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Assessing cost impact

Methods guide

Assessing cost impact (previously known as Developing costing tools: methods guide)

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This document is intended to provide information for costing analysts and for stakeholders on the methods used in developing costing tools.

The document is available from the NICE website (www.nice.org.uk).

The formal process for updating this guide is undertaken 3 years after original publication. It will be reviewed again in a further 2 years' time. In some situations it may be necessary to make small changes to individual sections before the guide is updated formally – for example, where a change in the guidance development process has an impact on the costing process. For small changes to be put in place without reconvening the working group or consultation, either of the following criteria must be satisfied:

- a fundamental element of either process or methodology is not changed
- the accuracy, clarity or fairness of the process or methodology will be improved.

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- The NICE Senior Management Team.
- The Cost Impact Panel.
- Health economists from the National Collaborating Centres.
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- The NICE Technical Forum.
- The NICE Senior Management Team.
- The Costing Methodology Working Group comprising staff representing all the guidance producing centres advisory to NICE.
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- Warren Cowell, Health Economist, representing the Association of the British Pharmaceutical Industry.

1 Introduction

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.'

NICE produces the following types of guidance:

- [Clinical guidelines](#) – guidance on the treatment and care of people with specific diseases and conditions.
- [Technology appraisal guidance](#) – guidance on the use of new and existing health technologies (including drugs, medical devices, diagnostic techniques and surgical procedures).
- [Interventional procedures guidance](#) – guidance on the efficacy and safety of surgical, endoscopic and endovascular procedures and related techniques.
- [Public health guidance](#) – guidance on the promotion and protection of good health and the prevention of disease.

The interventional procedures programme assesses the safety and efficacy of (mainly) new procedures that are used for diagnosis or treatment that involves incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy. Because the advice concerns safety and efficacy rather than clinical and cost effectiveness, we do not assess the cost impact of interventional procedure guidance.

In addition to producing guidance, NICE develops [quality standards](#) which define the standards of healthcare that people can expect to receive. NICE also oversees the development of indicators for the [quality and outcomes framework](#) (QOF) – a voluntary incentive scheme for GP practices. Quality standards and QOF indicators are not new guidance, but measures and indicators drawn from underpinning evidence-based guidance (both NICE guidance and other accredited sources) that will support the achievement of better outcomes.

[NHS Evidence](#) provides everyone working across health and social care with easy access to a wealth of quality information and best practice so that every care decision made can be based on the best possible evidence. NHS Evidence includes the Quality, Innovation, Productivity and Prevention (QIPP) collection. The collection provides users with real examples of how staff are improving quality and productivity across the NHS and social care, and Cochrane topics drawn from systematic reviews by the Cochrane Collaboration that may help to inform local initiatives to address the quality and productivity challenge. The costing team is involved in the quality assurance process for submitted QIPP case studies. For more information, see <http://www.evidence.nhs.uk/qipp>

Putting NICE guidance into practice can be challenging, and NICE has a programme to help support the implementation of its guidance and standards (further details about the implementation strategy can be found in appendix A). Costing tools (defined in section 1.2) are part of this programme, and they assist those responsible for implementing guidance recommendations to estimate the cost impact arising from implementation – usually from the perspective of the

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public sector commissioner of services. Costing tools are published at the same time as the guidance and standards.

Cost impact is defined as the assessment of the net costs (or savings) arising from implementing guidance recommendations for the purpose of informing budget setting. Cost impact considers the impact on budgets for both one-off costs and recurring costs within a defined time period and for a defined population.

1.1 Aim of this guide

This guide has been prepared primarily to support costing analysts who are responsible for producing costing tools and providing advice on cost impact for NICE guidance and standards.

It provides advice on the technical aspects that the costing analysts need to consider when considering and estimating cost impact.

The guide may also be useful for other audiences such as:

- those responsible for implementing NICE guidance and standards
- external stakeholders who may use the guide to improve their understanding of how the costing tools are developed.

Although this guide is not for use primarily when developing economic analysis (either for submission to NICE or on behalf of NICE), it is likely to be of general interest to academic groups and health economists. Close collaboration between costing analysts and health economists working on cost effectiveness is encouraged because there are often common data sources underpinning both types of work.

Costing analysts should also be aware of the latest NHS operating framework, which will include such issues as:

- the latest QIPP target (this is currently to realise up to £20 billion in efficiencies for re-investment into services over the next 4 years, commencing April 2011)
- indicators relating to new commitments and reform
- clinically relevant indicators from existing measures
- maintaining and improving quality and outcomes
- accountability arrangements
- assessments of pay and prices inflation, and efficiency expectations.

1.2 Costing outputs

1.2.1 Objective of the costing tools

The objective of the costing tools is to assist people implementing NICE guidance and standards in financial planning, typically over a period of 3–5 years. Where implementation and the cost impact are anticipated to change over the course of 3–5 years, the costs over time should be analysed as well as the costs at full implementation.

NHS bodies should have a clear implementation plan linking operational and financial aspects and integrated into mainstream financial planning and budgeting. The costing tools can be used to estimate the local cost of implementing NICE guidance in order to inform implementation plans and business cases.

The costing tools are estimates only and are not to be taken as NICE's view of desirable – or maximum or minimum – figures. They should be used to facilitate discussions. Local circumstances can and will differ, so users are encouraged to consider local assumptions.

1.2.2 What is a costing tool?

'Costing tool' is a generic term for cost information provided to support the implementation of NICE guidance. The intended audience for costing tools is people responsible for implementing guidance. Costing tools are produced in three main formats (see table 1).

- Costing template – provides users with the ability to estimate local cost impact for areas considered to involve significant change in costs or savings based on their population and changing assumptions to reflect local circumstances. Costing templates are produced where it is possible to quantify the cost impact. This is not possible for all topics.
- Costing report – summarises the national cost estimate and discusses the assumptions made when estimating the financial impact of implementing the guidance. For some topics the report is included as a separate sheet within the costing template. Occasionally, a narrative report is produced that discusses the costs and savings to be considered locally when estimating the national cost is impossible because of lack of data or significant regional variations.
- Costing statement – explains why the cost impact is not considered to be significant, or why estimating the cost impact is not possible. In these circumstances no costing report or costing template is usually produced.

Table 1 Summary of costing tools supporting each guidance type

	Costing report	Costing template	Costing statement ^a
Clinical guidelines	✓	✓	✓
Technology appraisals	✓ ^b	✓	✓
Public health guidance	✓	✓	✓
Medical devices	✓ ^b	✓	✓
Diagnostics	✓ ^b	✓	✓
^a Produced instead of a report and template when the financial impact is not considered to be significant or it is not possible to quantify the cost			
^b Report incorporated into the costing template for technology appraisals, devices and diagnostics			

The national cost estimate is based on the population of England; however, the costing template includes local population details for Wales and Northern Ireland so that it can also be used in these countries.

The process and output for supporting quality standards is evolving. Currently quality standards are accompanied by a 'NICE support for commissioners and others using the quality standard' that combines consideration of cost impact with issues people involved in commissioning healthcare services should consider. However, discussions are ongoing regarding the most appropriate format for this kind of supporting information.

NICE also produces commissioning guides.

The purpose of [commissioning guides](#) is to:

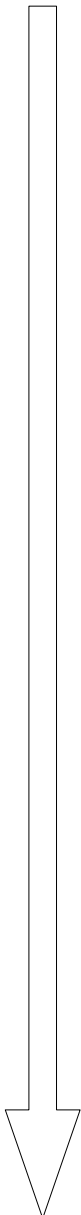
- support general commissioning decisions on potential service reconfiguration in England
- support the commissioning of evidence-based care for patients in line with NICE guidance and standards
- assist financial modelling and costing by offering a commissioning tool to calculate and cost local service provision
- assist with the preparation of a business case
- provide a framework for investment decisions
- highlight and support relevant national priorities
- signpost NICE guidance and other relevant supporting information.

The commissioning tool may be informed by cost impact work for related topics, but the objective is different. Whereas cost impact analysis assesses the incremental cost or saving, the commissioning tool will look at the full costs of commissioning a service.

1.2.3 Development processes

The processes for developing the costing tools are outlined in the appendices. The process depends on the type of guidance and is designed to connect with the guidance development process at key stages. This guide will improve the transparency, reliability and consistency in the development of the costing tools.

Table 2 summarises the key actions in developing the costing tools, the tasks involved and where to look in this guide for further information.

Table 2 Overview of costing actions and links to methodology guide


Action	Tasks involved	Costing manual
Read guidance - identify the significant recourse impact recommendations	Talk to guidance developers / technical team within NICE	Section 3
Check if there is existing NICE publications on similar or overlapping topics	Consult any previous costing tools to inform on populations and treatment assumptions previously used	Section 9
Identify high level population affected by the guidance (i.e. Males aged 55 and over , all under 18s etc)	The population and population selection sheets on the template need to be updated to reflect this and allow users to manually select or input their local population	Section 4,5
Identify assumptions for the population (prevalence, incidence etc) within the current care pathway	Design the assumptions input sheet to show all assumptions made and allow space for users to input their own assumptions	Section 4,5,6
Identify assumptions on the treatments options within the current care pathway	Design the assumptions input sheet to show all assumptions made and allow space for users to input their own assumptions	Section 4,6
Identify changes to these assumptions as a result of the guidance	Add the prediction assumptions to the assumption input sheet and allow space for users to input their own assumptions	Section 4,6
Develop care pathway before and after publication of the guidance using the above assumptions	Alongside the assumptions create a care pathway which shows the current care pathway and expected changes to the care pathway following publication of the guidance	Section 6
search for price and cost data for any relevant treatment and medication	Add relevant price and cost data to the assumption input sheet	Section 7
Calculate costs	Use the costing template sheet to calculate the total costs before and after implementation of the guidance using the assumptions previously made on the population and care pathways	Section 8
Produce sensitivity analysis	Populate the sensitivity analysis sheet using the sensitivity working sheet	Section 8.8
Write costing report	Write a narrative explanation of the key findings and implications of the costing work	Section 8.6
Quality assure costing template and report (or costing statement)	Internal review meeting to discuss, followed by limited consultation and final sign-off, before submitting tools to Guidance Executive	Section 8.6
Publish	Arrange for tools to be loaded onto website at the same time as guidance is published	n/a
Address post-publication queries	Check 'costing' inbox for queries, or queries forwarded by the NICE communication team, investigate queries and update tools if appropriate	Section 9

2 General costing principles

NICE agreed the following general principles to underpin the assessment of cost impact. Further clarification of these principles is provided in the following sections.

General principles relating to developing costing tools

- Cost-impact analysis should build on accounting principles. The objective is to inform local organisations' financial plans, therefore accounting principles are more appropriate than health economic principles (see section 2.1).
- Costs and savings should be a direct consequence of implementing the guidance or standards being analysed. The cost-impact analysis may refer to indirect consequences and opportunity costs, where appropriate (see sections 2.2 and 2.4.3).
- The final costing tools should be both realistic and consistent with the health economic analysis on which the guidance is based (see section 2.3).
- The costing tools do not form guidance to the NHS but aim to support implementation of NICE guidance. As such, the cost-impact analysis is kept separate from the main guidance and disseminated to the relevant audiences via the NICE website (no further clarification required).

General principles relating to updates to guidance and accompanying costing tools

- The focus should be on changes in the guidance or standards and to quantify the cost impact of service changes resulting from the guidance being implemented or standards supporting implementation of underpinning guidance.
- Each change to the guidance or standard should be reviewed individually to determine whether the cost impact is significant.
- The update should not be a re-costing of the whole guidance or standard, except where there is clear evidence the existing costing tool is no longer applicable. For example where clinical practice has changed.
- In circumstances where previous guidance or standards did not have a costing tool or where it is considered organisations may still be working toward implementation of recommendations in existing guidance or standards then a new costing tool may be prepared.

Further principles relating to cost types, costing perspective and equality are given in sections 2.4, 2.5 and 2.6, respectively.

2.1 *Accounting principles*

The financial reporting requirements for NHS bodies are determined by the Department of Health with the approval of HM Treasury. Bodies within the resource accounting boundary must follow the Treasury's Government Financial Reporting Manual (FReM). The FReM follows EU-adopted International Financial

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Reporting Standards (IFRS) extant at 1 January 2010 with effective date before or from 1 April 2010. NHS bodies must follow the FReM unless there are any agreed divergences. NICE operates under this guidance.

Key issues that will be considered when developing the costing tools are:

- Ensuring that costs and savings relate to the same time period, typically an annual period. Differences may arise where costs are incurred in early periods that will result in savings in future periods. It is not acceptable to combine costs and savings to produce a 'new cost saving' where periods don't match. However, it is reasonable to quantify the costs and the savings and present both separately.
- A conservative approach will be taken to recognising income when it is reasonably certain and expenditure as soon as it is reasonably possible.

2.2 *Direct and indirect consequences*

NICE determined that costs and savings should be a direct consequence of implementing the guidance being analysed. For the purposes of costing work, direct consequences are the changes in practice that will result from implementing the guidance. For example, this could include a change in prescribing practice or a change in the number of patient admissions. The follow-on impact – for example, preventing adverse events and avoiding future admissions – will also be considered as a direct consequence.

An example of an indirect consequence is a scenario in which a person having an intervention that prevents them from dying goes on to develop other diseases that are costly to treat. However, because the person could develop any disease totally unrelated to the guidance recommendations for their original condition, this indirect consequence cannot be considered in the costing work.

It is recognised that the new programme of diagnostics guidance may have greater uncertainty on the impact that new diagnostic tests may have on subsequent patient pathways. This area will be kept under review and explored further when experience of assessing the cost impact of the early guidance has been gained.

2.3 *Links between costing tool and health economic model*

The costing tool should be realistic and, wherever possible, it should be consistent with the health economic analysis on which the guidance is based. To achieve consistency, a two-way flow of information between costing analyst and health economist – or, for appraisals, the technical lead – will be encouraged when guidance is being developed. Because the health economic analysis is developed in advance of the recommendations being made, a two-way flow of information may not always be possible. However, the costing analyst will be available to act in an advisory capacity on an 'as required' basis for technical leads.

Typically, the health economic analysis will have looked at a variety of elements to determine the incremental cost per quality adjusted life year (QALY) gained. To calculate cost the health economist uses estimates of unit costs and levels of service use. The costing tools include, where relevant, the same costs, activity levels and assumptions to ensure consistency. However, there may sometimes be

differences for which there may be legitimate reasons, resulting from the theoretical foundations of economic evaluation and cost accounting.

The examples below illustrate where the unit costs used in the costing tool and the health economic analysis might differ.

- The health economic analysis may use reference costs, which are the average costs to provide activity, whereas the costing tool could use the Payment by Results (PbR) tariff, which is the price to commission activity. This will result in differences between the unit costs but the activity classification should be consistent. For example, if the health economic model used the non-elective cost for EB05Z Cardiac Arrest, then the costing tool should use the non-elective PbR tariff for EB05Z.
- The health economic analysis may include events avoided as part of considering the lifetime impact, whereas the costing tool would focus on the first 3–5 years for clinical guidelines and technologies appraisals; for public health guidance a longer period of up to 10 years may be appropriate.
- The costing tool may consider non-recurrent set-up costs such as purchasing a diagnostic machine and training staff in its use. On an ongoing basis only the running costs would be included in the costing tool. The health economic analysis may deal with set-up costs differently to the costing tools, depending on the timeframe of the health economic analyses. For example, the costing template might include the purchase of scanning equipment as a non-recurrent upfront cost, whereas the health economic analysis could include the cost of the machine as an overhead against each scan.
- The health economic analysis may include opportunity costs; these might not be direct costs (from the perspective of the commissioner) and are not usually included in the costing tool (for example, see section 2.4.3).
- Cost analysts need to be aware that avoiding admissions to hospital while reducing commissioner spend in areas covered by PbR will not necessarily lead to a reduction in expenditure in provider organisations. This can be for a number of reasons such as not being able to reduce fixed costs, or to close a ward because the reduction in activity is insufficient for this to happen.
- The health economic analysis may include productivity costs; this was a consideration for the public health guidance on workplace smoking ('Workplace health promotion: how to help employees to stop smoking' [[NICE public health intervention guidance 5](#)]). These might not be a direct cost (from the perspective of the commissioner) and are not usually included in the costing tool, however, in this topic were considered important to the intended audience of employers

Situations giving rise to differences that do not fall into the above categories will be discussed by the costing team as they arise.

If costing tools use vastly different unit costs to those employed in the health economic analysis, it could lead to confusion. It is therefore important that the costs used in the health economic analysis are reviewed. Any concerns regarding unit costs used when considering cost effectiveness should be raised at an early stage and discussed with the costing team before decisions are made by the

guidance producing centres, bearing in mind legitimate differences between the health economic approach and the cost-impact approach.

2.4 Cost types

2.4.1 Fixed and variable costs

Fixed costs remain unchanged as activity increases or decreases, whereas variable costs will vary proportionally with a change in activity. For example, an organisation is likely to have one chief executive and this fixed cost remains the same, but the staff required for outpatient clinics will vary depending on the outpatient activity. Another type of cost is a stepped cost, whereby changes can be absorbed to a certain point, after which they change to a different level. For example, beyond a certain increase in outpatient appointments held, additional clinic accommodation may need to be built.

When the costing tools use unit costs based on reference costs or the PbR tariff they are using costs that include both variable costs and a proportion of fixed costs. They may, therefore, overstate the cost to the provider of additional activity. However, the cost for the commissioner is based on the tariff so it is likely to reflect their cost to commission activity.

The understanding of fixed and variable costs is necessary when reviewing a QIPP submission. This is to ensure that the cost analyst can distinguish between cash-releasing savings and increased productivity. For example, improved use of theatres will reduce the unit cost of each operation, but is unlikely to release cash savings.

2.4.2 Recurrent and non-recurrent costs

A recommendation has a recurrent impact if its activity is repeated every year. It is important to determine the recurrent costs for financial planning purposes.

Recurrent costs are usually the annual costs of implementing a clinical recommendation or a public health prevention recommendation. For clinical conditions that are acute and of short duration this will be linked to the annual incidence. For chronic clinical conditions that last several years, consideration should be given to treating the stable population, not only the new cases presenting in the year. The identification of population is discussed further in section 5.

Many recommendations have an initial non-recurrent impact. This could be due to a variety of factors, including the following:

- There might be a need to treat a backlog of patients with a new technology before a steady state is reached, when only the incidence population is dealt with.
- There might be initial costs to set up equipment or to get ready to implement a recommendation.
- There might be a need for training to achieve compliance with a recommendation. Note that some training may need to be considered as a recurrent cost because of the need to offer refreshers or train new staff.

2.4.3 Actual and opportunity costs/savings and improved productivity

Costs and savings can be classified as actual, opportunity or productivity. Actual costs and savings are those that require cash or deliver cash-releasing savings through implementing the guidance. It is important to identify actual costs because they will need to be committed, and actual savings need to be realised in order to implement guidance. Costs and savings should clearly be noted as actual, productivity or opportunity; if the difference is not clear it could provide a false impression of the costs or benefits of implementation.

Opportunity costs are the benefits foregone by making/not making a decision. Within costing tools opportunity costs are used to indicate the costs and savings attributable to implementing guidance that may not immediately affect the cash position. For example, the cost of an additional appointment with a professional to introduce watchful waiting can be estimated. However, depending on prevalence, if this is a small number of additional appointments per professional it can be absorbed without resulting in an increase in staffing. Similarly, a small reduction in consultations will not result in a reduction in staff in the short term.

Similarly, when activity is prevented, it is necessary to understand what real savings are. Real savings occur when there is a reduction in expenditure. For example, stopping prescribing an expensive drug will mean an immediate cash saving because it is no longer necessary to purchase the drug. Other reductions may not have an actual impact unless they are combined with other changes. For example, reducing length of stay in critical care might not enable a whole critical care bed and its associated staffing to be removed, but when considered alongside population growth placing unrelated pressure on critical care it could delay the point at which additional investment is needed. Alternatively, over time, a number of reductions in activity may reach a critical mass and mean that staffing levels can be reduced or whole buildings or services are no longer necessary, at which point expenditure could be reduced and real cash-releasing savings made.

This is another area where different perspectives can deliver different results, both in differences between cost impact and cost effectiveness and between costs or savings to the commissioner or the provider (see also section 2.5). For example, avoiding acute admissions will reduce the activity paid for by the commissioner and be a real cash saving. For the provider, however, it represents lost income that may only be partly offset by reductions in variable costs, while fixed costs are still being incurred.

In some instances additional activity is only paid at marginal rates (a percentage of the national tariff as opposed to the full tariff). This is because fixed costs will have been recovered once an agreed baseline of activity has been achieved. An example is the emergency activity tariff where for 2011/12 a marginal rate of 30% of the relevant published tariff applies for increases in the value of emergency admissions. The marginal rate provides an added incentive for closer working between providers and commissioners, to support the shift of care out of hospital settings and to keep the number of emergency admissions to a minimum.

The health economic model and the costing tool can differ in the way in which they use actual and opportunity costs – for example, if drug treatment avoids the need for a liver transplant. For ‘Peginterferon alfa and ribavirin for the treatment of mild chronic hepatitis C’ ([NICE technology appraisal guidance 106](#)) the potential savings from avoiding a liver transplant were included in the health economic model, but they were excluded from the costing template. This is because avoiding a transplant in one group of patients is unlikely to reduce the overall number of transplants as the availability of suitable donors is limited.

As the NHS and other public sector bodies face challenging times in the need to make savings because of budget cuts or anticipated growing demand, it is more important than ever to ensure that value for money is achieved while ensuring the best possible outcome for patients or the public. It is therefore important that identification of potential costs and savings (whether they are real changes or opportunity/productivity changes) is comprehensive.

2.5 *Costing perspective taken*

The cost impact can differ when it is viewed from different perspectives. Typically the perspective taken is the costs to the implementer – and for clinical guidance and technology appraisals this is usually the NHS.

There could be a difference in the unit cost depending on whether the cost to provide activity or to commission activity is used. Where both costs are available the cost to commission activity is generally the one used in the costing tools. Secondary care acute activity is usually commissioned under PbR at a tariff rate. In this instance the cost to commission activity informs commissioners of what they might be expected to pay in the future, and helps the provider to estimate expected income. The provider is usually much better placed to review what the change will mean in practice and what the actual cost of providing activity will be.

Where recommendations in guidance, particularly public health guidance, are directed at sectors other than health, such as education or social services, then the perspective taken is costs or savings falling on the wider public sector. Occasionally the person responsible for implementation might be outside the public sector and the choice of tools in this instance will be determined on a case-by-case basis. For example, ‘Workplace health promotion: how to help employees to stop smoking’ ([NICE Public health guidance 5](#)) was aimed at employers, and two costing tools were produced – one looking at the impact on the NHS that anticipated an increase in referrals to smoking cessation services, and another aimed at employers. The employer costing tool was called a ‘business case’ because this was considered to be a term better understood by the private sector. The business case compared the employer costs in providing smoking cessation support with the potential benefits gained from having non-smoking employees, such as lower sickness rates and improved productivity.

The relevant cost to use is discussed in more detail in section 7.

2.6 *Assessment of equality impact*

The guidance producing bodies at NICE are responsible for ensuring that guidance takes appropriate account of equality considerations when making recommendations. With respect to implementation the NHS and other organisations are responsible for implementing the recommendations and should be reminded of their responsibilities under anti-discrimination and equalities legislation, as they consider their plans for implementing NICE guidance.

Care will be taken so that assessing the cost of recommendations does not lead to unintended discrimination and this will be reviewed as part of the quality assurance process before publication of the costing tool.

3 Identifying significant resource impact recommendations

3.1 Purpose of identification

Identifying the areas that may have a significant resource impact helps the NHS and others to plan where resources should be committed. This is important because guidance can differ greatly in scope, complexity and number of recommendations made. The scope of a technology appraisal is quite narrow, addressing specific technologies for specific indications. By contrast, clinical guidelines and public health guidance tend to have a much wider scope and a greater number of recommendations.

There are several ways to approach the costing work, ranging from costing every recommendation to selecting recommendations to cost. The concept of 'significant resource impact recommendations' is used to ensure that resources are focused on the recommendations that are likely to require the greatest change to implement, and therefore impact most on financial planning. It is acceptable to identify an area to cost that may cover a number of recommendations. For example, training might be a general area to cost if a number of recommendations relate to care being provided by suitably trained staff. In this instance costing a training course for staff working in this area is more logical than costing training elements from a number of recommendations.

Guidance may also include other recommendations that will have a local resource impact that was not identified as a problem nationally; local implementation plans are a useful source of identifying this.

When guidance is updated the costing work focuses on the revised or new recommendations arising from the update rather than producing a cost estimate for the previously published guidance. (For more information on updating costing tools see section 9.)

3.2 Definition of significant

There are various definitions of significant; therefore it is important to define it to ensure consistency across the different costing tools. To define it in this context it is important to consider what might cause something to be significant.

A significant resource impact could arise from:

- a relatively small cost or saving per person that affects a large number of people, resulting in a significant total amount
- a large cost or saving per person resulting in a significant total amount
- an estimated insignificant net total that could have a considerable effect on resource use by shifting resources from one activity or sector to another.

To achieve consistency, limits on either the number of people affected or the cost or saving have been determined.

The following impacts have been defined as not significant:

- Where the number of people affected by the guidance recommendations is estimated to be less than 300, it is not considered meaningful to produce a costing template. This is equivalent to one patient per 170,000 and in practice smaller populations may have no patients or possibly no more than one, particularly if it is a disease which runs in families and there is a cluster in one area. An explanation of the assumptions used to estimate the number of people affected, and a cost per patient, should still be included in the costing report or costing statement to aid local planning.
- Where initial costing work indicates that the national cost is less than £1 million, it could be deemed insignificant: this is equivalent to just under £2000 per 100,000 population.

Where the cost of an individual recommendation exceeds £1 million but is offset by a recommendation predicted to provide savings resulting in an insignificant total, this will be included in the costing work. Costing work should also detail the impact of recurrent and non recurrent costs. For example, the non-recurrent cost of installing new medical equipment to undertake scans that results in no significant difference in the cost per scan.

There may also be some instances where low cost recommendations could be clinically significant or address particular public health or equality concerns and there is a strong case for inclusion within the costing tool – for example, to provide reassurance that the cost of something has been considered and is estimated to be very low, or where the national figure is low but regional variations occur, meaning some areas may be disproportionately affected. The inclusion of less significant items will be decided on a case-by-case basis by the costing team.

The decisions taken regarding significance also determine which costing tools are produced, and this is presented in section 8.5 (see figure 8).

3.3 *Methods of identifying resource impact*

The process followed for identifying the resource impact depends on the guidance being costed. Technology appraisal recommendations may be fully costed, whereas it may not be appropriate to cost every recommendation in clinical guidelines or public health guidance. The following methods to identify resource impact are recommended:

- Technology appraisals, medical technologies and diagnostics technologies – the potential resource impact should be discussed with the technical lead for the topic, and documentation such as the draft guidance, assessment report, economic evaluations, Evidence Review Group report (for single technology appraisals) or manufacturer's submission may contain useful information.
- Clinical guideline – the potential resource impact should be discussed with the Guideline Development Group and the project team at the relevant national

collaborating centre, including the health economist, as they may have useful background information. The economic plan, economic evaluations, draft guidance and responses to consultation (when available) are also useful sources of information.

- Public health guidance – the potential resource impact should be discussed with technical staff within the Centre for Public Health Excellence and the Programme Development Group or members of the Public Health Interventions Advisory Committee (PHIAC). The draft guidance, evidence reviews, economic evaluations and response to consultation (when available) are also useful sources of information. Some topics test the recommendations using field work and it may be useful to be involved in these meetings, where field work is undertaken.
- The QOF indicators should be discussed with the technical team while they are being developed in order to identify areas which might have significant resource impact, such as increasing the number of patients referred for tests. Indicators in development are also subject to testing in a number of pilot practices which can inform consideration of cost impact.
- Quality standards – the potential resource impact should be discussed with members of the Topic Expert Group (TEG) and the quality standards team. In some instances it may be appropriate to group quality statements together for costing purposes. For example, a number of quality statements may make up an assessment process and it may be more relevant to cost the assessment process in total. The quality standards team is able to provide advice on which statements can be grouped together. Attendance at TEG meetings will also provide useful background information for costing purposes.

Estimating the cost impact of implementing recommendations involves uncertainty. Therefore it is better to start with a large number of areas to cost (which can be left out of final costing tools if subsequent consideration shows them to be insignificant) than to miss potentially significant areas.

The possibility that the guidance development group does not identify all recommendations that have a significant resource impact will always be considered. Further recommendations and areas of significant impact may be identified during the course of discussions or investigating other recommendations. It is good practice to test the assumptions on which recommendations could have a resource impact with as many people as possible, to ensure that the impact is representative of the wider NHS (and the wider public sector for public health guidance) and not skewed by the views of one individual.

3.4 *Dealing with resource impacts that cannot be quantified at a national level*

Occasionally, circumstances will be such that it is not possible to quantify the impact of implementing a guidance recommendation or standard.

This could be for a variety of reasons, including the following.

- Limited data about the current baseline – for example, a recommendation may require changes to infrastructure, but there may be limited data about which buildings currently comply with the recommendation.

- Uncertainty in identifying the population affected – for example, there are separate estimates of people who have sex with multiple partners, people who are drug users, or men who have sex with men, but to add together all three groups will double count the people who fit into two or more categories.
- Problems in predicting or estimating change in activity – for example, it is widely recognised that lack of physical activity is linked to certain diseases, but the impact of increasing physical activity on reducing disease has not been quantified.
- Services across the country may be at varying degrees of development or have different service models, and it is not possible to estimate the national cost impact of a particular piece of guidance.

It should be recognised that all cost impact assessments are subject to uncertainty regarding the effect of recommendations. However, the cost impact can usually be considered helpful in informing local decision makers about the magnitude of costs and savings involved, even if the exact cost is likely to be different. The uncertainty that leads to a resource impact not being quantified should be such that it makes it impossible to even begin to assess the cost, or any estimate of cost has the potential to be considerably wrong.

For the sake of completeness, recommendations that cannot be quantified but are considered to have an impact on costs or savings will be discussed in the costing report or the summary section of a technology appraisal template. This flags the issue and allows local implementers to make judgements about the likely impact based on local circumstances.

Where possible a costing template should still be developed for local use in order to allow organisations to assess their position based upon locally available data. Key unit costs should be provided in order to allow organisations to apply such costs to local activity data.

4 Identifying and appraising data sources

4.1 Sources of data to establish baseline

The data used to establish the baseline resource use vary depending on the topic of the guidance. This section looks at the sources of resource data; sources of cost data are discussed in section 7. In some cases there is little systematically collected data regarding a particular topic. A short selection and brief description of commonly used sources can be found below.

- [Hospital episode statistics \(HES\)](#) – a data warehouse containing details of all admissions to NHS hospitals.
- Prescribing analysis and cost tool (PACT) – covers prescriptions prescribed by GP practices in England and dispensed in the community in the UK. Prescriptions written in England but dispensed outside England are included.
- [Prescription cost analysis \(PCA\)](#) provides details of the number of items and the net ingredient cost of all prescriptions dispensed in the community in England. The drugs dispensed are listed alphabetically within chemical entity by British national formulary (BNF) therapeutic class. Information is available from the Information Centre for Health and Social Care (referred to as [the Information Centre](#) in this document).
- General practice medical databases – for example, IMS Health or THIN – available from [the Information Centre](#).
- The [QOF](#) data – QOF measures general practice achievement against a range of evidence-based clinical indicators and also includes a range of administrative indicators.
- [NHS Evidence](#) allows users access to a wide range of health information, including evidence, guidance and policy.
- Published data – may include regional or national audits and results of research available via OVID, MEDLINE and CINAHL.
- [Office for National Statistics](#) website for population and some activity data. This includes data from population that might be particularly useful for public health topics.
- [National Audit Office](#) and other national bodies who collect and collate data such as cancer registries and the Renal Registry.
- Expert opinion (see section 4.3 for more detail).
- Patient advocacy organisations such as Cancer Research UK or the British Heart Foundation, or other organisations like Sport England.

The background information produced in the course of developing the guidance (see below) may contain useful information or contain references that can be followed up to gain more information about the potential cost impact.

- Technology appraisal – the assessment report or manufacturer’s submission and Evidence Review Group reports for single technology appraisals, draft guidance and comments received during consultation.
- Clinical guideline – elements of the full guideline, particularly the economic plan and any resulting analysis.
- Public health guidance – effectiveness and cost-effectiveness reviews, as well as the economic analysis.

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- All guidance types – comments received on the draft recommendations because they may refer to particular concerns with resource utilisation and cite supporting studies.

Sometimes no data will be available, and in these circumstances it is recommended that expert opinion is sought, or a representative sample of providers is contacted. This approach is discussed in more detail below.

4.2 *Sources of data to establish future practice*

Predicting future practice following the implementation of a recommendation poses significant challenges. For example, a technology appraisal could recommend that a number of drugs are suitable for a specific condition. The decision about which of these drugs to use is made by a clinician following discussions with the patient. This means that the split between alternative drugs and the shift from existing treatments to new treatments is subject to uncertainty because of differing clinical preferences.

The following sources of information can be used to predict the uptake of guidance or the level of change needed for compliance.

- Background documents to the guidance, as noted above.
- Experts advising the guidance producing bodies (see paragraph 4.3).
- Previous uptake of similar drugs or technologies. These data can be analysed to inform any estimates made and are collected together in the [ERNIE database](#).
- Preference studies (although rarely available). They can be particularly helpful when risks associated with treatment may affect patient or clinician preference.
- Data on comorbid conditions that might exclude patients from treatment. If no specific data exists apply estimates of conditions in the whole population to the sub-group (see paragraph 4.4).
- Areas that have already implemented the recommended practice ahead of the guidance being issued (perhaps even contributing to the evidence base on which the recommendation is based) may provide useful information about impact. Cases studies on the [NHS Evidence QIPP collection](#) may be useful.
- Information used to inform the health economic models (see paragraph 4.5).

When predicting uptake it is important not to rely only on one source. The validity of assumptions made in the draft costing tool must be checked. This is subject to further scrutiny when the costing tools are consulted upon.

After consulting a number of sources a range of estimates may exist and it is useful to reflect these back at practitioners working in this area to see if a consensus can be reached; alternatively, the mid-point of the range, or the average of the values provided, could be used. The minimum and maximum values provided should be used in the sensitivity analysis (see section 8.8 for detail of sensitivity analysis).

4.3 *Use of experts/professional opinion*

Input from professionals is vital when attempting to predict future practice. The professionals selected must be relevant to the part of the pathway being analysed. For example, referral decisions are discussed with GPs who make referrals, in preference to specialists who only see those patients selected for referral. However, estimates made by individual practitioners can vary considerably because the estimates are based on personal experience. The practitioners chosen may be leaders in their field and this sometimes means that they have already adopted modern evidence based practice.

NICE will contact a number of practitioners to discuss estimates of either current practice or predictions of change. In order to get a representative view of practice across the country a geographical spread will be sought. Discussing opinions of current and future practice 'in general' rather than focusing on personal practice is also recommended. The range of opinions gained will be used to inform the assumptions made and the range covered by the sensitivity analysis.

4.4 *Sample techniques*

Sampling is a tool used to select part of a population for data collection and analysis, where it is not possible or practical to contact the whole population. Planning a sampling exercise usually involves the following stages.

- Definition of the sample population – which types of organisation are affected by the recommendation? For example, this could be general practices for recommendations affecting primary care, or schools for public health recommendations.
- Specification of the sample frame – what elements are included in the sample? For example, when contacting acute trusts is the Chief Executive the best contact or will the Theatre Manager be able to provide quicker and more useful input? If contacting general practices, is it better to speak to a GP or will the Practice Manager be able to answer questions?
- Specification of the sample method – a variety of methods could be used such as random selection, stratified sampling or cluster sampling. All may be appropriate for different elements at different times. For example, working with all organisations within two different local networks may give results that are just as useful as a random sample.
- Determining the sample size – the sample size is likely to be limited by the time and resources involved in collating and analysing data, but will be large enough to contain a representative sample in terms of types of organisations and geographical spread. Early identification of the need for sampling is advisable to allow sufficient time to make contact and receive a response.

Throughout the sampling exercise it is advisable to review the interim results and reassess the sample methodology. If wide variation is uncovered then the sample will be widened to lessen the effect of outliers in line with standard statistical practice.

In any sample some of the individuals identified as part of the sample might not be willing to participate or be impossible to contact. This can cause a number of

potential problems because the difference between the willing and the unwilling could cause a bias in the conclusions made. The importance of getting a range of views/current practice and anonymity of results will be emphasised to encourage full participation and the sample widened to ensure sufficient responses are included.

Some participants who are asked to make predictions of future practice may be unwilling to speculate. In these instances NICE will present an assumption, based on a range of other responses, and ask the person's opinion on whether the reality will be higher or lower. Care will be taken in how assumptions are presented to avoid leading the participants, which would result in false validation.

Variation might exist in the results achieved and this can be dealt with by reflecting it back to practitioners working in this field and trying to get consensus (see last paragraph of section 4.2).

4.5 *Use of decision models*

Sometimes the health economic modelling used to help draft the guidance, or related research, will present the patient pathway in the form of a decision tree or Markov model. Health economists use decision trees and Markov models to test which of several options is clinically and cost effective. For costing purposes, only the section that describes either current or future practice will be relevant.

Discussion with health economists on the robustness and applicability of any applicable health economic models can provide good information that informs the assessment of cost impact. The economic model can provide information on the clinical pathway and assist understanding of cost impact.

Figure 1 is an example of a decision model developed to depict contact tracing¹ that informed the costing work for the clinical guideline 'Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control' ([NICE clinical guideline 117](#)). The probabilities of positive and negative results were calculated and added to the relevant branches of the current treatment algorithm endorsed by the British Thoracic Society. Additional information about BCG² provision and the proportion of the population who are aged 16 years and over were added to the model for current testing for latent tuberculosis to calculate current costs of the tests being performed and of chemoprophylaxis that is started following a positive result.

¹ Contact tracing is the practice of tracing friends, family and acquaintances of someone with a disease in case they have also contracted the disease.

² Bacillus of Calmette and Guérin is a vaccine against tuberculosis, named after two French doctors.

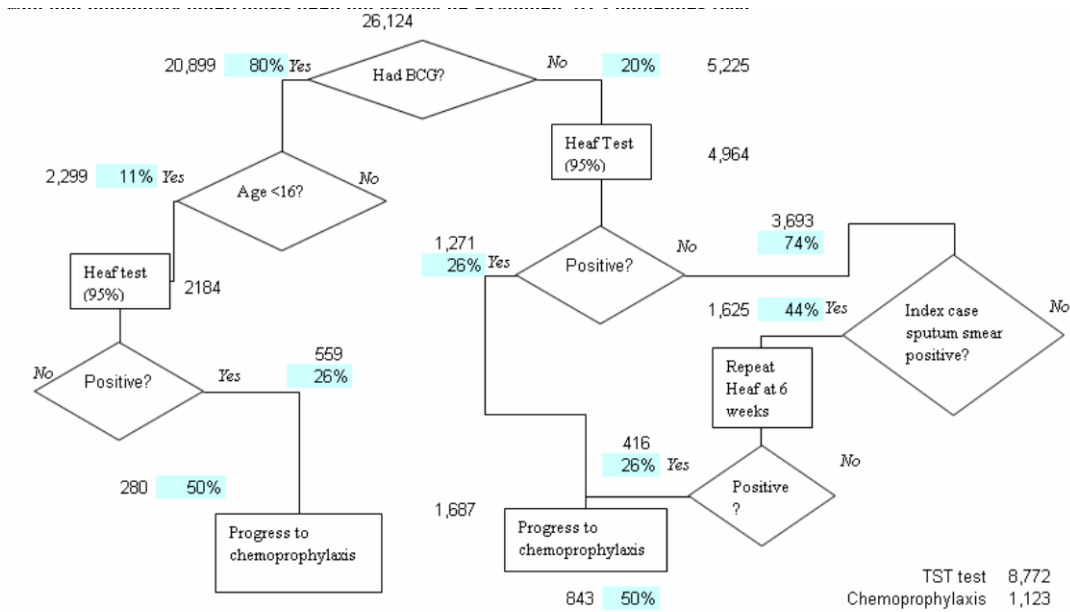


Figure1 Contact tracing – examination of close contacts of patients with pulmonary tuberculosis

(Adapted from the British Thoracic Society guideline on tuberculosis)³

4.6 Conclusion

This section has looked at a variety of methods for identifying data sources. In practice a variety of different methods could be used within one costing exercise. The use of different methods to produce and validate estimates is useful not only because it provides additional reassurance that assumptions are suitable but it may also detect differing opinions. The costing team will discuss, on a case by case basis, the strategy for dealing with disagreements that may arise between professionals or situations where the data indicates different assumptions to the views of professionals.

³ British Thoracic Society (2000) Control and prevention of tuberculosis in the United Kingdom. Thorax 55: 887–901.
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5 Identifying the population affected

5.1 *Population sources to use*

A fundamental step in estimating the cost impact of implementing guidance recommendations is to identify the people affected by them. For example, guidance aimed at preventing teenage pregnancies might start with a population comprising the number of females aged between 13 and 19 years.

National estimates for England will be based on the relevant population for England to calculate the national cost impact of implementing the recommendations in England. The same assumptions can also be applied to a local population. In the past, standard populations such as strategic health authorities, primary care trusts, local health boards for Wales and Northern Ireland and cancer and cardiac networks have been provided in costing templates to facilitate estimating the local cost impact. As the NHS in England goes through structural change and GP commissioning consortia are introduced, the population sources for costing tools will be changed. In the interim, existing populations for primary care trusts and strategic health authorities will continue to be used and it is possible to select combinations of whole or parts of primary care trusts.

There are two main sources of population – resident population and registered population. The estimated **resident population** of an area includes all people who usually live there, whatever their nationality. Members of UK and non-UK armed forces stationed in the UK are included and UK forces stationed outside the UK are excluded. Students are taken to be resident at their term-time address. The methodology used to update the population estimates accounts for flows of long-term international migrants. A long-term international migrant is defined as somebody who changes his or her country of usual residence for a period of at least 1 year. This is available from the [Office for National Statistics](#) and updated annually.

The **registered population** is the number of patients registered with GP practices. This is higher than the resident population for a number of reasons – most notably people leaving the country and not notifying their GP, but also the delay between a patient registering with a new GP and being removed from the register with their original GP. Calculations of the cost impact of QOF should be based on the registered population.

5.2 *Incidence and prevalence data*

Prevalence and incidence measure different aspects of disease burden in a population, although they are related. The **incidence** of a particular condition is the number of new cases of the condition among a certain group of people over a certain period of time. The **prevalence** of a particular condition is the number of people in a given group or population who are reported to have the condition at a given time. It is important to understand the basis on which these data are gathered and presented. For example, a general survey of the population will probably identify a greater number of people with a condition than those that are based on numbers who present to their GP. This is because a general survey is

likely to identify people who are not registered with a GP, or who are self-managing their condition.

Some examples of incidence and prevalence are given below.

- Annual incidence – the number of people who will develop a disease over the course of a year; it is the most common way of expressing incidence.
- Point prevalence – a measure of the burden of disease in a population at a particular point in time.
- Lifetime prevalence – a measure of how many people may be affected by a disease during the course of their lifetime.

Both prevalence and incidence data may need to be considered within one costing tool to enable accurate calculation of the cost impact of different significant recommendations. For example, the annual treatment cost for a chronic condition lasting many years will require the prevalence to be known, whereas the annual cost relating to initial diagnosis will be linked to the annual incidence rate.

The prevalence of a disease can be related to the incidence by considering the nature of the disease. This could include considerations such as those given below.

- The duration of a disease. For example, a condition that resolves in a short period of time such as flu will have a prevalence rate much lower than the incidence rate, and a disease such as asthma, which lasts many years, will have a prevalence rate much greater than the incidence rate. It is advisable to use annual incidence where the disease duration is less than year.
- Whether a disease is treatable. For example, an infection that can be cured using antibiotics may have a shorter duration than something that is long-term such as arthritis.
- The typical progression of a disease. For example, aggressive cancers with a high mortality rate might have a prevalence that is similar to the incidence, whereas the prevalence of a condition such as asthma, which lasts many years and often starts when people are young, will be many times the annual incidence.

Various sources of prevalence and incidence data can be used during the production of costing tools. Some examples are given below.

Incidence

- IMS Health Disease Analyser, available from [The Information Centre](#).
- Key national bodies for the subject area in question.
- Available literature/research papers.
- Health Improvement Network (THIN), available from [The Information Centre](#).
- General Practice Research Database (GPRD); limited access via [The Information Centre](#).

Prevalence

- QOF data available from [The Information Centre](#).
- [Health Survey for England](#), available from the Department of Health website.

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- [Office for National Statistics](#) website.
- [Association of Public Health Observatories](#), the umbrella site for local public health observatories – each of which lead on different clinical areas.
- Key national bodies for the subject area in question, for example [Cancer Research UK](#).
- Available literature/research papers.

Several different sources may need to be examined and compared to derive robust prevalence/incidence data. When appraising sources of prevalence and incidence data it is important to consider the location of the study, whether the study is comparable to the UK and how recent it is, particularly for diseases such as asthma where the incidence is considered to be changing over time. Variation between different sources of data should inform sensitivity analysis.

5.3 *Subgroups within a disease area*

Some disease areas may contain several subgroups, and this will need to be taken into account during the costing process. For example, costing a technology recommended for early-stage HER-2-positive breast cancer requires the annual incidence of breast cancer, the number of women diagnosed at an early stage and the number of these who are HER-2 positive.

The relevant population within each subgroup should be identified using the sources outlined above, or if these do not hold detailed data of subgroups, professional opinion should be used.

Various factors may affect the population of each subgroup. For example, if deprivation is a factor affecting the incidence of depression, then this should be noted. This will enable local users to amend national assumptions to take account of local factors.

It is important to consider whether there are limitations imposed on the target population regarding who is able to access current services. Referral criteria for services need to be considered and understood.

The national cost estimate uses populations that match the population affected by the guidance. The examples below indicate how local knowledge of subgroups can be used to adapt the costing template to determine local cost.

- Statins can be initiated on the basis of cardiovascular risk, which increases with age ('Statins for the prevention of cardiovascular events' [\[NICE technology appraisal guidance 94\]](#)). Therefore a commissioning organisation with a larger proportion of elderly residents than the national average could be affected more than a commissioning organisation that has a younger demographic mix.
- Parent-training programmes are recommended in the management of children aged 12 years or younger or with a developmental age of 12 years or younger ('Parent-training/education programmes in the management of children with conduct disorders' [\[NICE technology appraisal guidance 102\]](#)) but

programmes are being offered to different age ranges in some areas – for example, as part of Sure Start⁴ services.

- Mammography is recommended for women aged 40–49 years who are at risk of familial breast cancer ('Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care' [[NICE clinical guideline 41](#)]), whereas in practice the people who have been through the family history service tend to be 45 years and over.

Where guidance refers to a specific age range the costing tools will consider the same age range. Where guidance is aimed at 'children' without defining the age the default population selected will be 0–18 years of age. This is in line with the legal definition of '[a child](#)'.

Care must be taken when looking at more than one subgroup to avoid double counting if subgroups overlap. For example, in 'Pregnancy and complex social factors' ([NICE clinical guideline 110](#)), there were four main populations with estimates for the size of each population (see table 3). However, it is not possible to add together the subgroups because one woman may experience a number of factors at the same time, such as a woman who misuses substances and experiences domestic abuse.

Table 3 Breakdown of births in England by exemplar group

Group	Percentage (estimate)	Number of births
Women who misuse substances (alcohol and/or drugs)	4.5	30,200
Women who are recent migrants, asylum seekers or refugees, or who have difficulty reading or speaking English	10.2	68,400
Young women aged under 20	6.1	40,900
Women who experience domestic abuse	7.0	47,000

⁴ Sure Start is the government programme to deliver the best start in life for every child. They bring together early education, childcare, health and family support.

6 Identifying activity levels

6.1 *Identifying the baseline – current care pathway and treatment levels*

One of the most important elements of the costing tool is identifying the baseline and predicting how this might change. The cost impact relates to the change required and can be estimated using the following formula:

$$\text{(predicted activity x predicted cost)} - \text{(current activity x current cost)}$$

Changes could include either changes to the levels of service provided or changes in how services are provided, such as providing staff training or new items of equipment such as positron emission tomography (PET) scanners.

Appendix B provides a list of potential costs and activities that could change as a result of implementing recommendations.

NICE asks a series of questions during the search to identify the baseline – ‘what?’, ‘who?’, ‘where?’, ‘for how long?’. When asking these questions it is important to consider the population affected. If the recommendation affects children, advice is sought from people working with children. (See section 4 for more detail on sources of data, including use of clinical opinion.)

6.1.1 **What? The intervention/activity**

The activity being identified should be clearly defined. Alternative definitions should be included in the search because the same activity might be described using different names in different areas. For example, if a procedure is undertaken as a day case in some areas and as an outpatient procedure in other areas, the costing analyst should consider a weighted average cost or including both options in the costing tool.

If the activity can be performed in several different ways, sufficient questions are asked to understand how the activity is being performed and to enable the results to be compared. For example, when trying to assess the level of current training provision, it is necessary to clarify the resource implications of the particular type of training being provided, rather than simply asking whether training is available. Some of these questions are given below.

- How are trainers trained?
- How often is training offered to staff?
- Is the training core health and safety training or is it specific to this guidance?
- Is backfill for participating staff required or is training time built into rotas?
- Is the training accredited and does this incur costs?
- Does initial training vary from refresher training?
- How often might refresher/update training be required?
- What proportion of the total eligible staff population can realistically receive training in 1 year?
- Who could deliver the training – internal or external staff?

6.1.2 Who? The person responsible for the activity

Where there are different professionals performing a similar function it is important to clarify whether there are any limitations to the way the activity can be performed by particular professional groups, and to note the typical grade(s) of staff for each relevant staff group. The range of professionals performing the activity, the relative proportion of each professional carrying out the activity, and their pay banding should be noted in order to calculate a weighted staff cost if required. Often the professional input depends on the severity of the particular disorder and the seniority or level of ability of a particular professional. In cognitive behavioural therapy (CBT), for example, the professional most appropriate to deliver CBT may depend on whether the treatment is to address mild depression or severe post-traumatic stress disorder.

Whether the professional group offering new appointments or initiating treatment differs from the professional group providing follow-up appointments and maintaining treatment is also considered.

6.1.3 Where? The location of the intervention

The location of the intervention is intrinsically linked to 'Who?' However, some recommendations state that an intervention can or should be delivered in a variety of locations, such as an inpatient ward, outpatient clinic or GP surgery. For example, the costing of 'Parent-training/education programmes in the management of children with conduct disorders' ([NICE technology appraisal guidance 102](#)) indicated that group parent-training programmes could be offered in clinic and community settings and that individual programmes could be delivered in the clinic or the client's home. Each option in this case would result in a slightly different unit cost because of different overheads and travel requirements. Therefore when assessing current performance the assumptions should be clearly stated and the potential for practice to vary should be noted.

6.1.4 How? For how long?

Determining the length of an average course of treatment is an important part of the costing process. Treatment could be either drugs or another treatment – for example, a course of CBT. The treatment length may vary for different drugs included in the costing work.

The 'British national formulary' (BNF) indicates that some drugs should be taken only in the short term, or the dose needs to be altered when moving from the initial phase to a maintenance phase. The doses used and the length of each treatment should be clearly stated in the assumptions.

Where there is a difference between the licensed treatment course and standard practice the baseline usually reflects standard practice. For example, when looking at the cost of 'Docetaxel for the treatment of hormone-refractory metastatic prostate cancer' ([NICE technology appraisal guidance 101](#)), expert opinion that patients typically underwent six cycles of chemotherapy was used as the basis for costing, although the license and recommendation is for a maximum of 10 cycles.

Other questions to consider include the following.

- How many contacts a patient has with the service are normal?
- What is the dropout rate and how much of a course of treatment would be completed by those who drop out? Reasons for dropout might include adverse reactions as well as patient choice/non-adherence.

Once the baseline of current practice has been established the next step is to predict the impact of recommendations. Decision models can be a useful source of describing both current and future pathways (see section 4.5).

6.2 *Predicting the impact of recommendations*

Predicting the impact of recommendations is a forecast of how a service will respond to the guidance once it is issued and of the potential for indirect consequences arising from changes in service delivery. There is less certainty in predicting impact compared with establishing the baseline.

The objective is to send a signal to commissioners and providers of the cost impact of guidance and standards. This should be realistic rather than optimistic (for example, expecting guidance to be implemented straight away in 100% of the population eligible). Experts can sometimes provide information on realistic levels and timeframes for implementing guidance to inform the cost impact over time.

Sometimes the indirect consequence arising from a change can be predicted with reasonable certainty because research provides the comparison between current and alternative treatment. For example, the research regarding the use of trastuzumab for early stage breast cancer reported rates of recurrences and rates of cardiac events compared with existing treatment.

Assessing how many people would (a) be eligible for treatment and (b) choose treatment is an important part of predicting the impact of recommendations. Section 5.3 describes how subgroups within a disease area are assessed and this includes estimating the subgroup that would be eligible for treatment. The impact of treatment choice depends on two factors – clinician preference and patient preference. To determine clinician preference a number of professionals are contacted to establish their view on whether they would choose the recommended method and to find out what percentage of the population they are dealing with. Patient preference may be indicated in submissions from patient groups regarding willingness to try new therapies.

6.3 *Diffusion and timeframe for implementation*

Some changes can be effected with relatively little lead in time, whereas others may require more substantial system change and cannot be achieved overnight. The availability of equipment, trained staff and premises, and the time to plan and effect change all need to be considered. For example, switching patients from one combination of drugs to another combination where all drugs are in general use could be done relatively quickly. By contrast, an innovative drug that has one manufacturer could have supply chain problems that limit its use until the systems gear up to increased production and distribution.

Section 5.2 discussed the difference between incidence and prevalence and how they impact on estimating the population for a given treatment or activity. They could also impact on the timescale for implementation planning. Whether a recommendation affects the whole population of patients living with the same long-term condition or only new cases can affect the estimation and timing of activity required. For example, when costing drugs for psoriasis ('Etanercept and efalizumab for the treatment of adults with psoriasis' [[NICE technology appraisal guidance 103](#)]) the recurrent cost of treating the new presentations each year and the non-recurrent cost of treating a backlog of patients were separately identified.

Financial planners are usually working 3–5 years ahead and costing tools aim to help them with this process. However, some changes in practice may take longer than 5 years to implement, in which case the timeframe for the costing tools should normally follow this 3–5-year horizon, with associated savings also following the principle of savings delivered within 3–5 years rather than looking at full implementation if this will not be achieved within 5 years. Occasionally it may be appropriate to look at a different timeframe. For example, the longer term benefits from some public health interventions may be included in the costing tools to try to encourage implementation. Decisions on extended timeframes will be made on a case by case basis.

The timeframe for reaching saturation point when prescribing a drug for a chronic condition will depend on how long, on average, people live with the condition. For example, if 100 people get a condition each year, and each year 10% of the total population with the condition discontinue treatment – either because of death or side effects – then the number of patients treated each year can be modelled (see table 4).

Table 4 Example of diffusion in a chronic condition

	Year 1	Year 2	Year 3	Year 4	Year 5
Existing Patients	0	90	171	243	308
New Patients	100	100	100	100	100
Dropouts from treatment (10%)	10	19	27	34	41
Continuing patients	90	171	244	309	367

The number of continuing patients is increasing each year as the number of new people starting therapy is greater than the number dropping out. A steady state occurs when the number of patients dropping out equals the number of new patients. The above example indicates that costs will not stabilise until the number of dropouts is equal to the number of new patients each year, and this occurs at year 50 (see figure 2).

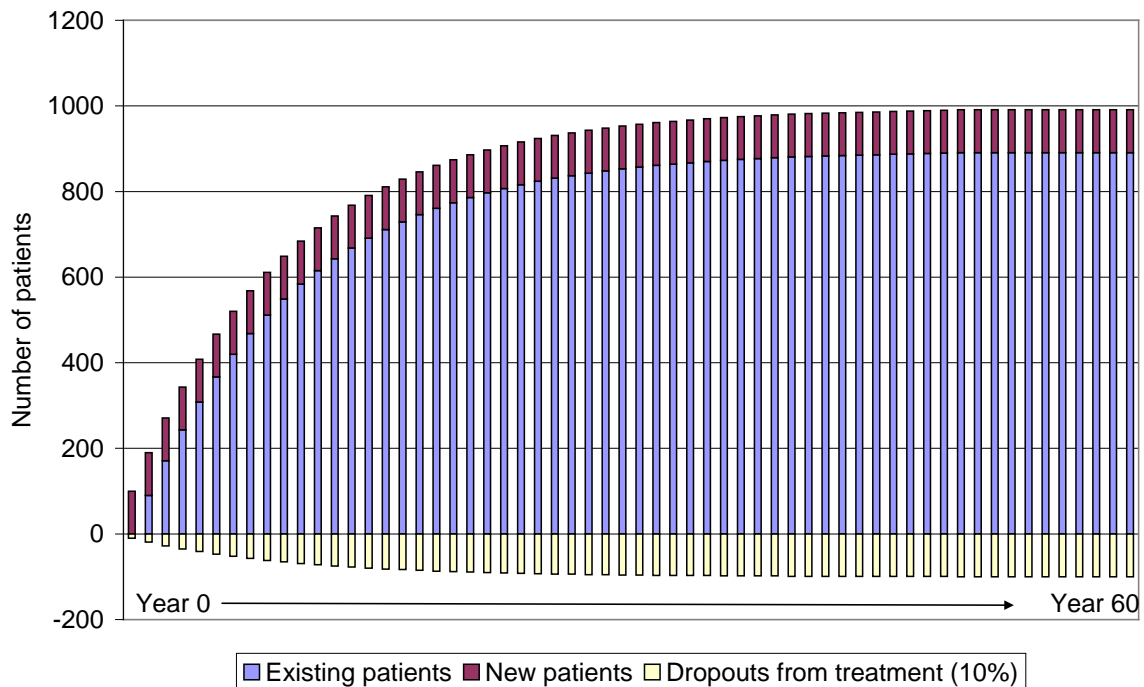


Figure 2 Achieving steady state when prescribing for long-term conditions

When defining the time required to fully implement change, the following sources of information may be useful:

- information submitted by manufacturers, assessment groups and experts as part of the technology appraisal process
- staged processes that need to be followed to implement a recommendation
- professional opinion
- typical survival rates
- results of research trials – these may indicate numbers not responding to treatment, dropping out because of adverse events, or natural attrition
- experience of equivalent change – either through the use of uptake data to define the rate of change over time or the length of time taken to implement a similar change – that is, changes to comply with national service framework standards.

If there is uncertainty regarding the timescale for implementation, the focus will be on the costs for the first 3–5 years because this is the typical horizon for financial planning purposes.

Technology appraisals have a [3-month direction](#) but uptake data indicate that the provision of drugs following the publication of a NICE appraisal does not simply flatline at 3 months after publication. Consequently, some consideration of costs at full implementation and of the rate of diffusion is warranted. However, the costing tool does not in any way override the 3-month funding direction – its objective is to assist with financial planning. Similarly, lack of funding should not be used as a rate-limiting criterion for staging implementation.

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The funding direction is extended for a few technology appraisals, generally when there are significant implementation issues that would make implementation within 3 months unrealistic. In these cases the approach taken for both the costing work and consideration of diffusion is closer to that taken with clinical guidelines.

6.4 *Calculating costs and savings over time*

The actual calculation of costs over time can be straightforward once the costing model has been defined. To calculate costs over time for a constant rate of change, the same costing model is replicated for each year of the implementation process. The variables in the first year will be the same as those used to calculate the current position and the variables in the final year will be same as those used to calculate the future position. Information on the rate of change over time has to be added to enable the baseline position to move to the final position.

It is sometimes necessary to include additional information when considering costs over time where there is a rate limiting step, when a process has different stages or when there are multiple starting points. These different approaches are shown below.

Example 1: A constant rate of change

The example in table 5 shows the costs over time for one element of 'Heavy menstrual bleeding' ([NICE clinical guideline 44](#)) – that a full blood count test should be carried out on all women with heavy menstrual bleeding.

Table 5 Costs incurred over time for carrying out a full blood count test in women with heavy menstrual bleeding

	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12
Increase in women presenting to practice with heavy menstrual bleeding		1%	1%	1%	1%	1%
Proportion of women with a diagnosis of heavy menstrual bleeding who have a full blood count	39.3%	48.2%	57.2%	66.1%	75.1%	84.0%
Number of full blood counts	158,667	196,708	235,494	275,036	315,346	356,434
Increased proportion of women who have a full blood count test	8.9%	8.9%	8.9%	8.9%	8.9%	8.9%
Cost of current full blood count tests	£4.00	£4.00	£4.00	£4.00	£4.00	£4.00
Total cost of full blood count tests	£634,668	£786,832	£941,976	£1,100,144	£1,261,384	£1,425,736
Change in cost compared with previous year		£152,164	£155,144	£158,168	£161,240	£164,352

The shaded cells provide the rates of change over time for two elements of the model. The first shaded row gives a rate of change that affects the total population of women with heavy menstrual bleeding who present to services. This will affect all elements in the costing model. The second shaded row shows the rate of change in the number of women with heavy menstrual bleeding who are given a full blood count test, from the current position of 39.3% to the future position of 84%.

In this example there was no clear case for a particular pattern of change over time, so a constant annual rate of change was used. This means that the rate of change over time is the same for each year and that the results would plot as a straight line on a graph of costs over time.

Example 2: A staged process affecting costs over time

If a staged process needs to be followed in order to implement a particular recommendation, the timings and requirements of different stages can be used to describe change over time.

The postnatal care guideline proposed the implementation of the Baby Friendly Initiative (BFI) ('Routine postnatal care of women and their babies' [\[NICE clinical guideline 37\]](#)). Implementing this is a staged process where administrative costs arise at key points along a development pathway towards accreditation (table 6).

Table 6 Costs incurred over time for implementing the Baby Friendly Initiative (BFI)

Year on BFI	UNICEF BFI fee £	Description of activity	Assumption in costing model
Year 1	720	Initial BFI work plan	Trusts with a pre- certificate of commitment will start at this point
Year 2	0		Trusts with a certificate of commitment will start at this point
Year 3	6720	Initial assessment fee and follow-up visit fee	
Year 4	0		Accredited units will start at this point
Year 5	0		
Year 6	4460	Re- assessment and follow-up visit fee (required by 50% of units)	
The costs incurred between years 4 and 6 will be repeated every 3 years			

When developing BFI accreditation, maternity units generally start at one of three distinct points along the pathway. Based on information about the current BFI status of all maternity units, it is possible to plot how long it might take all units to achieve accreditation according to the development pathway above and outline when the administrative costs and other costs resulting from implementation activities would arise nationally (table 7).

Table 7 Example of change in costs over time with a staged approach

Current BFI award status	Number of maternity units	UNICEF BFI fees incurred over time,£000s							
		2006/07	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14
Accredited	21	0.0	0.0	93.7	0.0	0.0	93.7	0.0	0.0
Certificate of commitment	94	0.0	631.7	0.0	0.0	419.2	0.0	0.0	419.2
Pre certification	124	89.3	0.0	833.3	0.0	0.0	553.0	0.0	0.0
Total	239	89.3	631.7	927.0	0.0	419.2	646.7	0.0	419.2

(BFI) Baby Friendly Initiative

Savings over time

Just as costs of implementation might vary over time, potential indirect savings will also occur at different time points.

The postnatal care guideline described both costs and savings arising from the implementation of the BFI. Savings relate to lower incidence of childhood diseases in babies that are breastfed. The costs and savings were calculated over time and are shown in table 8.

Table 8 Extract from the costing template for 'Routine postnatal care of women and their babies' ([NICE clinical guideline 37](#)), showing the costs and savings for implementing the Baby Friendly Initiative (BFI)

	2006/07 £000s	2007/08 £000s	2008/09 £000s	2009/10 £000s	2010/11 £000s	2011/12 £000s	2012/13 £000s
Cost of structured programme that encourages breastfeeding	8575	8176	7227	4362	4781	5008	4362
Cost of changes birth to provision in birth to five	214	211	211	211	211	214	214
Savings from improvements in breastfeeding rates	-1956	-2948	-3960	-4972	-5548	-5596	-5596
Net resource impact	6833	5439	3478	-399	-556	-374	-1020

The net cost impact of the recommendations with significant resource impact is shown in figure 3.

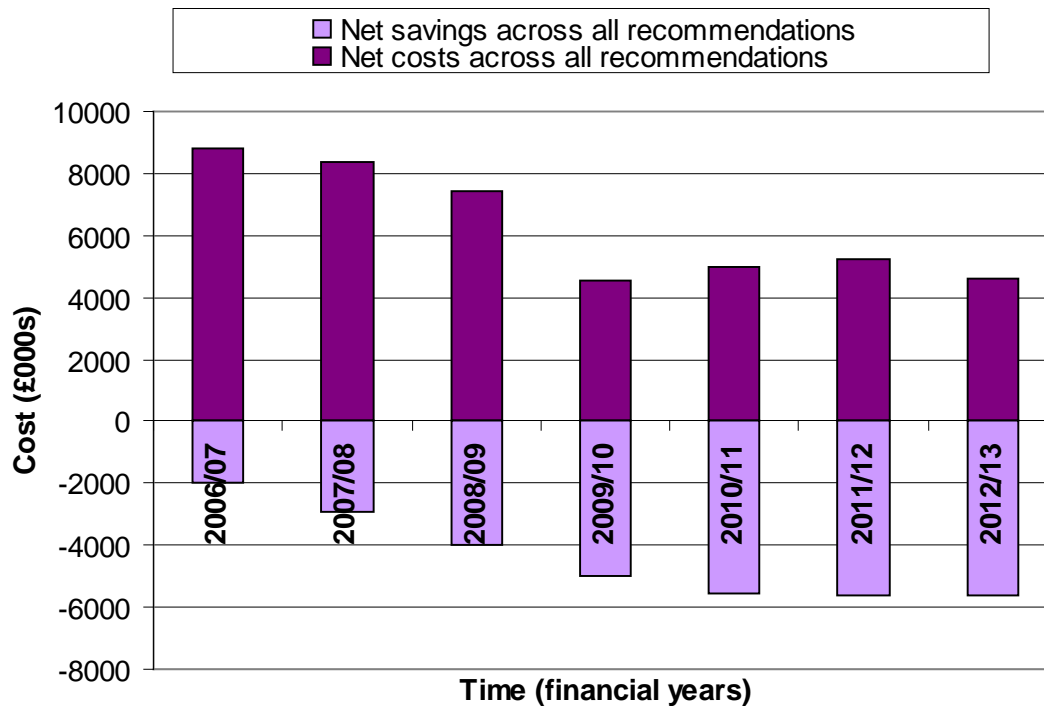


Figure 3 Cost impact of recommendations with significant resource impact from 'Routine postnatal care of women and their babies' (NICE clinical guideline 37)

The graph clearly shows that initial costs outweigh the potential savings but that this position changes over time to favour savings over costs.

Sometimes the level of savings over time will not be constant. For example, if the objective of the guidance is to avoid onward transmission of infectious diseases, then this will require a different type of modelling.

When estimating savings the following should be considered:

- when the savings might realistically arise after the relevant activity (it may take time for the positive outcome to occur after the activity has been completed)
- for how long the savings are likely to accrue
- whether savings will diminish over time
- whether savings will affect non-health public sectors or different departments within a single NHS trust.

Rate-limiting steps

The rate of change over time might be best described by considering what the rate-limiting step in the implementation process might be. Examples of rate-limiting steps include:

- access to training and time taken to complete training
- the number of trained staff and the maximum workload
- patient preference in switching treatment, for example moving from drug treatment for depression to receiving CBT
- the time taken to switch from current medication to new regimens
- the number of patients that require treatment, particularly where there is a backlog of patients that can only be reviewed in line with clinic capacity
- the availability of additional equipment or premises.

6.5 Conclusion

This section has discussed the methods that can be employed to identify the activity levels – both baseline and predicted levels – that arise from implementing the recommendations that significantly affect resources used. The next step is to apply a cost to the activity levels and resources that will change, and this is discussed in the next section.

7 Identifying unit costs

7.1 Introduction

The costing templates normally consider costs to the NHS for clinical guidelines and technology appraisals and costs to the public sector for public health. It is anticipated that public health guidance will make recommendations affecting sectors such as social services, education, housing and transport. But there may be times when it is appropriate to vary this, particularly where the costs or savings for other sectors are significant; this in turn might encourage better uptake. In these circumstances the costs or savings for the NHS and for other sectors will be shown separately.

7.2 NHS Budget 2010/11⁵

In order for a costing analyst to identify the appropriate unit cost, it is important to have an understanding of where NHS resources are spent and where the activity typically occurs. Table 9 below highlights the NHS Budget for 2010/11 and indicates the amount of spend that is within the remit of PbR.

Table 9: NHS budget 2011/12

Budget heading	£ billion	%
Total budget	104	100
Revenue	99	95
Capital	5	5
Revenue	99	100
PCT allocations	84	85
Central Budgets	15	15
PCT allocations	84	100
Payment by results	26	31
Other PCT expenditure including non-PBR, prescribing and primary care	58	69
PbR, Payment by Results; PCT, primary care trust		

7.3 Consistency with the health economic model

NICE guidance developers consider both the clinical effectiveness and the cost effectiveness when developing recommendations. This may involve the development of health economic models, or consideration of health economic analysis developed by others.

Care is taken to ensure that data used from health economic analysis on which the guidance is based are in the public domain and do not contain information provided in confidence for commercial or academic reasons without explicit permission to use the data.

⁵ Department of Health (2010) A simple guide to Payments by Results Assessing cost impact – methods guide

7.4 *National available cost data*

The different types of national cost data and the decisions on which costs to use and the order in which different types of costs are considered is shown in figure 4 on the next page.

7.4.1 **Payment by Results(PbR) national tariff**

The PbR tariff can be summarised as follows:

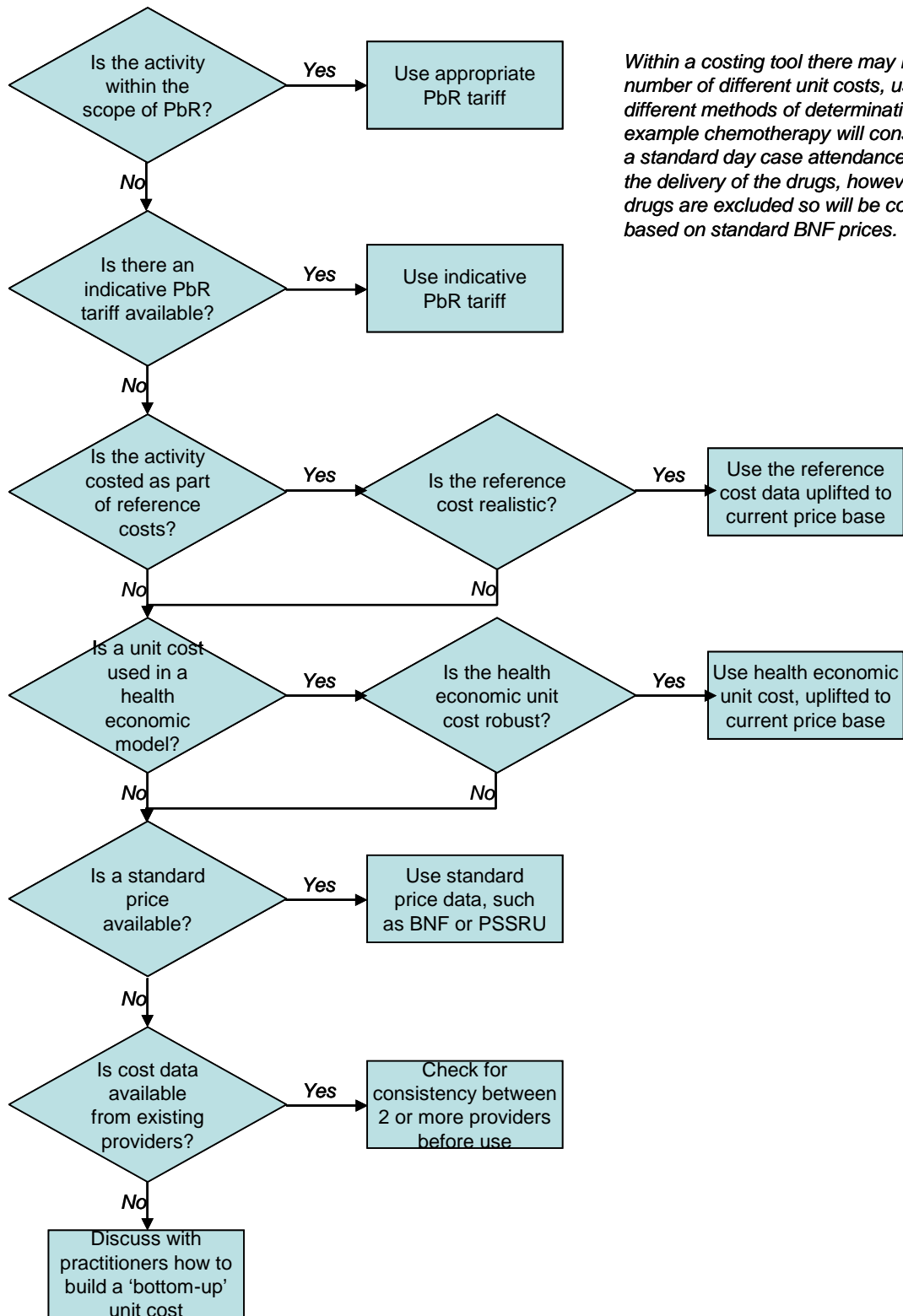
- PbR is the hospital payment system in England in which commissioners pay providers a national tariff or price for the number and complexity of patients treated or seen.
- There are national tariffs for admitted patient care, outpatients, and accident and emergency.
- The currency, or unit of payment, for the admitted patient care tariff is Healthcare Resource Group version 4 (HRG4), covering a spell of care from admission to discharge.
- When a patient is discharged, clinical coders translate their care into codes using two classification systems, ICD-10 and OPCS-4.
- Patient data are submitted to a national database called the Secondary Uses Service (SUS), which groups clinical codes into HRGs and calculates a payment.
- Commissioners agree monthly contract payments to providers in the NHS standard contract, which are then adjusted for the actual value of activity in the monthly SUS report.

The national tariff is a simple average of reference costs collected annually from providers. There is currently a 3-year time lag, for example, the 2011/12 tariff was calculated using the 2008/09 reference costs.

The reference cost data are filtered to remove services outside the scope of PbR and costs that vary significantly from the average.

Various adjustments are then made to ensure the reference costs reflect the desired scope and structure of the tariff. For example, day cases and ordinary electives are collected separately in reference costs and generally combined in the tariff, and diagnostic imaging costs are also collected separately and rebundled into outpatient attendances. Some costs, notably those arising from NICE recommendations on the use of new medicines and treatments, have come into effect after the reference cost period and need to be added.⁶

⁶ A simple guide to Payments by results Department of Health 2010
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Within a costing tool there may be a number of different unit costs, using different methods of determination, for example chemotherapy will consist of a standard day case attendance for the delivery of the drugs, however, the drugs are excluded so will be costed based on standard BNF prices.

Figure 4 Determining which unit costs to use

The tariff is subject to an uplift to reflect local market forces that takes account of regional variations in price – the market forces factor (MFF). To use the published tariff price would result in understating the national cost. In order to reflect the impact of uplifting by the MFF, the tariff should be multiplied by the national average MFF.

There may be occasions when it is appropriate to use a source of unit cost (such as reference costs) other than the tariff price. A ‘common sense’ check of all the unit costs needs to be undertaken to ensure that the one chosen is the most appropriate one to use.

Another example is where a surgical procedure is being appraised and both the procedure under consideration and the comparator fall within the same HRG. Using the same tariff for both procedures will result in zero impact. In this instance, if there is a significant difference in cost between the two procedures, then this will eventually feed into the calculation of reference costs and affect the tariff price, so the differential cost between the procedures should be estimated. An example would be the use of different implants in a hip operation: a provider would be paid the same tariff for the operation whichever implant was used. The cost of implants and therefore the operation cost would however be different.

There may also be non-recurrent issues such as equipment purchase or training to reflect in the costing tools.

Figure 5 shows the structure of codes using HRGv4. Quite often a procedure could fall within a range of HRG codes depending on factors such as age of the patient, or whether there were complications or comorbidities (noted as ‘with CC’ on HRG descriptions) that affect the cost of activity.

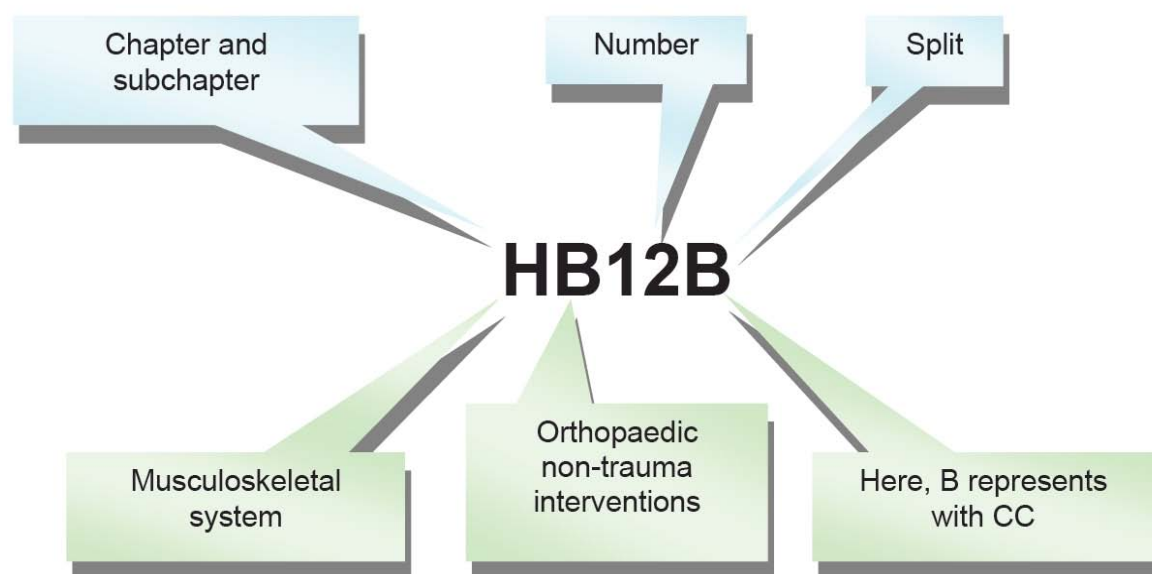


Figure 5 Structure of the HRGv4 code

Although the tariff covers a substantial amount of hospital activity, there are areas where no tariff exists. The Department of Health provides an indicative tariff for some activity that is calculated on the same basis as the tariff for commissioners to use if they chose; however, this is not mandatory. Where a non-mandatory tariff exists, then it should be used.

In preparation for bringing more activity within the tariff the Department of Health has specified currencies for some clinical areas such as mental health and community services. Commissioning should take place using these currencies, but local tariffs for the activity should be negotiated.

It is important to identify clearly whether changes in activity at tariff rates correspond with what would be included within the tariff. If a recommendation changes the price base but does not change the activity provided then it may be more appropriate to cost it using local prices. For example, the lung cancer guideline made a number of recommendations relating to the role of lung cancer nurses. This led to an assumed increase in the number of lung cancer nurses, which would improve the care and coordination of care for patients with lung cancer but would not alter the activity delivered. In this instance it was more appropriate to estimate the additional cost because no tariff rate was applicable and the care provided cut across inpatient, outpatient and community services.

7.4.2 Reference costs

The reference costs are the average of the actual costs of activity carried out by all the providers – both in secondary care and primary care. The Department of Health uses reference costs as a baseline for calculating the tariff. So there may be activity that is not included in the tariff or indicative tariff, but which is included in the reference costs. If this is the case then the reference cost should be considered as the basis for the unit cost.

In areas such as mental health, there are issues with the unit of measurement being difficult to establish – for example, a client contact could range from a brief meeting to a long counselling session. A national currency has been developed based on a ‘care cluster’. The clusters identify patient need over a given period of time, and apply to both admitted patient and community care. Judgement should be exercised about whether reference costs are the best source for a unit price or whether other costs are used.

In addition to publishing reference costs, the Department of Health also includes the cost for the 25th and 75th percentile. The variation of costs from average cost is a useful guide to inform the minimum and maximum range for unit costs within the sensitivity analysis.

7.4.3 Standard prices – drug costs

Most technology appraisals and some clinical guideline recommendations relate to drugs. The way that drug costs have an impact on different NHS bodies varies. Drugs issued in primary care are charged at a standard price and this includes allowances for dispensing costs. Costs are also net of any prescription charges that the patient contributes; no VAT is payable on these drugs. By contrast, drugs issued to secondary care patients from a hospital pharmacy cost the purchase

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price plus VAT; the purchase price could include discounts that are offered to buyers, particularly where a patient access scheme applies. Within the costing tool any assumptions regarding additional VAT and discounts will be made where applicable, clearly stated in the notes and able to be amended locally.

Costing tools should use standard prices that are from a verifiable source to be consistent with the health economic analysis on which guidance is based. This usually means using the latest BNF or Prescription Pricing Division drug tariff price. Quite often both the BNF and the drug tariff agree. However, whereas the BNF is updated twice a year, the drug tariff is updated monthly and will reflect price changes more quickly. Where there is a difference, the drug tariff should be used.

Dispensing fees or prescription charge income are not normally included in the costing tools, and it is assumed that one will offset the other. In exceptional circumstances, such as daily dispensing of controlled drugs to drug addicts, the dispensing fees will be significant and should be included. The basis of drug cost calculations should be clearly stated in the costing report. Local users are encouraged to update costs with local costs where they are known. This is particularly important when a costing tool is being used for drugs that may have come off patent and prices are dropping because of the entry of generic formulations.

Where drug costs are expressed as doses based on body surface area or weight, further calculations may be required. The standard body surface area used is 1.75 m². Where weight is used, health survey data for the population under consideration should be used to arrive at an average weight. For example, a drug used to treat breast cancer will be used mostly by females, who tend to be lighter than males.

Where drugs are provided in standard size vials the following should be considered:

- the impact of wastage can be estimated by rounding costs up to the number of whole vials used, including part vials
- whether the volume of patients is such that pharmacies can be expected to re-use part vials and avoid wastage (table 10).

Dose per m ²	75 mg
Average body surface area	1.75 m ²
Dose	131 mg
Concentration	40 mg/ml
Volume required	3.28 ml
Number of 2-ml vials required assuming no wastage	1.64
Number of whole 2-ml vials required	2.00
Cost per vial	£534.75
Cost per cycle	£877.00
Cost per cycle assuming wastage	£1,069.50

Table 10 Calculating drug dose required and financial impact of wasted vials

7.4.4 Local prices

Where it is not possible to use tariff or reference costs, unit prices could be obtained from NHS organisations currently providing the service to inform setting the unit cost. This is useful in the case of very new procedures that have not yet been included in the tariff, for example PET scanning. It also applies for high cost procedures that are specifically excluded from the scope of the tariff. If local prices are used, prices from more than one provider should be sought in order to establish that they reflect practice in the NHS and inform the sensitivity analysis.

Another option is to approach the costing from first principles and work out the inputs that would be needed. This is particularly useful for patient contact activity in mental health. The price can be based on assumptions about the percentage of patient contact time, the rate of pay using Agenda for Change pay rates and the estimated time the patient and professional are engaged with each other.

Where pay is the basis of unit costs the full cost of employing someone, including employer's contributions to national insurance and superannuation, must be used. The difference between what an employee might consider to be their pay and the cost to the employer is depicted in figure 6

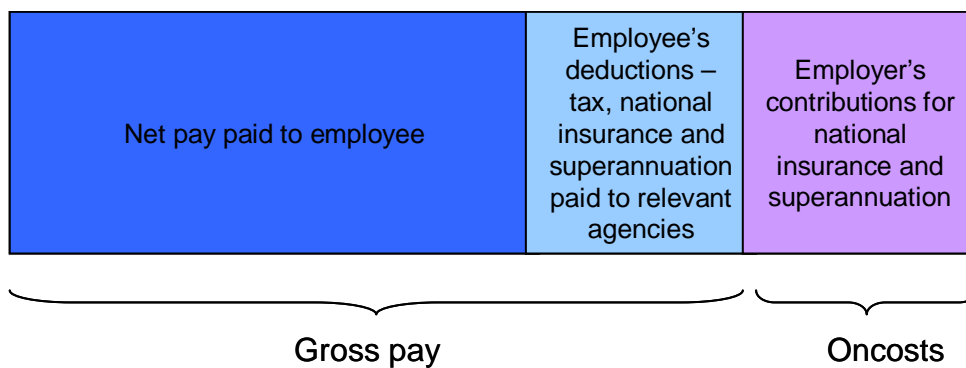


Figure 6 Example of full pay costs for an employer

Where possible data should be sought to establish the appropriate point of scale to be used. For example, using the mid-point of scale may not always be correct if the workforce typically consists of experienced staff likely to be at the top of the Agenda for Change pay band. Data on typical point of scale, average cost of enhancement to basic pay (for example, clinical excellence awards) can be obtained to ensure a more accurate costing. Clinical expert opinion can also assist in this area.

Having established the full cost to employ someone the next decision is which unit of measurement to use. Depending on the circumstances this could be the annual cost of employing one whole time equivalent or it could be the cost for a certain number of hours. The following example calculation (table 11) shows the difference between a straight conversion to cost per hour and the impact of reflecting non-productive time such as annual leave, and the percentage of patient contact time.

Table 11 Example of different methods of estimating cost per hour

	No allowance for leave, training or non-contact admin	Allowing for leave, training or non-contact admin
Annual cost to employ one whole time equivalent	£25,582	£25,582
Working week, hours	37.5	37.5
Percentage time spent with patients	100%	60%
Hours per week spent with patients	37.5	22.5
Weeks per year spent with patients	52	40
Equivalent cost per hour spent with patient	£13.12	£28.42

Assumptions regarding items such as patient contact time can be informed by the [Personal Social Services Research Unit \(PSSRU\)](#) data or discussions with professionals.

7.5 *Impact of inflation*

The costing tools will use all costs at current prices. Historic prices should be inflated to the price base at the time the costing tool is published. Pay costs, should be uplifted by NHS pay inflation rates and non-pay costs by the hospital prices index.

All prices will be shown at today's prices with no account taken of inflation, or the reducing value of the pound when modelling costs over a number of years. This is because the objective of the costing tools is to inform financial plans, and budgets are usually expressed at current prices with no discounting of costs. Discounting of costs is more applicable for the health economic analysis or when developing option appraisals as part of large business cases where the time value of money has a bearing on decision making.

Section 9 addresses the circumstances in which costing work is updated. Updating will not be routinely carried out for price changes; however, local users are encouraged to amend costs to reflect current local costs.

7.6 *Which cost data?*

The decisions made regarding which costs to use and the order in which different types of costs are considered is depicted in figure 4, section 7.4.1. It shows the usual choice of data; however, for reasons explained below the figure, it is important that a 'common sense' check is applied to all unit costs to ensure that the method for determining cost is the most appropriate one. For example, there may be occasions when it is appropriate to use a source of unit cost other than the tariff price.

8 Creating the costing tools

8.1 *Combining population/activity/cost*

When population, activity and cost data have been researched and the most relevant data have been collected for use within the tools, the data are combined within a spreadsheet to reflect the financial implication of the relevant recommendation(s).

It is recommended that a spreadsheet is created that combines population, activity and cost to estimate the national cost. This is useful in determining if the national cost is significant (see section 3.2 for advice on significance).

There are two methods for creating the spreadsheet, and the costing analyst should determine which method best suits the topic being costed. These methods are given below.

- The standard template can be used when the elements to be included are reasonably simple or similar to previous templates created. (For more information on standard templates, see section 8.4.)
- For more complex areas, it might be beneficial to develop a spreadsheet that can be shared with consultees and to re-format the information into the standard template once assumptions have been discussed and agreed.

The spreadsheet or draft template should clearly reflect what current activity is, and what the predicted change in activity arising from implementation will be. The difference between current resource use and predicted resource use will be the cost impact.

8.2 *Links to other guidance/costing tools/commissioning guides*

It is important to ensure that the costs estimated are solely for one particular piece of guidance and not to double count, which would inflate the costs of implementing recommendations from within other pieces of guidance. This is achieved through researching what related guidance has previously been published, and any costing tools that accompanied related guidance.

Guidance may often refer to other relevant guidance that has been published and which may have costing tools to support it. Costing tools supporting related guidance should be referred to in the current report and template where they are relevant. However, it is not the intention to re-visit previously costed elements. For example, the costing template for the depression guideline ('Depression (amended): management of depression in primary and secondary care' [[NICE clinical guideline 23](#)]) predicted the cost of providing CBT for patients with mild depression. So, when the impact of recommendations in the guideline on antenatal and postnatal mental health ('Antenatal and postnatal mental health: clinical management and service guidance' [[NICE clinical guideline 45](#)]) was considered the focus was on the extension of therapy and support to perinatal women with subclinical signs of depression. This was based on the assumption that those who met the criteria were within the costs estimated for the depression guideline.

Where commissioning and benchmarking tools are in existence or being developed at the same time, unit costs and activity data should be consistent. If for any reason this is not possible, the reasons for the difference should be stated. However, the objectives of the commissioning and benchmarking tools are different – it is used to estimate total cost to commission a service, rather than the incremental cost arising from implementing guidance recommendations. Therefore, there may be differences in approach.

8.3 *Discussion of rough draft*

Informal discussions within the costing team and with either the technical team within the guidance producing centre or with guidance development groups is normally undertaken when the tools are being developed, and having a draft spreadsheet or template will help these discussions.

It is important at this stage to ensure there is appropriate clinical engagement; this will usually require sending a series of questions to clinicians involved in the development of guidance. For example, clinicians on the Guideline Development Group for a clinical guideline may be able to advise on current practice and help predict change in practice as a result of implementation of the guidance.

A spreadsheet can be used to present the assumptions in as clear a manner as possible to stimulate meaningful discussion. This may involve separating out the current and predicted activity from the financial costs; using a care pathway approach or flow charts may help to illustrate the items identified as relevant to estimating cost impact. This will focus attention on the activity assumptions as these tend to have more uncertainty than cost information (see figure 7 for an example from the costing of 'Obsessive-compulsive disorder: core interventions in the treatment of obsessive-compulsive disorder and body dysmorphic disorder' [[NICE clinical guideline 31](#)]).

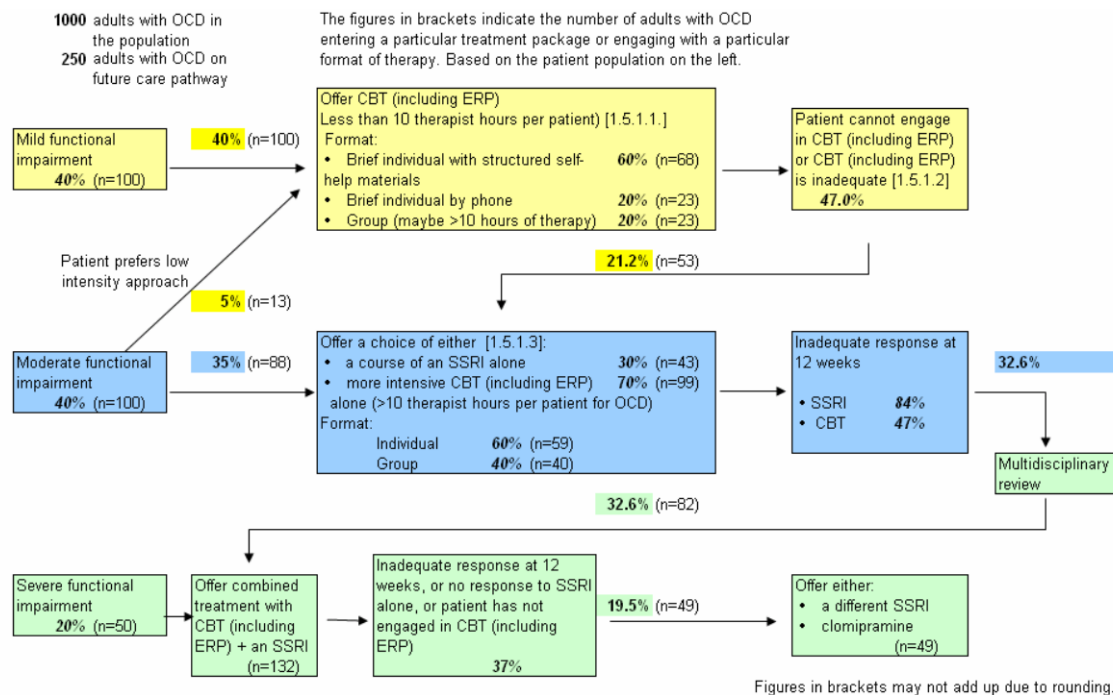


Figure 7 Presenting activity assumptions separately from cost data – example based on ‘Obsessive-compulsive disorder’ (NICE clinical guideline 31)

Once the costing analyst is satisfied that the draft spreadsheet or template represents the picture as accurately as possible, it is time to develop the costing report and template.

8.4 Formats to be used

The standard NICE templates should be used for the costing reports and templates, and there are different templates for different types of guidance. Using the standard templates aims to streamline the development process and provide consistency between tools. It is intended that users will become familiar with the format and presentation if they use more than one template.

Cross-referencing within the costing tools should be used to raise awareness of any other relevant guidelines or costing tools. This may also be useful when explaining why a particular issue has not been included – for example, to avoid double counting costs.

Where guidance is being updated and costing data from previous guidance will become unavailable, consideration should be given to developing a template to cover the whole guidance. For example, costing tools were developed for ‘Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery’ (NICE clinical guideline 46), which was shortly followed by ‘Venous thromboembolism: reducing the risk’ (NICE clinical guideline 92), which included both surgical and medical patients and incorporated the recommendations from the surgical patients guideline (NICE clinical guideline 46). When the updated guideline was published, the previous guideline and its associated implementation tools became unavailable

and a combined tool was developed to bring together costs relating to both pieces of guidance.

Occasionally, variation from the standard format may be called for; this will be decided at an early stage. For example, feedback from stakeholders indicated that the same group would be responsible for implementing guidance relating to drug misuse that was published in the same month ('Drug misuse: psychosocial interventions' [[NICE clinical guideline 51](#)] and 'Drug misuse: opioid detoxification' [[NICE clinical guideline 52](#)]). There was a request for a coordinated approach by developing one costing template and report that covered both pieces of guidance.

8.5 *Is a costing template appropriate?*

The criteria for determining whether something is significant include numbers of patients affected and overall cost. The same criteria should be used to determine which costing tools are appropriate. (See section 3.2 for guidance on determining significance.) There may be occasions where the costs are less than £1 million, suggesting that a costing statement is appropriate, but other circumstances such as local variation in practice justify the production of a costing template.

Figure 8 depicts the considerations that determine whether a costing statement or full costing tools are produced. It is intended to be a guide only, and there may be exceptions. For example, costing work may indicate that the criteria for producing a costing statement are met, but it is considered that full costing tools are appropriate.

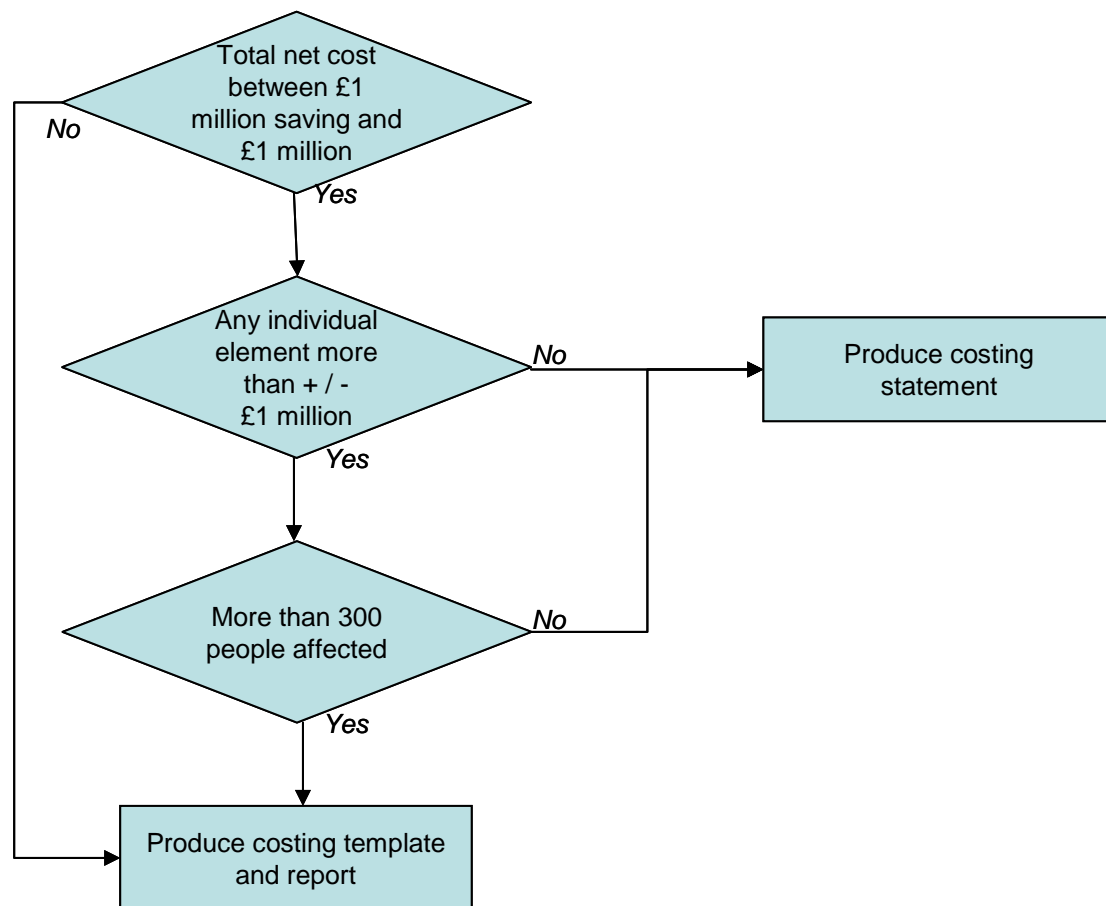


Figure 8 Determining which costing tools to produce

There may also be circumstances where it is not appropriate to produce a costing template. In all cases the reasons for this should be communicated using either a costing report or a costing statement. Where there is significant uncertainty about the baseline position and impact of implementation or there is the potential to mislead people regarding the cost of implementation, it may be appropriate to highlight the issues but not to quantify the impact. For example, in the clinical guideline on violence ('Violence: the short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments' [[NICE clinical guideline 25](#)]) a recommendation was made relating to the provision of seclusion rooms for mental health inpatients; there were no baseline data on how many inpatient units had compliant seclusion rooms, and depending on local circumstances the capital costs of creating or modifying premises could vary significantly. In this type of case potential impact would be highlighted in the narrative and local consideration recommended depending on local circumstances.

Where no costing report or template is produced a costing statement is used to explain the reasons for this.

8.6 Writing up costing work

This section applies mainly to the costing report that accompanies clinical guidelines or public health guidance. However, it is also pertinent to the summary report section incorporated into the technology appraisal costing template and

when summarising the cost estimates for use in other implementation tools such as the slide set.

The report template guides the developer towards which information should be included within the report. It is usual for reports to be preceded by an executive summary that notes the key factors but which does not include the discussion of the detailed assumptions. This is to enable busy professionals to determine whether they need to study the main body of the report in more detail.

When writing reports the following standards are applied.

- Background information on the topic should be provided to give context; this will include epidemiology information that informs the population identified.
- Where recommendations have been selected for inclusion these should be noted. For clinical guidelines that list key priorities for implementation it is also good practice to note why some key priorities have not been considered to be significant resource impact recommendations.
- The source of every assumption should be clearly stated, either by quoting the source document or, if it is not documented, referring to professional opinion. As noted in previous sections it is not usual to rely on the opinion of only one professional; validation by a minimum of three professionals is recommended.
- The net total should be clearly stated, either in the text or summarised in a table if more than one area contributes to the net total.
- Sensitivity analysis should be prepared and the three or four variables for which the model is most sensitive to changes should be discussed within the main body of the report.
- Include a graph showing example of costs over time, where appropriate.
- All costs quoted in the costing report should match the costing template. An exception is allowed to reflect the impact of roundings, but it is not anticipated that roundings should change any total by ± 1 .
- It is usual to present the national figures rounded to the nearest million in the summary and the nearest thousand in the main body of the report.
- It is usual to present local figures within the implementation slide set to the nearest pound, based on cost per 100,000, and to be consistent with the level of detail and headings used in the executive summary.
- Nothing should be presented in the executive summary that is not discussed in the main body of the report.

8.7 *Determining links between national and local template*

Following estimation of the national cost impact, consideration should be given to how cost impact can be estimated locally. This will usually be based on the local population. However, other methods by which local costs can be determined include:

- cost per organisation (primary care trust or employer)
- staff numbers (for training costs)
- risk adjusted costs. For example, local prevalence rates determined the tuberculosis inoculation strategy adopted in 'Tuberculosis: clinical diagnosis

and management of tuberculosis, and measures for its prevention and control'
[NICE clinical guideline 117](#)

It is acknowledged that when using data at a national level, this may not represent the local population, activity or cost. Therefore in the costing template all fields that can be updated to reflect the local circumstances and refine the cost estimate are highlighted using shaded cells.

8.8 *Sensitivity analysis*

There are a number of assumptions in the costing model and template that are subject to uncertainty, particularly predictions of future practice after recommendations are implemented.

Plausible minimum and maximum values of variables should be recorded when gathering evidence. These will inform sensitivity analysis that highlights which variables the cost impact estimation is most sensitive to. Ranges used for sensitivity analysis should reflect uncertainty over mean national figures, rather than possible variation between local providers. Sensitivity analysis may also be used to examine the impact of alternative modelling assumptions – for example, activity being undertaken as an outpatient rather than a day case.

Cost analysts should highlight those variables that are sensitive to a small change. The overall aim of the sensitivity analysis is to identify the assumptions the model is most sensitive to. These will have the most impact on the total cost estimate, so organisations need to pay most attention to ensuring that they reflect local circumstances for these variables.

It is not possible to arrive at an overall range for total cost because the minimum or maximum of individual variables might not occur simultaneously. One-way sensitivity analysis, altering each variable independently, is undertaken to identify those variables that have the greatest impact on total net cost. Occasionally, more than one related variable will need to be altered simultaneously. For example, increasing the uptake predicted for one drug will require alternative drugs to be reduced.

Results should be tabulated, with care taken to ensure that the range of variables for every assumption regarding current and predicted activity and unit cost are subject to analysis. A short narrative indicating the variables that have most effect on the total should be included.

8.9 *Review process*

All the costing tools produced are reviewed before publication. The review process involves an internal review and a final sign off and between the internal review and final sign off there is included limited consultation with relevant people outside of NICE.

The internal review is an opportunity for the costing analyst to check internally the assumptions included within the costing tool. This includes receiving comments from colleagues and peers within NICE to ascertain that all relevant and significant factors have been included within the tools, that both the costing report and costing

template follow a sensible and pragmatic approach and that all assumptions are corroborated.

After the internal review a limited consultation process takes place in which NICE invites external comments on the costing report and costing template. Comments are invited on whether the assumptions made are reasonable and the format, presentation and usability of the local costing template. The range of people approached to be part of this consultation includes:

- Two representatives from the cost impact panel – a standing group from across the NHS including the finance profession; this is to be expanded to include people from other public sectors
- Guideline Development Group for clinical guidelines
- Programme Development Group for public health programme guidance and appropriate consultees from PHIAC for public health intervention guidance to be discussed with the public health technical team
- Topic Expert Group for quality standards
- Department of Health
- Welsh Assembly Government
- Northern Ireland
- Quality Improvement Scotland (only for multiple technology appraisals)
- Other contacts who have informed the development of the tool, such as Health Economists.
- Manufacturer of the technology for technology appraisals; this may extend to manufacturers of comparator technologies who are registered stakeholders and who have been involved in the process.

The external consultation is for a minimum 2-week period and draft documents are emailed to those identified above.

The timing of the consultation is particularly important for technology appraisals. The external consultation should start within the time the final appraisal determination (FAD) is out for external consultation. Consulting before this is not possible because the decision is not in the public domain. Difficulties can arise if consultation is started after the end of FAD consultation. Consulting on costing tools could be perceived as not being responsive to changing circumstances where an appeal has been received. To wait for the outcome of appeal leaves very little time to consult before publication of the final guidance where it is not upheld.

In the event of an appeal being upheld, the costing team will review the outcome of the appeal and consult with the technical lead as to whether it will have a substantial impact on the costing tool. Where there is significant change to the recommendations it is usual for another appraisal consultation document (ACD) or FAD to be produced, providing a further opportunity to consult on the costing template, if necessary.

Following consultation, all comments are collated and passed to the costing analyst for review using a standard table format. The costing analyst should note their response in the table alongside the comment. This is an internal process to

inform the final sign-off process and is not usually published because the initial consultation was not a public consultation.

Comments that highlight significant variation with the draft tools should be followed up with the consultee. Following discussions, further advice may be taken from other professionals to validate revised assumptions. Where necessary, the tools should be amended and this response noted in the table.

8.10 Editing the costing tools

The draft template and report are edited during the limited consultation phase. The editor checks for consistency between the costing report and the guidance, and ensures that the tools are in the correct format, that they are easy to understand and navigate and that all the text is proofread. A second round of editing might be needed if tools change substantially after consultation.

8.11 Final checking before publication

Final checking of the tools before publication is undertaken by a cost impact review panel. This panel includes as a minimum:

- Associate Director for Costing.
- Senior Costing Analyst.
- Costing Analyst.
- representative from the guidance producing centre
 - for clinical guidelines this is usually the Guideline Commissioning Manager
 - for technology appraisals this is usually the Technical Analyst and/or Technical Advisor
 - for public health this is usually the Associate Director and Technical Lead.

Because of the increased volume of guidance being published, the Associate Director may not be able to attend both internal review and final sign-off meetings for every topic. However, they must be involved in at least one of the meetings, and their place at the other meeting will be undertaken by a Senior Costing Analyst who has not been involved in the costing tool development.

Other people involved, as appropriate, include the Implementation Programme Director, Clinical Advisor and representative from the implementation support team. As part of the cost impact review, the panel reviews the draft tools, the comments received and the responses from the developer. At this stage the tools are either approved to go forward to Guidance Executive or the developer is requested to do further work.

NICE's Guidance Executive has the final decision on what is published. It receives a report on the development of the costing tools, and is usually provided with:

- the detailed template, which includes the costing summary report (for technology appraisals), or
- the executive summary (for other guidance).

The full costing tools are available to Guidance Executive on request. The outcome from consideration by Guidance Executive is either the authority to publish via the

website at the same time as the guidance is published or a request for further work before publication.

Guidance is generally published on the website on the fourth Wednesday of the month (except for December, when publication may be earlier). However, dates can vary for individual pieces of guidance, for example, to coincide with the launch of a national campaign. The costing tools are normally available on the same day as launch.

Before publication the cost analyst should complete the quality assurance checklist. This should be filed within the relevant work files. The analyst should also ensure one final check is carried out, ideally by a senior analyst but, if this is not possible, by another costing analyst.

8.12 Working papers

At the completion of the costing tool, the costing analyst should ensure that all working papers are correctly filed. This is important because NICE can receive queries on a costing tool a number of years after publication of the guidance.

9 Updating the costing tools

9.1 *Circumstances in which updating is appropriate*

The costing work is based on assumptions about current practice and predictions of future practice. Sometimes issues concerning the costing tools come to light that were not identified before publication. This can happen particularly during the post-publication engagement with stakeholders validating other implementation tools. There are two ways of addressing this – to revise the original tools or to issue a supplementary report.

Revising the costing template is considered in the following circumstances.

- A significant flaw is identified in one or more assumptions relating to current or predicted practice that is considered to be greater than local variation.
- The basis of the costing is inconsistent with current practice or there has been an inaccurate use of costs – for example, a drug cost had been calculated on the basis of cost per kg, rather than cost m² of body surface area.
- Feedback indicates that a recommendation will lead to nationally significant costs or savings that were not identified in initial work (as described in section 3).

The criteria against which a decision will be made about whether to update the costing tools are given below.

- Revising the assumptions in the template affects the total net cost by more than $\pm 10\%$.
- Revising the unit costs in the template affects the total net cost by more than $\pm 10\%$.
- Estimated costs or savings arising from a new recommendation is considered to lead to a total net cost of $\pm \text{£}1$ million.
- Revising the costing template will correct obvious inaccuracies which, if left, will undermine user confidence in the tool, but the impact on the total net cost does not meet the thresholds noted above.

It is not considered appropriate to update template in the following two instances.

- There are differences in baseline and predictions arising from natural variation in local circumstances – these should be addressed locally through modifying the local template.
- Unit costs that have been used for drugs and activity are current as at the time of publication. It is not proposed to routinely update all templates for annual updates to activity costs such as pay rates or the PbR tariff. Again, there is the facility for local users to update unit costs to reflect current local costs.

Where a minor fault (no impact on calculation) is identified the fault is corrected as soon as it becomes known and the current tool on the website replaced with the amended one. This will be signed off by Associate Director Costing and Commissioning and advice sought from the Implementation Programme Director as to whether a report to Guidance Executive is required.

9.2 *Process for updating a costing summary and template*

Once feedback indicates there may be a problem with the costing tools, preliminary investigative work to determine the nature of the problem and the impact is initiated. The process for decision making is depicted in figure 9.

The implementation programme management team (IPMT) will consider the findings of the initial investigative work and decide whether the criteria to justify an amendment are met. Revised or supplementary tools will be submitted to Guidance Executive for final approval.

9.3 *Life expectancy of the costing tools*

It is important that the costing tools remain relevant and are not removed from the website prematurely. So, while the guidance is current the costing tools will also be available. This is because different organisations might be at different stages of implementing the guidance and could still find the tools useful long after publication.

The review and update of guidance will be a trigger for considering the related costing tool. For guidance that is to be updated a costing tool to support the update – a report, template or statement – will be produced.

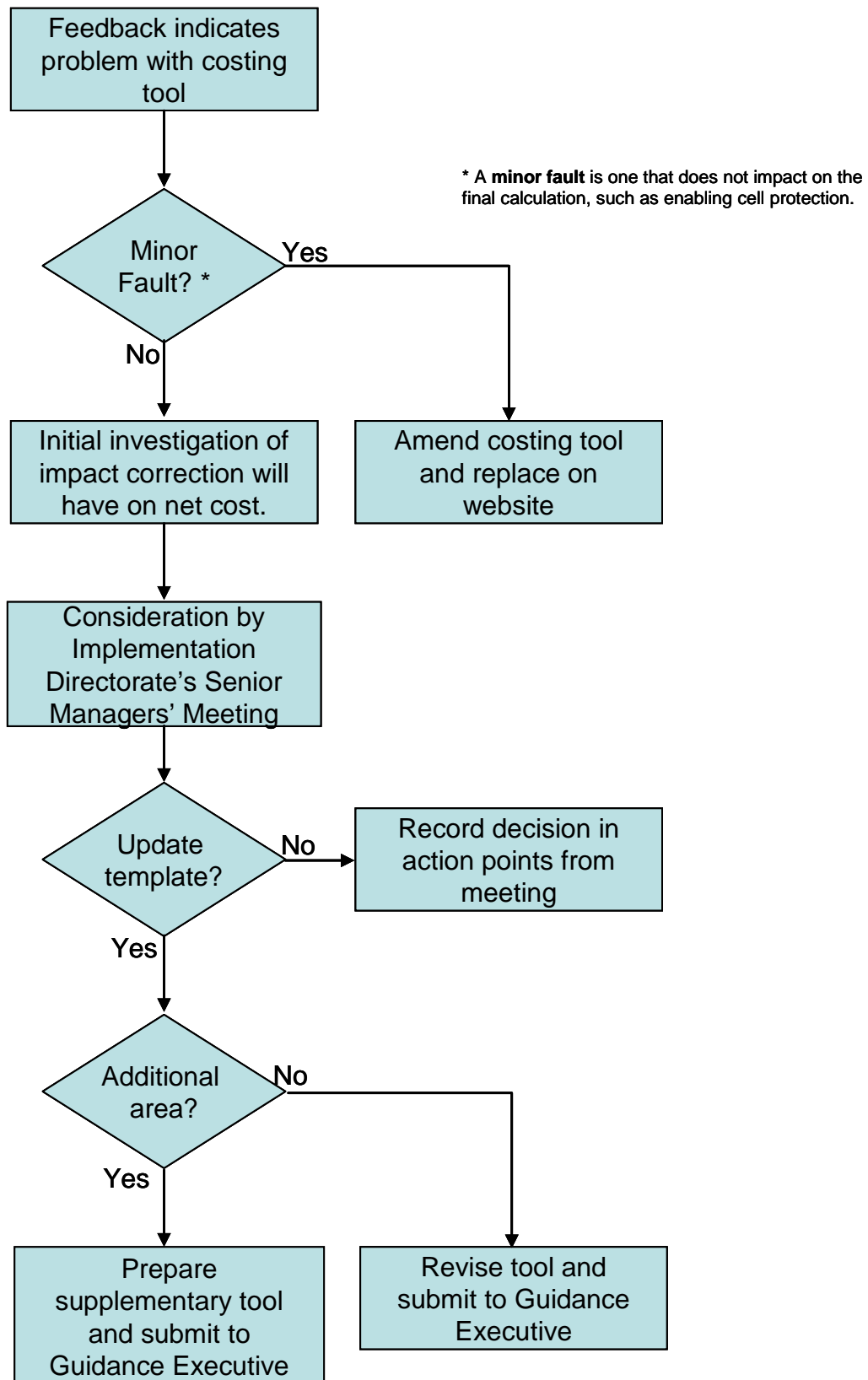


Figure 9 Process for revising costing tools

Appendix A Implementation strategy

Introduction

This appendix briefly describes where the costing tools fit into the wider implementation strategy, and the other work undertaken by the costing team.

Implementation strategy

Putting NICE guidance into practice can be challenging. NICE has set up a programme to help support implementation of NICE guidance. The implementation programme, which includes a field-based team does not get involved in developing the guidance recommendations but works alongside the guidance developers and the communications team. The three key aims of the NICE implementation programme are to:

- motivate and inspire
- provide practical support
- evaluate impact and uptake.

In addition to the costing tools the implementation directorate produces the following implementation tools.

- Slide sets – these are intended to support the implementation of a particular piece of NICE guidance. They aim to raise awareness of the guidance by highlighting key messages from the guidance and providing a framework for discussion at a local level. They are designed for a variety of audiences such as commissioners, clinicians or teachers and accompany all clinical guidelines and public health guidance, most medical technologies guidance and some technology appraisals.
- Audit support – the aim of the support is to make the process of developing clinical audit projects easier through the provision of ready-to-use criteria, and include exceptions, definitions and data source suggestions. General information to help implementers carry out the audit is also included.
- Baseline assessment – this is an Excel spreadsheet that can be used by organisations to identify if they are in line with practice recommended in NICE guidance and to help them plan activity that will help them meet the recommendations. These are produced for all clinical guidelines.
- Self-assessment tools– these are for use by any service or organisation to determine how close their practice is to that recommended in the guidance and to help them prioritise implementation activity. They are produced for public health guidance as required.
- Implementation advice – this considers implementation issues that are specific to a piece of NICE guidance and is targeted at those responsible for planning and implementing the guidance. They are produced for clinical guidelines, public health guidance and medical technologies guidance when a need has been identified.
- Educational resources – online educational modules are produced for clinical guidelines, through collaboration with BMJ Learning, after an assessment process.

- Commissioning guides – these are topic-specific resources to help the NHS to commission services for patients. The topics covered by the guides are selected from existing NICE guidance rather than being systematically produced for each piece of guidance. A commissioning guide could bring together recommendations on a specific topic from one or more pieces of guidance. Within each guide an interactive commissioning tool enables primary care organisations to estimate and inform the cost of local commissioning decisions. Each commissioning tool is produced following the costing methodology described within this guide.
- Forward planner – this is an Excel-based spreadsheet that summarises published guidance that organisations may still be implementing, to help them plan for and implement NICE guidance. It also lists forthcoming guidance to help organisations plan ahead.
- Other tools – bespoke tools, including clinical case scenarios, guides to resources, checklists for local authority health scrutiny committees and podcasts are provided where it is identified through the risk assessment process that the standard suite of tools is insufficient to meet support needs. Examples of this include where NICE wishes to tailor its tools to those produced by a key national organisation with whom it is working closely, when guidance is aimed at an audience outside the NHS for whom a bespoke tool is more appropriate or when the role of the tool is to facilitate signposting to other resources. When related pieces of NICE guidance are published close together, an integrated and planned approach of themed support may be adopted.

All of the above tools are web-based and available from www.nice.org.uk

Costing team

Developing the guidance-specific costing tools is a significant part of the costing team's work. In addition, the costing team does the following.

- Produces the [forward planner](#), and updates it on a monthly basis.
- Produces costing tools for the 'optimum practice review – [recommendation reminders](#)'. These highlight previously issued NICE recommendations that may help the NHS reduce ineffective practice.
- Advises on cost impact for potential topics considered as part of the topic selection process. One of the Department of Health's criteria for considering whether a topic should be considered by NICE is whether the proposed guidance relates to one or more interventions or practices which might impact significantly on NHS or other societal resources (financial and other).
- Liaises with the Department of Health regarding the impact that implementing NICE guidance has on the tariff set for activity commissioned under PbR.
- Provides advice on costing matters to the Patient Access Scheme Liaison Unit
- Provides quality assurance of QIPP case study submissions to the NHS Evidence team

Appendix B Checklist of areas of impact and cost types

Possible areas of resource impact

- Changes to the eligible population through:
 - increased awareness leading to increased referral
 - increased detection
 - improved diagnosis
 - exclusion and expansion.
- Changes to treatment including:
 - relative proportion of total population being treated
 - changes to treatment offered.
- Indirect costs – for example, treatment that requires additional monitoring
- Direct substitution – for example, moving from drug x to drug y.
- Cumulative impact – for example, patients starting therapy on diagnosis of a chronic condition then remaining on treatment for the rest of their life could lead to a build up of costs over the years.
- Changes to outcomes including:
 - increased survival
 - changes to length of hospital stay
 - changes in disease progression – for example, drug treatment for hepatitis may delay or prevent the need for a liver transplant
 - changes to adverse events such as reactions to treatment or reduction in recurrence.
- Changes to the model of care including changes to:
 - the location of care
 - the care provider
 - training required
 - equipment needed to deliver care.

Activity that might be affected

- Inpatient admissions – elective or non-elective (emergency). Within an admission the average length of stay may vary. Average time in theatre or consumable costs for operations may vary. Nursing input may vary if recommendations change nursing routines.
- Day case admissions. Average time in theatre or consumable costs for operations may vary.
- Outpatient attendances – new referrals and follow-up attendances.
- GP attendances.
- Direct contacts with professions allied to medicine such as physiotherapists or dieticians.
- Direct contacts with community mental health teams.
- Referrals for diagnostic tests either by primary care or secondary care may change.

Possible revenue costs

Pay and staff related costs

- Grade of staff and number of staff (expressed in whole time equivalents)
 - direct care provision
 - managerial/supervision
 - administrative support
- Training costs: initial training and ongoing development
- Travel and subsistence expenses (if community based)
- Medical reports

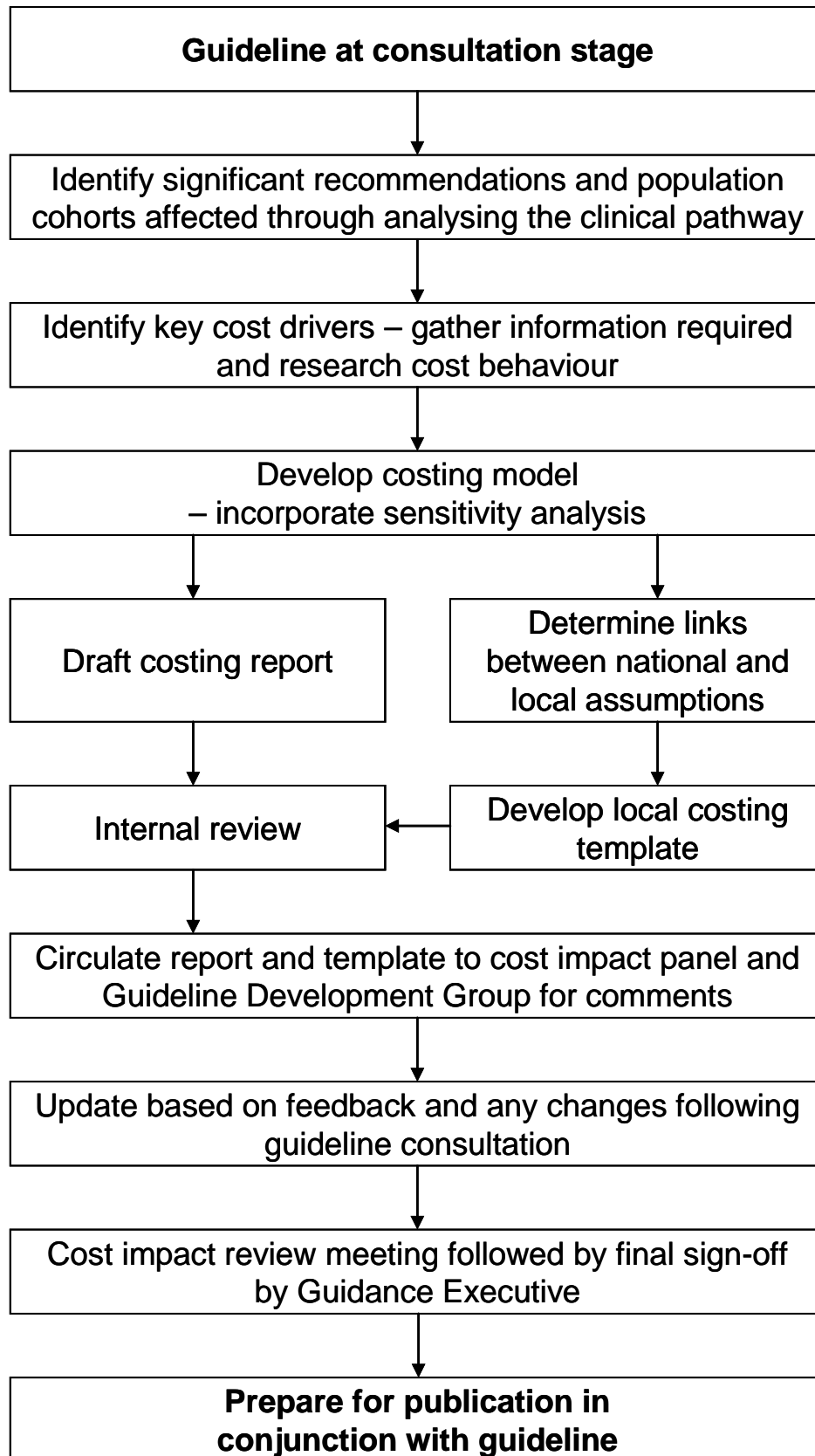
Non-pay costs

- Drugs
- Medical equipment
- Equipment maintenance
- Protective equipment and protective clothing
- Laundry costs
- Linen – disposable items used for procedures
- Premises and establishment expenses:
 - printing, stationery and postage
 - telephone rental and calls
 - utilities
 - cleaning materials and contracts
 - furniture and fittings
 - office equipment
 - photocopier rentals
 - rents
 - building maintenance
- Computer expenses:
 - hardware purchase
 - software purchase/licence fees (initial/annual)
 - maintenance
 - consumables
 - networking/cabling
- Insurances:
 - buildings
 - employers' liability
 - clinical negligence
- Audit fees
- Management consultants' fees
- Bank charges
- Lease charges (if not purchased from capital)
- Capital charges (based on life/value of capital assets)

Capital expenditure

- Equipment value individually or collectively more than £5000 with a life of more than 1 year
- Medical equipment
- Land and buildings

Appendix C Process for costing a clinical guideline



Appendix D Process for costing a short clinical guideline

This process is similar to the clinical guideline process as noted in appendix C, but with adapted timelines.

Appendix E Process for costing a multiple technology appraisal

Each technology appraisal topic is allocated a costing lead. The costing lead has responsibility for developing the costing report and costing template, in conjunction with the technical lead within the Centre for Health Technology Evaluation. The costing lead is responsible for liaising with the implementation lead, and liaises with key external players and regional contacts as necessary.

Key stages of the costing process are linked to the stages of development for the technology appraisal and are discussed below.

Submission of draft assessment report

An overview of the unit costs used in the cost effectiveness model **may** be undertaken to ensure that they are also suitable for cost impact assessment work at a later stage. This will highlight any inconsistencies at a stage where they can be addressed and avoids the subsequent cost impact work potentially undermining the technical appraisal cost effectiveness modelling.

At this stage, potential cost impacts arising from the appraisal cannot be determined. However, background research into current practice throughout the NHS may be initiated for subjects that are not supported by robust data.

Following appraisal committee meeting to develop an ACD

Once the committee has made a recommendation the ACD will be drafted by the NICE project team. The main work on cost impact – assessing the cost of changing to recommended practice compared with current practice – will begin.

Following appraisal committee meeting to develop a FAD

Once the final wording of the recommendation is known the cost impact model will be finalised. This will be used as the basis for the national costing report and local costing template.

The costing report and template will be subject to a limited consultation with the cost impact panel, the manufacturer(s) of the technology and any key players that have contributed to its development.

An internal sign-off meeting will be held to review the costing model, and the process will be followed. This will be attended by the costing lead, the Associate Director for Costing, and technical lead for the appraisal. Any revision arising from this meeting will be made.

Appeal

If an appeal is not received, the costing report and template will be sent to the editors for a full edit.

If an appeal is received, the costing tools will be reviewed in the light of any decision arising from the appeal. Any necessary revisions will be made before the costing report and template is sent for a full edit.

The [Appeals process](#) is set out on the NICE website.

Publication

Final approval for publication will take place at Guidance Executive. Ideally this will be at the same time that the relevant technology appraisal is also considered but may be shortly afterwards, due to time required to consult on the cost impact assessment.

The national costing report and local costing template will be published on the NICE website at the same time as the technology appraisal guidance.

Appendix F Process for costing a single technology appraisal

This process is similar to the process for costing a multiple technology appraisal, but with adapted timelines and reflecting that some decisions go straight to final appraisal determination.

Appendix G Process for costing public health intervention guidance and public health programme guidance

The process followed is very similar to costing a clinical guideline. Work starts when the guidance is at a draft stage and discussions occur with the guideline developers to identify the best professionals to discuss assumptions with.

There is an internal review and limited consultation before checking consistency with the final guidance and holding a final sign-off meeting, before submission to the Guidance Executive for final approval to publish costing tools.

Note: the process for costing quality standards is still evolving.

Appendix H Glossary and abbreviations

Glossary

Term	Definition/explanation
Algorithm (in guidance)	A flowchart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Appraisal Committee	A standing advisory committee of NICE. Its members are drawn from the NHS, patient/carer organisations, relevant academic disciplines and the pharmaceutical and medical devices industries.
Assessment report	In technology appraisals, a critical review of the clinical and cost effectiveness of a health technology/technologies. It is prepared by the Assessment Group. To prepare the report, the Assessment Group carries out a review of the published literature and the submissions from manufacturers and sponsors.
Baseline	The initial set of measurements at the beginning of a study, with which subsequent results are compared.
Consultation	The stage at which stakeholder organisations and/or internal members of NICE are invited to comment on draft documentation (in most cases written comments are requested).
Cost impact	Cost impact is the assessment of the net costs (or savings) arising from implementing guidance recommendations for the purpose of informing budget setting. Cost impact considers the impact on healthcare budgets for both one-off costs and recurring costs within a defined time period and for a defined population.
Costing lead	The person responsible for developing the costing tools for allocated topics and works closely with the implementation adviser. Other costing work includes topic selection costing and forward planning tools.
Developers	Persons responsible for developing NICE guidance. This includes national collaborating centres, staff in the guidance development centres at NICE and members of the centres' independent groups or committees.
Diffusion	Diffusion is the process by which a new idea or new technology is accepted by potential users. The rate of diffusion is the speed at which the new technology spreads from one user to the next.
Equality	A revised term for 'equal opportunities', reflecting recent equality and anti-discrimination legislation. NICE must comply with legal obligations to promote race, disability and sex equality, and eliminate

Appendix H Glossary and abbreviations

Term	Definition/explanation
	unlawful discrimination on grounds of race, disability, sex, sexual orientation, religion or belief, and age. NICE is also concerned with inequality associated with socioeconomic factors, an area not covered by legislation.
ERNIE database	Evaluation and Review of NICE Implementation Evidence database. A source of information on the implementation and uptake of NICE guidance.
Field work	<p>The Centre for Public Health Excellence conducts fieldwork meetings as part of their consultation process on draft guidance.</p> <p>Sometimes the term is used to describe the meetings, interviews or observations conducted by Implementation Consultants with practitioners in health and social care and local government to ascertain the applicability and uptake of NICE guidance in practice.</p>
Guidance	A set of evidence based principles and recommendations created through a systematic process, to provide a benchmark and standard for health and social care service delivery within the public health sector. NICE uses guidance to refer to all types of guidance products including technology appraisal guidance, clinical guidelines and public health guidance.
Guidance Executive	<p>The Guidance Executive comprises the NICE Chief Executive and executive directors, guidance centre directors and the Communications Director. Their role is to consider and give final sign off to NICE publications including draft consultation documents, final guidance and implementation tools.</p> <p>Other documents such as guidance scopes or corporate publications are considered by the Senior Management Team, not by the Guidance Executive.</p>
Guidance related implementation support tools	A suite of tools published alongside NICE guidance to support and enhance the implementation opportunities for guidance.
Health economic analysis	Comparative analysis of alternative health strategies in terms of both their costs and consequences.
Healthcare Resource Group	HRGs are a UK national standard aggregation of healthcare interventions and the resources required to provide them. A key national use is the annually published National Schedule of Reference Costs.
Implementation lead	The Implementation Adviser who works alongside the guidance developers from the scoping stage through to post-publication activities, liaising with the internal NICE teams, development teams and

Appendix H Glossary and abbreviations

Term	Definition/explanation
	external organisations to support the implementation of NICE guidance, including the development of implementation support tools.
Implementation planning meeting	A meeting arranged and hosted by the implementation support team during the consultation phase of the guidance development. Its purpose is to discuss with external national organisations the implications for implementing the draft recommendations, to identify target audiences and any barriers or levers for effective implementation.
Incidence	The incidence of a particular condition is the number of new cases of the condition among a certain group of people over a certain period of time.
National collaborating centres	Independent bodies based at healthcare professional organisations (such as medical or nursing Royal Colleges) and in the NHS, funded by NICE to develop clinical guidelines on its behalf.
Opportunity cost	The opportunity cost of investing in a healthcare intervention is the other healthcare programmes that are displaced by its introduction. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Pathway (as in care pathway)	A care pathway is a pre-determined plan designed for patients who have a specific diagnosis.
Payment by Results	The aim of Payment by Results (PbR) is to provide a transparent, rules-based system for paying trusts. Payment will be linked to activity and adjusted for case mix. Importantly, this system will ensure a fair and consistent basis for hospital funding rather than being reliant principally on historic budgets and the negotiating skills of individual managers.
Prevalence	The prevalence of a particular condition is the number of people in a given group or population who are reported to have the condition at a given time.
(The) reference case	When estimating clinical and cost effectiveness, the reference case specifies the methods considered by NICE to be the most appropriate for the Appraisal Committee's purpose and consistent with an NHS objective of maximising health gain from limited resources.
Sensitivity analysis	Sensitivity analysis is the study of how the output of a model (numerical or otherwise) varies when the inputs are varied. In one-way sensitivity analysis each parameter is varied individually in order to isolate the consequences of each parameter on the results.

Appendix H Glossary and abbreviations

Term	Definition/explanation
Shared learning website	A NICE website database which contains examples of other organisations' experiences of implementing NICE guidance. Organisations using NICE guidance are invited to submit examples of shared learning which are added to the website following a quality assurance process to ensure they meet the minimum standard.
Significance	Having or likely to have a major effect.
Stakeholder	Persons or organisations that have an interest in NICE and its outputs.
Supportive environment	Conditions that are supportive to implementation – for example, a national organisation develops a competency matrix which supports the competencies identified in a NICE clinical guideline.
Systems change	A process whereby systems adapt and change in response to a variety of prompts (such as additional funding or a change in policy).
Technical lead	Technical leads are based in the Centre for Health Technology Evaluation and the Centre for Public Health Excellence. They are the persons responsible for working with the relevant independent groups or committees to develop guidance.
Technology appraisal	Recommendations on the use of new and existing medicines and other treatments within the NHS in England and Wales, such as medicines, medical devices, diagnostic techniques and surgical procedures.
Timeline	A project management tool which identifies key stages/dates for specific activities. (Central or master timelines for guidance production are managed by the guidance producing centres at NICE).
Topic selection	The process by which specific treatments, drugs or ways of caring for people with specific conditions or diseases, preventing ill health or promoting good health are selected to inform the Department of Health decision making about which topics to refer to future NICE work programmes.

Abbreviations

Abbreviation	Full detail
ACD	Appraisal consultation document
BFI	Baby Friendly Initiative
BNF	British national formulary
CBT	Cognitive behaviour therapy
ERNIE	Evaluation and Review of NICE Implementation Evidence
FAD	Final appraisal determination
HRG	Healthcare resource group
NHS	National Health Service
NICE	National institute for health and clinical excellence
PbR	Payment by Results
PCT	Primary care trust
PET	Positron emission tomography
QIPP	Quality innovation prevention productivity
QOF	Quality outcomes framework

Appendix I Useful links

[Audit Commission](#)

[Cancer Research UK](#)

[Care Quality Commission](#)

[ERNIE database](#)

[Health Survey for England](#)

[Hospital Episode Statistics \(HES\)](#)

Information Centre for Health and Social Care (also known as the [Information Centre](#)).

[National Audit Office](#)

[Office for National Statistics](#)

[Personal Social Services Research Unit \(PSSRU\)](#)

[Prescription cost analysis \(PCA\)](#)

[Quality and outcomes framework \(QOF\)](#) data – from the [Information Centre](#)