in consumables because the user no longer requires multiple daily injections. NICE assumed these to be £400 per user annually. Using pumps should also reduce the quantity of insulin required per user; this has been valued at about £150 per user.

(<http://guidance.nice.org.uk/TA151/Costingtemplate/xls/English>).

The net increase in consumable costs is about £950 (excluding depreciation) per pump user. The costs in the first year are £444,620 and increase by this amount each year as an additional 470 users are added to the existing number of users. In year 5, the additional cost for consumables for 2,350 pumps is £2.2 million. Over the 5 years, the NHS boards will incur estimated additional operating costs of £6.7 million for the additional pumps.

Table 7-9 tabulates the estimated additional capital and operating costs associated with providing an additional 470 CSII pumps each year for 5 years.

Table 7-9 Estimated additional capital and operating costs (excluding VAT) by NHS board

NHS board	Capital costs per year	Total capital costs over 5 years	Additional consumable costs per year	Additional annual consumable cost at year 5	Total additional consumable cost
Ayrshire & Arran	£94,300	£471,500	£43,516	£217,580	£652,740
Borders	£16,400	£82,000	£7,568	£37,840	£113,520
Dumfries & Galloway	£32,800	£164,000	£15,136	£75,680	£227,040
Fife	£47,150	£235,750	£21,758	£108,790	£326,370
Forth Valley	£57,400	£287,000	£26,488	£132,440	£397,320
Grampian	£104,550	£522,750	£48,246	£241,230	£723,690
Greater Glasgow & Clyde	£235,750	£1,178,750	£108,790	£543,950	£1,631,850
Highland	£65,600	£328,000	£30,272	£151,360	£454,080
Lanarkshire	£133,250	£666,250	£61,490	£307,450	£922,350
Lothian	£116,850	£584,250	£53,922	£269,610	£808,830
Orkney	£4,100	£20,500	£1,892	£9,460	£28,380
Shetland	£4,100	£20,500	£1,892	£9,460	£28,380
Tayside	£43,050	£215,250	£19,866	£99,330	£297,990
Western Isles	£8,200	£41,000	£3,784	£18,920	£56,760
Total	£963,500	£4,817,500	£444,620	£2,223,100	£6,669,300

Estimated costs for a) structured education programmes and support for those under 16 years old; b) multidisciplinary assessment clinics; and c) support for new adult pump users

The relevant unit costs for each of these elements are all staff related. The salary, overheads and hours worked for each relevant grade are presented in Table 7-10. The staff rates were obtained from <http://www.nhscareers.nhs.uk/details/Default.aspx?Id=766> and the assumptions on hours of patient contact by function from Personal Social Services Research Unit (PSSRU) <http://www.pssru.ac.uk/uc/uc2009contents.htm>.

Table 7-10 Staff costs per hour by AfC grade

Function	AfC grade	Mid point	Plus 23% on costs	Total staff costs	Hours with patients per year	Cost per hour
Specialist Diabetic Nurse	7	£34,410	£7,914	£42,324	1,239	£34.16
Specialist Diabetic dietician	6	£28,816	£6,628	£35,444	1,239	£28.61
Administrator	3	£16,700	£3,841	£20,541	1,575	£13.04
Consultant	MC72 (6)	£120,000	£27,600	£147,600	1,793	£82.32

Applying these rates to the hourly resources detailed in the previous section gives the following costs to support children in using pumps, including some structured education (Table 7-11), assessing potential users for pumps (Table 7-12) and supporting new adults in using pumps (Table 7-13).

Table 7-11 Estimate of additional costs to deliver education and support to those under 16 years by NHS board

NHS board	Number of people under 16 years fitted for pumps	Diabetes nurse	Dietician	Consultant	Admin	Total
Ayrshire & Arran	6	£3,894	£86	£247	£78	£4,305
Borders	1	£649	£14	£41	£13	£718
Dumfries & Galloway	2	£1,298	£29	£82	£26	£1,435
Fife	3	£1,947	£43	£123	£39	£2,153
Forth Valley	4	£2,596	£57	£165	£52	£2,870
Grampian	7	£4,543	£100	£288	£91	£5,023
Greater Glasgow & Clyde	15	£9,736	£215	£617	£196	£10,763
Highland	4	£2,596	£57	£165	£52	£2,870
Lanarkshire	9	£5,841	£129	£370	£117	£6,458
Lothian	8	£5,192	£114	£329	£104	£5,740
Tayside	3	£1,947	£43	£123	£39	£2,153
Islands	1	£649	£14	£41	£13	£718
Total	63	£40,890	£901	£2,593	£822	£45,205

Table 7-12 Estimate additional assessment costs by grade by NHS board

NHS board	Consultant	Specialist diabetic nurse	Specialist diabetic dietician	Total
Ayrshire & Arran	£1,562	£2,852	£543	£4,956
Borders	£275	£503	£96	£874
Dumfries & Galloway	£551	£1,005	£191	£1,747
Fife	£808	£1,476	£281	£2,566
Forth Valley	£944	£1,724	£328	£2,997
Grampian	£1,763	£3,219	£613	£5,595
Greater Glasgow & Clyde	£3,924	£7,165	£1,364	£12,452
Highland	£1,104	£2,017	£384	£3,505
Lanarkshire	£2,257	£4,121	£784	£7,162
Lothian	£1,947	£3,554	£676	£6,177
Orkney	£65	£119	£23	£207
Shetland	£69	£126	£24	£219
Tayside	£725	£1,323	£252	£2,299
Western Isles	£125	£228	£43	£396
Total	£16,119	£29,431	£5,601	£51,152

Table 7-13 Estimate of additional costs required to support new adult users on CSII by NHS board

NHS board	Number of adults (>16 years) fitted for pumps	Consultant	Specialist diabetic nurse	Specialist diabetic dietician	Total
Ayrshire & Arran	40	£1,646	£17,763	£572	£19,982
Borders	7	£288	£3,109	£100	£3,497
Dumfries & Galloway	14	£576	£6,217	£200	£6,994
Fife	20	£823	£8,882	£286	£9,991
Forth Valley	24	£988	£10,658	£343	£11,989
Grampian	44	£1,811	£19,540	£629	£21,980
Greater Glasgow & Clyde	99	£4,116	£44,408	£1,430	£49,954
Highland	28	£1,152	£12,434	£400	£13,987
Lanarkshire	57	£2,305	£24,869	£801	£27,974
Lothian	50	£2,017	£21,760	£701	£24,478
Orkney	2	£82	£888	£29	£999
Shetland	2	£82	£888	£29	£999
Tayside	18	£741	£7,993	£257	£8,992
Western Isles	3	£123	£1,332	£43	£1,499
Total	407	£16,752	£180,741	£5,821	£203,314

The total annual costs of providing 470 pumps (63 to children and 407 to adults over 16 years old) to people with type 1 diabetes who are unable to achieve their glycaemic targets or experience recurring episodes of severe hypoglycaemia are almost £0.75 million a year, as shown in Table 7-14.

Table 7-14 Estimate of additional costs required to support 470 new CSII pumps by NHS board

NHS board	Assessment clinics	Education and follow up: under 16 years	Adult follow up	Pump consumables (year 1)	Total (year 1)
Ayrshire & Arran	£4,956	£4,305	£19,982	£43,516	£72,759
Borders	£874	£718	£3,497	£7,568	£12,656
Dumfries & Galloway	£1,747	£1,435	£6,994	£15,136	£25,312
Fife	£2,566	£2,153	£9,991	£21,758	£36,467
Forth Valley	£2,997	£2,870	£11,989	£26,488	£44,344
Grampian	£5,595	£5,023	£21,980	£48,246	£80,843
Greater Glasgow & Clyde	£12,452	£10,763	£49,954	£108,790	£181,960
Highland	£3,505	£2,870	£13,987	£30,272	£50,634
Lanarkshire	£7,162	£6,458	£27,974	£61,490	£103,084
Lothian	£6,177	£5,740	£24,478	£53,922	£90,317
Orkney	£207	£0	£999	£1,892	£3,098
Shetland	£219	£0	£999	£1,892	£3,110
Tayside	£2,299	£2,153	£8,992	£19,866	£33,310
Western Isles	£396	£718	£1,499	£3,784	£6,396
Total	£51,152	£45,205	£203,314	£444,620	£744,291

At year 5, the additional annual costs are estimated to be £2.5 million, as shown in Table 7-15. The increase is caused by the additional annual costs to supply consumables for 2,350 pumps.

Table 7-15 Estimate of additional annual costs, year 5, required to support 2,450 CSII pumps by NHS board (£'000)

NHS board	Number of pumps	Assessment reviews	Education and follow up: children pumps	Adult follow up	Pump consumables	Total
Ayrshire & Arran	230	£4.3	£5.0	£20.0	£217.6	£246.8
Borders	40	£0.7	£0.9	£3.5	£37.8	£42.9
Dumfries & Galloway	80	£1.4	£1.7	£7.0	£75.7	£85.9
Fife	115	£2.2	£2.6	£10.0	£108.8	£123.5
Forth Valley	140	£2.9	£3.0	£12.0	£132.4	£150.3
Grampian	255	£5.0	£5.6	£22.0	£241.2	£273.8
Greater Glasgow & Clyde	575	£10.8	£12.5	£50.0	£544.0	£617.1
Highland	160	£2.9	£3.5	£14.0	£151.4	£171.7
Lanarkshire	325	£6.5	£7.2	£28.0	£307.5	£349.0
Lothian	285	£5.7	£6.2	£24.5	£269.6	£306.0
Orkney	10	£0.0	£0.2	£1.0	£9.5	£10.7
Shetland	10	£0.0	£0.2	£1.0	£9.5	£10.7
Tayside	105	£2.2	£2.3	£9.0	£99.3	£112.8
Western Isles	20	£0.7	£0.4	£1.5	£18.9	£21.5
Total	2,350	£45.2	£51.2	£203.3	£2,223.1	£2,522.8

VAT

VAT at 17.5% is payable on the pump purchase costs and consumables. Thus the annual capital cost to purchase 470 pumps rises from £963,500 to £1,132,113 when VAT is included. The annual consumable costs increase from £444,620 to £522,429.

7.5 Sensitivity analyses

The key parameter for the cost of the CSII recommendation is the number of people assessed for and subsequently offered a pump. The central case assumed 470. The capital and operating costs associated with an annual rise to 600 or a fall to 350 are presented in Table 7-16.

Table 7-16 Sensitivity analyses assuming 350 and 600 additional pump users a year

Number of pumps a year	Capital costs			Operating costs (cash only ie excluding depreciation) £'000		
	Year 1	Year 5	Cumulative costs	Year 1	Year 5	Cumulative costs
470	£963,500	£963,500	£4,817,500	£744.3	£2,522.8	£,8167.7
350	£697,760	£697,760	£3,488,800	£554.3	£1,878.7	£6,082.3
600	£1,196,160	£1,196,160	£5,980,800	£950.2	£3,220.6	£10,426.9

8 Gestational diabetes

8.1 Background

Two randomised controlled trials have shown that interventions to manage gestational diabetes mellitus (GDM) improved clinical outcomes for the mother and baby. This evidence led the Guideline Development Group's recommendation that NHS boards should offer all women, during their pregnancy, a screening programme to detect and treat diabetes. The Guideline noted there was some uncertainty about the best screening strategy but noted the International Association of Diabetes and Pregnancy Study Group's (IADPSG)^v consensus document recommended that all 'high-risk' women should be offered screening using a glucose tolerance test.

High risk was defined as:

- body mass index (BMI) more than 30 kg/m²
- previous macrosomic baby weighing 4.5 kg or more
- previous gestational diabetes
- family history of diabetes (first degree relative with diabetes)
- family origin with a high prevalence of diabetes
- south Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh), black Caribbean and Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt).

The final recommendations were:

- A suitable programme to detect and treat gestational diabetes should be offered to all women in pregnancy. Grade A
- Pregnant women with GDM should be offered dietary advice and blood glucose-lowering therapy depending on target values for fasting and postprandial targets. Grade A
- Metformin or glibenclamide may be considered as initial pharmacological, glucose-lowering treatment in women with gestational diabetes. Grade B

Accompanying these recommendations were the several best practice points including that:

- All women with risk factors should have a 75g oral glucose tolerance test (OGTT) at 24–28 weeks.
- A fasting plasma glucose at 24–28 weeks is recommended in low-risk women.

The approach to costing this recommendation draws heavily on the work of NICE on clinical guidelines on 'Diabetes in pregnancy and antenatal care' (CG0620)

http://www.nice.org.uk/usingguidance/implementationtools/costingtools/costing_tools_doc.js

[p?o=40131](#). The assumptions in the NICE Guidelines have been revised following consultation with SIGN Guideline Development Group members and Ms Lesley Marr, Reproductive Health Programme Co-ordinator NHS Quality Improvement Scotland.

8.2 Patient group

The relevant patient group is pregnant women with high risk factors. Data from the SMR02 records (<http://www.datadictionaryadmin.scot.nhs.uk/isddd/9066.html>) provided by ISD, in December 2009, identified that 19% of pregnant mothers in Scotland were obese (defined as BMI \geq 30) and under 1% had previous gestational diabetes. Some members suggested this figure was low but no alternative robust source was available. In addition, 5% of pregnant women were assumed to be in a high-risk ethnic group and 10% have a family history of diabetes. NICE assumed all factors were independent (<http://guidance.nice.org.uk/CG62/Guidance/pdf/English>). Using the same assumption, this suggests about 34% of pregnant women have one or more risk factors. (The equivalent value from NICE was 44%, with the main difference being NICE assumed that 30% of pregnant women were obese).

Total maternities in Scotland in 2009 were 60,366, suggesting 20,524 women may qualify to be screened. This report rounds this to 21,000 in view of the rise in obesity rates and the general concern that the ISD data under report obesity in this group.

8.3 Additional resources required

The additional resources required are to carry out different and more diagnostic tests and to subsequently manage the additional women who are found to have GDM.

Additional diagnostic tests

The main resources required are the additional oral glucose tolerance tests (OGTT) and the staff time to take and report them. The total number of tests needed can be predicted from the number of women in the high-risk group. However, to calculate the additional number of tests needs a robust estimate of the numbers currently conducted by the NHS boards. In the absence of any specifically collected data, a brief literature search was undertaken. This identified that NICE used data from a survey by Mires *et al* (1999)^{vi} to inform its assumptions on the current forms of screening and testing for GDM in England (<http://www.nice.org.uk/nicemedia/pdf/CG063CostReport.pdf>).

SIGN Guideline Development pregnancy sub-group members were asked if they were aware of a more recent reference source which generalised to Scotland. Responses indicated there was no published source. However, some members advised that the Mires data overstated the use of OGTT tests in Scotland, whilst others felt it understated their use. In February 2010, the SIGN lead of the pregnancy sub-group, advised that the Mires data were sufficiently robust to inform a central case for costing purposes (Personal communication, Dr Robbie Lindsay, Senior Lecturer in Diabetes and Endocrinology, University of Glasgow).

The key assumptions in the central case thus use the Mires data and are:

1. Currently a diagnostic test is offered to pregnant women with risk factors in 40% of units; the diagnostic test used is the 2-hour 75 g OGTT and the risk factors are similar to those listed in the Guideline.
2. A biochemical test, followed by a diagnostic test where indicated, is offered to pregnant women with risk factors in 32% of units. The biochemical test is assumed to be a random blood glucose test, the diagnostic test used is the 2-hour 75 g OGTT, and the risk factors are similar to those listed in the Guideline.
3. A biochemical test, followed by a diagnostic test where indicated, is offered to all pregnant women in 17% of units. The biochemical test is assumed to be a random blood glucose test, and the diagnostic test used is the 2-hour 75 g OGTT.
4. Eleven per cent of units do not screen.
5. The 2-hour 75 g OGTT was assumed to have a sensitivity and specificity of 100%. Of women tested, 16.1% were assumed to have glucose concentrations that exceeded the recommended international diagnostic thresholds for GDM. The rate and the diagnostic threshold were reported from analysis of the findings of the Hyperglycaemia & Adverse Pregnancy Outcome (HAPO) study of 25,505 pregnant women at 15 centres in nine countries (IADPSG, in press 2010).
6. The random blood glucose test was assumed to have a sensitivity of 48% and a specificity of 97%. In a high-risk group this test was assumed to detect 6.7% of women as GDM positive, falling to 4.5% if the test was performed on all women. This affects the number of women who are not diagnosed with gestational diabetes currently and hence do not proceed to treatment.
7. An OGTT takes 45 minutes and a random blood test takes 5 minutes of the time of a nursing or midwifery assistant or equivalent. This includes giving information to the woman.

Numbers screened

Table 8-1 applies these assumptions to 21,000 women with high risk factors and 60,366 maternity events to give current and future numbers of women screened and tested. The recommended practice would save annually almost 17,000 biochemical tests, increase the number of OGTT tests by about 11,700 to 21,000 and result in an additional 1,600 women identified with GDM.

Table 8-1 Numbers of women screened and tested for gestational diabetes

Current practice	Biochemical tests	Positive cases	OGTT	Positive cases
In 40% test high-risk women with OGTT			8,400	1,352
In 32% high risk get biochemistry: if +ve OGTT	6,720	448	448	254
In 17% biochemistry for all: if +ve OGTT (11% no test)	10,262	466	466	172
Total tests and positives	16,982		9,315	1,779
Recommended practice				
Test all high-risk women with OGTT			21,000	3,381
Additional tests and women detected	(16,982)		+11,685	1,602

The additional annual staff resources required are 7,350 hours, comprising:

- 45 minutes of a midwife assistant for 11,685 additional OGTT tests, equivalent to 8,765 hours; minus
- savings of 5 minutes each for 16,982 tests.

Table 3.1 shows the allocation of these additional hours to NHS boards using the number of live births in 2009 as the basis for the allocation.

Additional resources to manage the extra cases

The management of these additional women is assumed to follow a pathway set out by NICE and agreed as appropriate for Scotland (Personal communication, Dr Robbie Lindsay, Senior Lecturer in Diabetes and Endocrinology, University of Glasgow, February 2010).

Diet and lifestyle changes are assumed to be sufficient to achieve a reduction in hypoglycaemic levels in 65% of women identified with GDM, with 20% requiring oral medication and 15% insulin or insulin analogues. These women may also require more intensive consultant-led management. However, most of these women will have been identified as having higher risk pregnancies at the outset and thus managed in consultant-led clinics.

8.4 Additional costs required

The additional costs required are to carry out different and more diagnostic tests and to subsequently manage the additional women who are found to have GDM.

Additional costs of diagnostic tests

The costing of diagnostic tests has two components; the staff time with the women and the cost of the testing process. The estimated staff cost per hour of patient contact for a nursing assistant or midwifery assistant is shown in Table 8-2. This has taken the midpoint of the bands 3 and 4, 1 April 2009 pay scales plus 23 % for on costs. The proportion of time spent on patient contact is taken from the Personal Social Services Research Unit (PSSRU) 'Unit costs for health and social care 2007 (<http://www.pssru.ac.uk/uc/uc2007contents.htm>)'.

Table 8-2 Hourly staff costs for midwifery assistant

AfC Band mid point B3/B4	£18,157
Employers on costs 23%	£22,333
Annual working hours	1,655
% clinical activity	60%
Number of hours patients contact	993
Cost per hour of client contact	£22.49

(Note: cost for a band 7 midwife would be £42.62)

The estimated costs of an OGTT test and a random blood test, including the staffing element are given in Table 8-3.

Table 8-3 Unit cost of tests

Task or consumable	Cost	Source
OGTT test (2 samples) lab. staff, reagents, instruments	£1.14	Personal communication; Dr J Burns, Quality Manager, Department of Biochemical Medicine, NHS Tayside, 9 December 2009
Transport to lab and reporting from lab	£0.30	Assumption based on marginal cost
Staff time to take test	£16.87	45 minutes band 3 or 4
Total	£18.31	
Random blood test	£1.50	NICE
Staff time	£1.85	5 minutes band 3 or 4
Transport to lab and reporting from lab	£0.30	Assumption based on marginal cost
Random blood test	£3.65	

The additional annual costs required are £151,965, comprising:

- £213,950 for 11,685 additional OGTT tests: minus
- £61,985 savings from 16,982 fewer biochemical tests.

Additional costs of managing more women diagnosed with GDM

Table 8-4 provides the unit costs assumed to monitor GDM and of the two drug-based interventions. The cheapest combination of lancets, strips and blood glucose meter has been assumed. The cost of £3.09 for oral medication is an average of the cost to manage a woman on glibenclamide (15 mg daily) and metformin (1,500 mg daily) for 90 days. The cost of £60.95 is the unit cost of insulin or insulin analogue treatment of GDM, assuming the former has a 9% market share. All the costs are from the NICE Costing Report

(<http://www.nice.org.uk/nicemedia/pdf/CG063CostReport.pdf>).

Table 8-4 Unit costs of managing women with GDM

Unit cost of glucose monitoring	
Additional blood glucose meter	£5.63
Additional lancets	£11.40
Additional test strips	£97.79
Total unit cost of glucose monitoring	£114.82
Post-natal fasting plasma glucose test	£3.37
Cost of treatment with oral medication	£3.09
Cost of treatment with insulin or insulin analogues	£60.95

The estimated additional annual costs of managing the 1,600 additional women diagnosed with GDM are shown in Table 8-5.

Table 8-5 Additional annual costs to manage additional women diagnosed with GDM

	Number on pathway	Total costs
Additional blood glucose meter	1,600	£9,008
Additional lancets	1,600	£18,240
Additional test strips	1,600	£156,464
Cost of treatment with oral medication	320	£989
Cost of treatment with insulin or insulin analogues	240	£14,628
Post-natal fasting plasma glucose test *2	3,200	£10,784
Total annual costs		£210,113

The additional annual cost of implementing these recommendations is thus estimated to be about £362,088 comprising £151,965 for the additional diagnostic tests and £210,113 to manage the increase in the numbers of women detected with GDM.

Table 8-6 analyses the additional costs and staff time by NHS board. The allocation basis is live births in 2009.

Table 8-6 Additional costs and staff time by NHS board

NHS board	Total live births	% of all births	Additional costs	Additional hours
Ayrshire & Arran	3,914	6.6%	£24,002	487
Borders	1,157	2.0%	£7,095	144
Dumfries & Galloway	1,507	2.6%	£9,241	188
Fife	4,135	7.0%	£25,357	515
Forth Valley	3,345	5.7%	£20,512	416
Grampian	6,433	10.9%	£39,449	801
Greater Glasgow & Clyde	14,015	23.7%	£85,944	1,744
Highland	3,189	5.4%	£19,556	397
Lanarkshire	6,575	11.1%	£40,320	818
Lothian	9,719	16.5%	£59,600	1,210
Orkney	199	0.3%	£1,220	25
Shetland	273	0.5%	£1,674	34
Tayside	4,358	7.4%	£26,724	542
Western Isles	227	0.4%	£1,392	28
Total	59,046	100.0%	£362,086	7,349

VAT

VAT is payable on the non-staff component of the costs. Including VAT at 17.5%, the annual costs increase to £396,778, comprising:

- £149,895 for additional tests; and
- £ £246,883 for additional management of women detected with GDM.

It should be noted that the estimated cost of the additional tests is slightly lower including VAT because the cost of the OGGT is lower than the cost of the blood test; adding VAT increases the saving from the consumables.

8.5 Sensitivity analyses

If 80% rather than 40% of units are currently testing women with high-risk factors with an OGTT test then the additional diagnostic tests could fall to £56,000 a year, with an additional 520 women being detected with GDM. The additional management costs would fall to about £70,000 a year.

If the proportion of women found with GDM was 8%, rather than 16.1%, then the number of additional women detected would fall from 1,600 to 580, with the additional management costs being £76,000 per year. If the proportion was 20%, then the number of additional women detected would rise from 1,600 to 2,100 with the additional management costs being £275,000 per year.

9 Lipid-lowering therapy

9.1 Background

Two randomised controlled trials have demonstrated that in people with diabetes and previous myocardial infarction (MI), or other objective evidence of coronary heart disease, prescribing atorvastatin 80 mg reduced major cardiovascular events, compared with prescribing pravastatin 40 mg.

The relevant SIGN guideline recommendation in section 8.4.7 is:

- Intensive lipid-lowering therapy with atorvastatin 80 mg should be considered for patients with diabetes and acute coronary syndromes, objective evidence of coronary heart disease or following coronary procedures. Grade A

9.2 Patient group

The relevant patient group for this recommendation was assumed to be patients with acute coronary syndromes (ACS) plus those who have undergone cardiac revascularisation. SIGN 93^{vii} defined ACS to include patients with unstable angina and acute MI.

The Scottish Diabetes Survey 2009 identified that 1,026 patients registered with type 1 diabetes and 20,445 patients with type 2 diabetes, have a recorded previous MI. This is a prevalence of 9.5%. The same survey identified that 736 patients with type 1 diabetes and 13,584 patients with type 2 diabetes have taken cardiac revascularisation; an event rate of 6.3%. Together these sum to 35,791 patients.

The recommendation requires that patients with unstable angina be considered for atorvastatin 80 mg. If one assumes this therapy is prescribed on discharge from hospital then a further 350 patients a year could be switched to atorvastatin 80 mg. This is estimated from the number of patients admitted to hospital with unstable angina, about 3,680, (ISD analysis of inpatients coded to ICD10 code I20, described as unstable angina.) and assuming a 9.5% prevalence of diabetes as a co-morbidity (the same as the MI prevalence).

The estimated number of people with diabetes who could be prescribed atorvastatin 80 mg is about 36,140. Table 9-1 shows this by NHS board. Of these 3% are assumed to be contraindicated and 4% will suffer adverse events. These people could be prescribed drugs such as a fibrate or nicotinic acid and these are assumed to be unaffected by the recommendation. Thus around 33,600 will be maintained on statins. These estimates are taken from earlier work for a Clinical and Resource Impact Report to accompany SIGN 97 'Risk estimation and the prevention of cardiovascular disease' <http://www.sign.ac.uk/pdf/chdaudit.pdf>.

Table 9-1 Estimate of people with diabetes and ACS or cardiac revascularisation

NHS board	MI	Cardiac revasc.	Unstable angina	Total ACS + revasc and diabetes	Less 7%
Ayrshire & Arran	1,697	1,050	28	2,775	2,581
Borders	481	308	8	797	741
Dumfries & Galloway	569	373	11	953	887
Fife	1,532	900	26	2,458	2,286
Forth Valley	1,291	768	20	2,079	1,934
Grampian	2,042	1,427	35	3,504	3,258
Greater Glasgow & Clyde	5,004	3,631	81	8,716	8,106
Highland	1,198	771	20	1,989	1,850
Lanarkshire	2,542	1,746	40	4,328	4,025
Lothian	2,899	2,003	49	4,951	4,604
Orkney	77	52	1	130	121
Shetland	54	33	1	88	82
Tayside	1,980	1,192	28	3,200	2,976
Western Isles	105	66	2	173	161
Total	21,471	14,320	350	36,141	33,611

9.3 Additional resources required

Atorvastatin 80 mg

The main resource requirement was assumed to be the costs of switching from the existing lipids regimen to one with atorvastatin 80 mg. All patients with diabetes and established heart disease were assumed to be prescribed a statin. To estimate the higher cost it was necessary to know the current lipid-lowering drugs prescribed. This used information from the NHS formularies and ISD prescription data.

The web-based joint formularies for NHS Greater Glasgow & Clyde, NHS Lothian, NHS Grampian, NHS Tayside, NHS Ayrshire & Arran and NHS Fife (the web version for NHS Lanarkshire was not available) were reviewed for lipid-regulating therapies. All formularies had simvastatin 40 mg as first line. Most did not distinguish between secondary prevention with diabetes, as opposed to no diabetes. The common pathway was first-line simvastatin 40 mg, with titration up to atorvastatin 80 mg according to response to treatment.

The first step was to estimate how many of these patients currently may be prescribed atorvastatin 80 mg. A prescription cost analysis for Scotland for year ending 31 March 2009 reported that the total number of prescribed items for atorvastatin 80 mg was 147,491, with an associated cost of £6.6 million (source http://www.isdscotland.org/isd/information-and-statistics.jsp?pContentID=2241&p_applic=CCC&p_service=Content.show&).

The monthly cost of atorvastatin 80 mg is £28.21 (source: British National Formulary, <http://bnf.org/bnf/bnf/59/60592.htm> checked 2 April 2010), equivalent to £338 a year. Dividing the £6.6 million by £338 suggests about 19,500 people are prescribed atorvastatin 80 mg. There is no information to identify the how many of these have ACS and diabetes. However those post-MI and with diabetes are a high-risk group and thus candidates for this therapy. The base case assumes 15,000 of the 21,471 people with MI and diabetes (70%) are already on atorvastatin 80 mg and the remaining 18,611 (33,611–15,000) are on other lipid-lowering statins. This is equivalent to assuming that in 2009 almost 77% of the prescribing of atorvastatin 80 mg was to people with ACS and diabetes.

Other lipid-lowering therapies

The prescription cost analysis was used to estimate the lipid-lowering therapies prescribed to the remaining 18,611 people. The market shares, ranked by quantity dispensed, were obtained (see column 2 Table 9-2). Thus simvastatin 40 mg had a 40% market share.

The efficacy of each drug was obtained from the earlier work <http://www.sign.ac.uk/pdf/chdaudit.pdf>. These rates are shown in column 3 of Table 9-2.

The statins prescribed to this patient group were assumed to be equally, or more, efficacious compared with simvastatin 40 mg. Removing statins with a lowering efficacy than simvastatin 40 mg, and re-calculating the market shares for 2009, suggested simvastatin 40 mg had a 63% share of the market for these more effective lipid-lowering drugs. If people with diabetes received the same lipid-lowering therapy as the general population, then in year to 31 March 2009, 63% were prescribed simvastatin 40 mg, 26% atorvastatin 20/40 mg, 5% atorvastatin 80 mg and 6% rouvastatin 10/20 mg. These rates are shown in column 4 of Table 9-2.

Table 9-2 Market share of all lipid-regulating drugs in 12 months to 31 March 2009

Lipid-regulating drugs	Market share by volume	Efficacy	Revised market share
Simvastatin 40 mg	40%	28%	63%
Simvastatin 20 mg	18%	26%	
Atorvastatin 20/40 mg	17%	32/36%	26%
Atorvastatin 10 mg	6%	27%	
Simvastatin 10 mg	4%	20%	
Pravastatin 40 mg	3%	22%	
Atorvastatin 80 mg	3%	39%	5%
Rouvastatin 10 or 20 mg	4%	33%	6%
Others	5%		
Total	100%		100%

However, simvastatin 40 mg is also used as a first-line treatment for primary prevention. Ideally this group would be removed from the ISD prescribing data to leave secondary prevention prescribing data only. Such information was not available but was estimated by assuming 300,000 people were prescribed statins for secondary prevention for coronary vascular disease in 2009 (source: <http://www.sign.ac.uk/pdf/chdaudit.pdf>.)

This group was assumed to be prescribed statins starting with the most efficacious first, then the second most efficacious. The ordering was thus atorvastatin 80 mg, then atorvastatin 40 mg, rouvastatin 10 or 20 mg and atorvastatin 20 mg. Those who were not prescribed one of these statins were assumed to be prescribed simvastatin 40 mg. The number of people prescribed the more efficacious statins was estimated by taking the total cost for these statins to NHSScotland and dividing by the annual cost to prescribe to one patient. For example, the total annual costs of atorvastatin 10/20 mg was £31,484,33, and the annual cost to prescribe to one person was £295.68, suggesting about 106,480 people received this drug (see columns 2,3 and 4 of Table 9-3).

However, the number receiving atorvastatin 80 mg was capped at 15,000 (see earlier section on atorvastatin 80 mg). This approach suggested that the simvastatin market share for secondary prevention was 52%, with atorvastatin 20/40 mg having 36%, rouvastatin 10/20 mg having 7% and atorvastatin 80 mg having 5%. These values are shown in Table 9-3.

Table 9-3 Estimated market share of statins for secondary prevention in 12 months to 31 March 2009

Lipid-regulating drugs	Annual costs to NHSScotland	Per patient	Number of full year patients	2 nd prevention	% of market share
Simvastatin 40 mg	£3,912,435	£15.84	246,997	156,860	52%
Atorvastatin 20/40 mg	£31,484,333	£295.68	106,481	106,481	36%
Atorvastatin 80 mg	£6,595,755	£338.52	19,484	15,000	5%
Rouvastatin 10 or 20 mg	£5,252,194	£242.50	24,275	21,659	7%
Total	£47,244,717			300,000	100%

In summary, the base case assumed that there are 36,141 people in Scotland with diabetes and ACS or having had a revascularisation procedure; that 7% of these cannot tolerate, or have a contraindication precluding, use of statins, leaving 33,611 currently prescribed lipid-lowering therapies. An estimated 15,000 of these are assumed to be prescribed atorvastatin 80 mg and the remaining 18,611 people are on a variety of statins comprising simvastatin 40 mg (52%), atorvastatin 20/40 mg (36%) and rouvastatin 10 or 20 mg (7%).

Consultant-led outpatients

Discussions at a national meeting which launched the Guideline on 23 March 2010 identified variation in practice initiating atorvastatin 80 mg; in some NHS boards GPs are trained to initiate this drug, whilst elsewhere the drug is administered at a consultant-led clinic. This analysis assumes 30% of the additional patients titrated to atorvastatin 80 mg will be prescribed the drug at an outpatients clinic. This resource is only assumed to be required in the first year.

9.4 Additional costs required

Cost of additional atorvastatin 80 mg

The relevant factors are the cost of these drugs, particularly the cost of atorvastatin when the drug loses its patent protection in the UK in November 2011, http://www.mwe.com/info/pubs/Euralex_HS.pdf. Two assumptions are made; that generic prices are 50% and 30% of the current price of atorvastatin. The resulting pricing structures are shown in Table 9-4. The other drug prices were obtained from the British National Formulary, <http://bnf.org/bnf/bnf/59/60592.htm>, and were checked 2 April 2010.

Table 9-4 Price of lipid-lowering drugs

Drug	Current price	50% price reduction in generic atorvastatin	70% price reduction in generic atorvastatin
Atorvastatin 80 mg	£28.21	£14.11	£8.46
Atorvastatin 20/40 mg	£24.64	£12.32	£7.39
Simvastatin 40mg	£1.40		
Rouvastatin 20 mg	£18.03		
Rouvastatin 40 mg	£26.02		
Weighted average of rovastatin	£20.21		
Price of statins	£12.35	£7.27	£5.24

The statins comprised simvastatin 40 mg (52%), atorvastatin 20/40 mg (36%), rovastatin 10 or 20 mg (7%) and atorvastatin 80 mg (5%).

Table 9-5 shows the total costs assuming a range of patients are switched to atorvastatin 80 mg. The first cost of £295,226 assumes 18,611 are switched, being the ACS and revascularisation population on statins of 33,611 minus 15,000 already assumed to be prescribed atorvastatin 80 mg; with no generic available. The second cost of £147,613 assumes 50% of the 18,611 are switched and the third cost of £88,568 assumes 30% are switched. The 30% may be regarded as the central case because currently 70% of the diabetes population has a total cholesterol level of less than or equal to 5 mmol/l (Table 32 of Scottish Diabetes Survey 2009). If one assumes this pattern applies to the ACS group then this group are most likely to be titrated by switching to atorvastatin 80 mg.

Table 9-5 Costs to switch to atorvastatin 80 mg

Patients switching to atorvastatin 80 mg	Atorvastatin prices as at April 2010	Atorvastatin generic prices at 50% level of April 2010	Atorvastatin generic prices at 30% level of April 2010
18,611 (all)	£295,226	£127,225	£60,025
9,306 (50%)	£147,613	£63,613	£30,012
5,583 (30%)	£88,568	£38,168	£18,007

Cost of additional attendances at outpatient-led clinics in first year

ISD publishes the mean direct and allocated costs of each attendance at outpatient clinics by specialty http://www.isdscotland.org/isd/costs-book-detailed-tables.jsp?pContentID=3606&p_applic=CCC&p_service=Content.show&. In the year to 31 March 2009, the mean direct cost to attend a cardiology clinic was £113, compared with £101 to attend a general medicine clinic. There were no published costs for attendance at a diabetes clinic. A cost of £115 per outpatient appointment at a cardiology clinic was assumed for 2010, and this cost is maintained in real terms. It was assumed the allocated costs of about £40 were unaffected by the change in numbers attending the clinics.

Assuming 30% of the 5,583 patients are seen at an outpatients clinic before commencing atorvastatin 80 mg, the first year costs for the patient groups are estimated at £192,625, rising to £642,084 if the numbers titrated are 18,611. These are shown in Table 9-6. The total costs for the three different patient groups are also shown. Only drug prices prior to the patent expiring in November 2011 are used, assuming all patients are assessed before November 2011.

Table 9-6 Additional first year costs of switching to atorvastatin 80mg

Patients switching to atorvastatin 80 mg	Additional clinic costs	Additional drug cost (atorvastatin prices as at April 2010)	Total costs
18,611	£642,084	£295,226	£937,310
9,306	£321,042	£147,613	£468,655
5,583	£192,625	£88,568	£281,193

The estimated first year costs of implementing this recommendation, assuming about 5,580 patients are switched from their current statin to atorvastatin 80 mg, are an additional £192,625 for more outpatient appointments and £88,568 for higher drug costs; £281,193 in total. In 2011 this could fall to under £88,000, and thereafter to an extra £38,200 a year (assuming a 50% price difference between generic atorvastatin and the current price of atorvastatin).

In summary, the additional annual costs assumed a central case:

- 15,000 of patients with diabetes and ACS or revascularisation were currently prescribed atorvastatin 80 mg;
- 30% the remaining 18,611(5,583) are switched to atorvastatin 80 mg from another statin;
- the generic price after November 2011 falls to 50% of the current price; and
- 30% of the 5,583 are commenced on statins at an outpatient clinic at a direct cost of £115 per appointment.

Costs have been allocated to NHS boards based on the number of people with MI plus those who have had a revascularisation, using the information from the Scottish Diabetes Survey. The additional annual costs by NHS board, for years 2 and for year 1, including the additional clinic costs, are shown in Table 3.1 and 3.2 respectively.

VAT

VAT of 17.5% is payable on the drug costs. The steady-state costs thus would rise from £38,168 to £44,848. In year 1 the costs would increase from £281,200 to £296,692.

9.5 Sensitivity analyses

The only additional sensitivity analysis provided is to assume only 5,000 people are currently prescribed atorvastatin 80mg, compared with 15,000 as assumed in the base case. Assuming 30% of all those not on atorvastatin 80 mg are switched to it, then the additional costs would be £136,157 with no generic in the market, £58,675 if the generic price of atorvastatin was 50% of current price and £27,683 with a price fall of 70%. Additional clinic costs in the first year are estimated at £296,125.

10 Drug-eluting stents

10.1 Background

Systematic reviews and meta analyses have identified that drug-eluting stents are associated with a lower rates of in-stent re-stenosis and lesion revascularisation than bare metal stents in patients with diabetes who are undergoing percutaneous coronary intervention (PCI).

The relevant SIGN guideline recommendation in section 8.6.4 is:

- In patients with diabetes, drug-eluting stents (DES) are recommended as opposed to bare metal stents (BMS) in stable coronary heart disease or non-ST elevation myocardial infarction to reduce in-stent re-stenosis and target lesion revascularisation. Grade A

10.2 Patient group

The Scottish Coronary Revascularisation Register Annual Report 2008–09 analysed patients who received elective PCI for chronic stable angina and unstable angina for co-morbidities, including diabetes. The data were presented for each of the five centres providing PCI procedures. Table 10-1 shows the total number of patients who had PCI and a co-morbidity of diabetes for each centre; this sub-group formed about 16% of all patients who underwent PCI.

Table 10-1 PCI patients with diabetes by catheterisation centre

By catheterisation centre	PCI unstable angina	PCI elective angina	Total
Edinburgh Royal Infirmary	151	111	263
Golden Jubilee National Hospital	129	119	248
Lanarkshire Cardiac Catheter Lab	18	23	41
Ninewells Hospital	23	20	43
Aberdeen Royal Infirmary	52	45	97
Total PCI with diabetes	373	318	692
Total all PCI	2,384	1,889	4,273
Patients with diabetes as % total	16%	17%	16%

In September 2008, NHS Quality Improvement Scotland published a costing tool to assist in implementing NICE Technology Appraisal Guidance (TA152) on drug-eluting stents, available at <http://www.nhshealthquality.org/nhsqis/4769.html>. Analyses at that time showed:

- the mean number of stents per procedure was 1.64
- drug-eluting stents were used in 46% of cases, compared with 56% for bare metal stents.

However, the use in people with diabetes is likely to be much higher because such patients are at increased risk of complications during revascularisation procedures (see section 8.6.4 of the Guideline). Guideline Group members agreed with the assumption that currently in 75% of PCIs performed on people with diabetes, the cardiologist will insert a drug-eluting stent rather than a bare metal stent.

10.3 Additional resources required

The only implication of implementing this recommendation is an additional cost; no staff or other resources will be needed.

10.4 Additional costs required

In summer 2008, National Procurement negotiated national contracts for stents. These showed a price differential in favour of bare metal stents of approximately £255 in 2008/2009.

Assuming 700 patients with diabetes in 2010 will undergo PCI, with a mean number of stents of 1.7 per patient and that 25% would otherwise receive a bare metal stent, 300 stents should be switched to drug-eluting stents. With an extra cost of £255 per stent the extra cost is estimated to be about £73,200. The cost per centre is estimated in Table 10-2.

Table 10-2 Additional cost of switching to drug-eluting stents

By catheterisation centre	Additional cost
Edinburgh Royal Infirmary	£27,788
Golden Jubilee National Hospital	£26,243
Lanarkshire Cardiac Catheter Lab	£4,339
Ninewells Hospital	£4,527
Aberdeen Royal Infirmary	£10,288
Total additional cost	£73,185

The analysis by NHS board is provided at Table 3-3. The costs were allocated using the prevalence rates from Table 1 of the Diabetes Survey 2009.

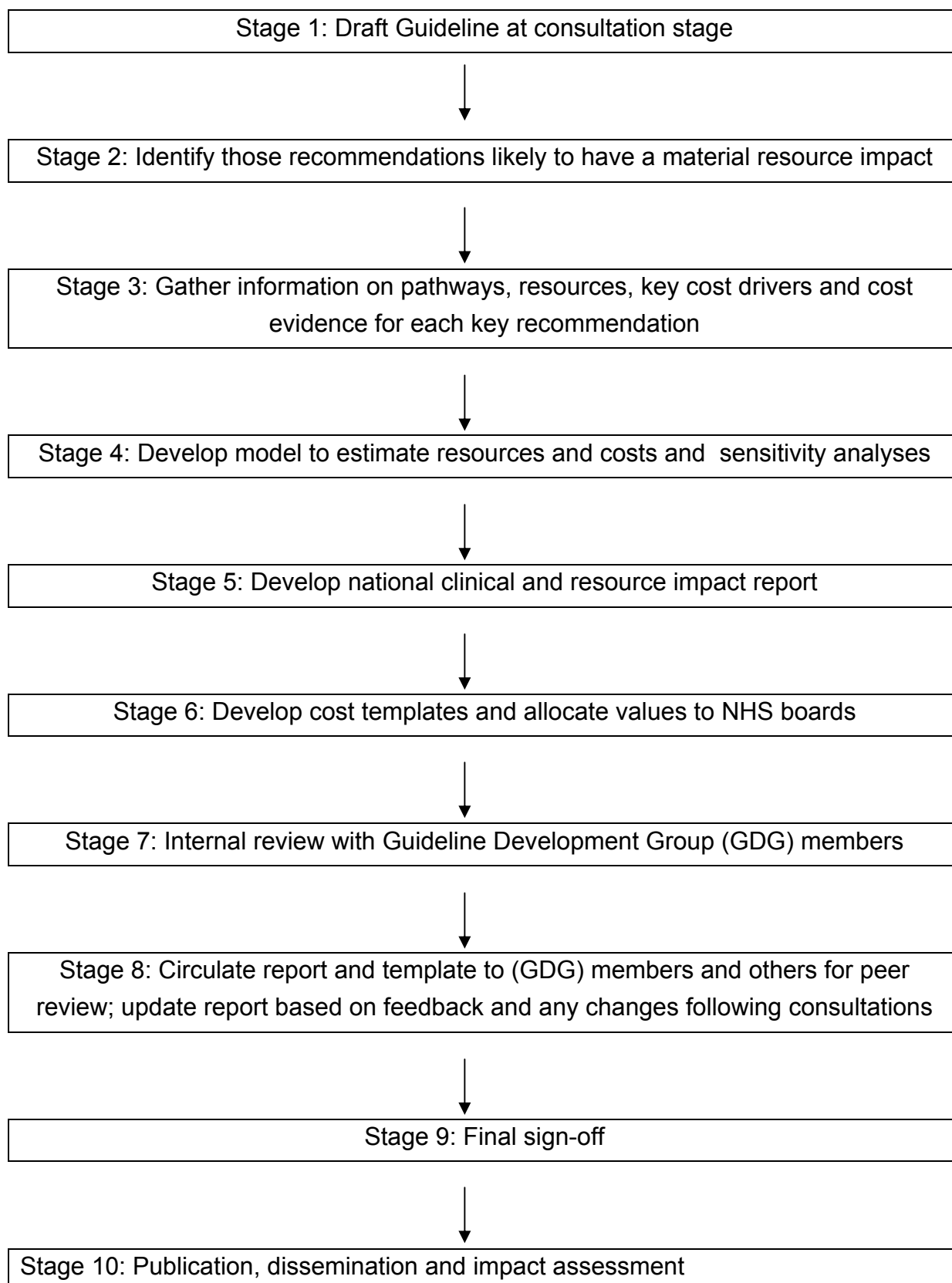
10.5 Sensitivity analyses

If the mean number of stents was two, rather than 1.7 then the additional cost could rise to £89,250. If only 50% of this sub-group currently received a drug-eluting stent, then the cost could rise to £178,500, falling to £35,700 if the current usage rate was 90%.

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Appendix 1 Resource and cost impact assessment process



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The Scottish Health Council, the Scottish Intercollegiate Guidelines Network (SIGN) and the Healthcare Environment Inspectorate are also key components of our organisation.

