

**Assessing resource impact process
manual: technology appraisals and highly
specialised technologies**

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1 Introduction

1.1 Overview of NICE

- 1.1.1 The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.
- 1.1.2 NICE was originally set up in 1999 as the National Institute for Clinical Excellence, a special health authority, to reduce variation in the availability and quality of NHS treatments and care.
- 1.1.3 In 2005, after merging with the Health Development Agency, we began developing public health guidance to help prevent ill health and promote healthier lifestyles. Our name changed to the National Institute for Health and Clinical Excellence.
- 1.1.4 In April 2013 we were established in primary legislation, becoming a non-departmental public body, which places us on a solid statutory footing as set out in the Health and Social Care Act 2012. We took on responsibility for developing guidance and quality standards in social care, and our name changed to its current form to reflect these new responsibilities.
- 1.1.5 As a non-departmental public body, we are accountable to our sponsor department, the Department of Health, but operationally we are independent of government. Our guidance is developed by independent committees. The NICE Board sets our strategic priorities and policies, but day-to-day decision-making is the responsibility of our senior management team.
- 1.1.6 The way in which NICE was established in legislation means our guidance officially applies only to England. However, we have agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland. Decisions on how our guidance applies in these countries are made by the devolved

administrations, who are often involved and consulted during the development of NICE guidance.

1.2 Centre for Health Technology Evaluation

1.2.1 The Centre for Health Technology Evaluation is made up of 11 teams. It develops guidance on the use of new and existing medicines, including highly specialised technologies, treatments, medical technologies, diagnostics and surgical procedures within the NHS. In addition to its guidance producing activities, the centre is responsible for the Patient Access Scheme Liaison Unit, the science policy and research programme, scientific advice, topic selection and the office for market access.

1.3 NICE technology appraisal guidance

1.3.1 Technology appraisal guidance assesses the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also includes procedures, devices and diagnostic agents. This is to ensure that all NHS patients have equitable access to the most clinically- and cost-effective treatments that are viable. The technology appraisals team develops multiple technology appraisals and single technology appraisals. Appraisals provide recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales.

1.4 NICE highly specialised technologies

1.4.1 Highly specialised technologies evaluations are recommendations on the use of new and existing highly specialised medicines and treatments within the NHS in England. The highly specialised technologies programme only considers drugs for very rare conditions.

1.4.2 Recommendations are made by an independent advisory committee. The highly specialised technologies evaluation

committee considers a range of health and non-health related criteria and, after reviewing the evidence and commentary, reaches a consensus on whether the highly specialised technologies can be recommended for national commissioning.

1.5 Compliance with a NICE-approved medicine or treatment

1.5.1 Commissioners have a statutory responsibility to make funding available for a drug or treatment recommended by a NICE technology appraisal or highly specialised technologies within the timeframe recommended in that guidance. Compliance is therefore achieved if a clinician and their patient think a health technology is the right treatment and it is available on the NHS, as described in the NHS Constitution, which should not be impeded by national or local funding or formulary restrictions, or other health system or process barrier.

1.5.2 When NICE recommends a drug as 'an option', this is an option for the clinician and patient to consider alongside other potential treatments, not an option for commissioners or providers to not make the treatment available.

1.6 The purpose of this process manual

1.6.1 This process manual describes the role of the resource impact team in estimating the resource impact (cost or saving) of technology appraisals and highly specialised technologies and

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providing support products to help organisations implement this NICE guidance.

1.6.2 Process manuals are produced to ensure that NICE work programmes are carried out in an open, credible, transparent and timely way, allowing input from internal and external stakeholders.

1.6.3 This process manual is written to:

- help the resource impact team work effectively with the technology appraisal and highly specialised technologies teams
- help other NICE teams and external stakeholders understand the role of the resource impact team.

1.6.4 It does this by:

- defining how the resource impact team works alongside technology appraisal and highly specialised technologies teams that produce the guidance
- describing the processes involved in developing resource impact products
- highlighting when liaison with internal and external stakeholders takes place.

1.6.5 The resource impact team works closely with technology appraisal and highly specialised technologies programmes, and this process manual should be read in conjunction with the following manuals:

- [Guide to the processes of technology appraisal](#)
- [Guide to the methods of technology appraisal](#)
- [Interim process and methods of the highly specialised technologies programme](#)
- TA and HST Budget Impact Test procedure.

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1.6.6 This manual covers technology appraisal and highly specialised technologies programmes only. A separate manual has been produced for guidelines.

1.7 Overview of resource impact

1.7.1 The resource impact team estimates the cost or saving of implementing technology appraisal and highly specialised technologies guidance.

1.7.2 The team follows guidance development from an early stage and informs key stakeholders (NHS England, NHS Improvement) in order to help NHS financial planning about guidance that may have significant cost. This is normally at the stage when a draft recommendation is known and an appraisal consultation document is produced.

1.7.3 As well as costs and savings, the team gives advice to committees on wide-ranging issues such as workforce, capacity and demand, training, facilities and educational implications of the recommendations. It may also advise on where responsibility for implementation rests (by identifying the commissioners and providers) and who the costs or savings are for (the commissioner or provider).

1.7.4 The resource impact team also consider where services are delivered, for example primary or secondary care.

1.7.5 The team also gives strategic advice and information about the resource impact of guidance to national partner organisations including the Department of Health, Department for Education, NHS England, NHS Improvement and Public Health England.

1.7.6 The team's overall aim is to:

- help in the development of technology appraisal and highly specialised technologies guidance, by providing an initial

estimate of the resource impact of implementing the recommendations

- inform healthcare organisations as early as possible about the likely resource impact of implementing the guidance, to support their financial planning
- support future financial planning by profiling the resource impact over the coming 5 financial years if possible
- provide a clear and concise resource impact report and template of the resource impact of implementing technology appraisal and highly specialised technologies guidance.

1.7.7 There is more information about how resource impact is calculated and how the resource impact team works in chapters 4 and 5.

1.8 Key audiences

1.8.1 Resource impact products are of interest and relevance to many external stakeholders:

Organisations

- Department of Health
- Department for Education
- NHS England
- Local authorities
- Public Health England
- NHS Improvement
- Clinical commissioning groups
- Royal Colleges
- Health Education England
- NHS Digital
- Health and social care providers
- Pharmaceutical companies
- Medical and diagnostic technology companies
- Academic Health Science Networks

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- Organisations representing people who use health and social care services.

Individuals

- Health and social care professionals responsible for putting new technology appraisal guidance into practice
- Clinical directors and clinical managers
- Social care managers
- Business managers and finance managers in provider organisations
- Commissioning staff, including clinical leads and chairs in clinical commissioning groups and clinical and commissioning networks
- Staff with a responsibility for quality improvement
- People who use health and social care services, their families and carers, and the public.

2 Resource impact principles and perspectives

This chapter sets out the principles behind NICE resource impact products. This applies to all work undertaken by the resource impact team.

2.1 Principles

2.1.1 The following key principles underpin development of NICE resource impact products:

- Standard accounting principles are applied. These are set out in the NHS manual for accounts and NHS foundation trust annual reporting manual
- Only direct consequences of implementing individual guidance recommendations are included (see section 4.2 for further detail)
- Resource impact changes cover only those funded by the NHS (this includes the funding of services provided by the public, private, third and charity sectors)

- Assessments are consistent with the economic analysis in the guidance
- The best available datasets are used and supplemented with expert opinion
- Key stakeholders are consulted
- National estimates are provided wherever possible.

2.1.2 The resource impact report focuses on the financial impact of guidance but also looks at other areas of resource impact, if relevant, such as:

- workforce
- capacity and demand
- infrastructure
- training and education.

2.2 Perspectives

2.2.1 The resource impact may differ when it is viewed from either the commissioner's or the provider's perspective. There will be a difference in whether activity for care and services is being commissioned or provided. For example, in the NHS acute activity falls mainly under national tariff, so 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.

2.2.2 It is recognised a significant number of technologies appraised by NICE are high cost drugs and devices which are outside of the scope of national tariff.

2.2.3 For highly specialised technologies, which may not be paid by national tariff and for which bespoke arrangements are in place, the resource impact team works with the highly specialised technologies team and the commissioner. This ensures the

resource impact of commissioning such activity is correctly identified.

2.2.4 Generally resource impact reports focus on the cost to the commissioner. The provider is usually better placed than the commissioner to review what the change will mean in practice and to assess the actual cost of providing the activity.

2.2.5 It is difficult to provide full cost details for providers because of structural resource variations between providers. Implications for providers are highlighted if the information is robust.

3 Populations affected, activity levels and unit costs

This chapter describes the process of estimating populations and of identifying activity levels and unit costs of activity.

3.1 Background

3.1.1 To prepare a resource impact product we need to identify the population affected by the guidance, the likely change in activity as a result of the guidance and the unit cost associated with the recommended activity.

3.1.2 Resource impact processes meet information governance standards. This includes requesting, receiving, storing, sharing and destroying data in line with information governance requirements of NICE.

3.1.3 Where NHS Digital provide data (such as Hospital episode statistics) for resource impact assessments, the resource impact

team meet contractual and information governance requirements set out by NHS Digital.

3.2 *Population sources*

3.2.1 There are 2 main measures of population: resident population and registered population. The estimated resident population of an area includes everyone who usually lives there. The registered population is the number of people registered with a GP.

3.2.2 If possible, the resident population is used because the registered population may be overstated. The main reasons for this are people leaving the country or area and not notifying their GP, and the delay between a patient registering with a new GP and being removed from the register of their original GP.

3.3 *Incidence and prevalence data*

3.3.1 Incidence and prevalence measure different aspects of disease or care need in a population, although they are related.

3.3.2 The cumulative incidence of a particular condition is the proportion of a population who develop the condition in a defined time period. The incidence rate is the rate at which new events occur in a population.

3.3.3 The prevalence of a 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 data on incidence and prevalence are gathered and presented.

3.3.4 Examples of incidence and prevalence:

- Annual incidence – the number of people who will develop a disease or have a care need over the course of a year; this is the most common way of expressing incidence
- Point prevalence – the burden of disease or care need in a population at a particular point in time

- Lifetime prevalence – a measure of how many people may be affected by a disease or have a care need during the course of their lifetime.

3.3.5 Both prevalence and incidence data may need to be considered within a single resource impact tool so that the resource impact of different recommendations can be calculated accurately. For example, to determine the annual treatment cost for a chronic condition lasting many years we need to know the prevalence, whereas the annual cost relating to initial diagnosis is linked to the annual incidence.

3.3.6 For highly specialised technologies, rare disease incidence and prevalence data are limited. Additional information to give clarity may be requested from commissioner and patient groups.

3.4 *Data sources for establishing current activity.*

3.4.1 The data used to establish the current practice vary depending on the topic of the guidance. In some cases multiple sources may be needed. The data used should be accurate and credible and its source referenced.

3.4.2 Commonly used types of data and sources used to establish a baseline may include:

- hospital data – such as Hospital episode statistics
- prescribing data – such as Electronic prescribing analysis and cost tool (ePACT) system
- primary care data – such as GP medical databases, for example THIN (provided by Quintiles IMS, through NHS Digital)
- Hospital pharmacy audit index (provided by Quintiles IMS, through NHS Digital)
- NHS Digital
- Personal Social Services Research Unit
- Pharma (industry/company submission)

- publications that measure uptake of NICE guidelines.

3.4.3 It should be recognised that for highly specialised technologies disease incidence and prevalence data are limited and may not be available from these sources (see section 3.3).

3.5 *Data sources to establish future practice*

3.5.1 Predicting future practice following the implementation of a recommendation poses significant challenges. Predictions of future uptake should not rely on a single source.

3.5.2 Assumptions made are documented and fully referenced, and checked with topic experts, who may be involved in the guidance development. This could be an expert in the area the guidance relates to, a commissioner either from specialised commissioning or a clinical commissioning group, committee members involved in guidance development, and technology appraisal and highly specialised technologies team members.

3.5.3 Sources used for estimating future practice include:

- company submission
- previous uptake of similar drugs, technologies or other interventions
- NICE Medicines and Prescribing Associate programme
- information used to inform related economic models.

3.6 *Activity and unit costs*

3.6.1 The estimated activity for care and services resulting from the recommended guidance is checked to see if there is an identifiable

cost assigned to the activity or whether there are specific unit costs that can be used.

Healthcare

3.6.2 In healthcare there are a number of sources for which activity and cost are linked as follows:

- Secondary care hospital acute activity has a national tariff (price) or reference costs can be used when assessing the resource impact. However recognition is needed where local flexibility is possible in respect of national tariffs.
- National tariff should always be used when available
- If it is not possible to use tariff or reference costs, unit prices may be obtained from NHS organisations currently providing the service. This is useful for very new procedures that have not yet been included in the tariff. It also applies to high cost procedures that are specifically excluded from the scope of the tariff.
- The technology price is that used in the cost effectiveness model. Where this is not subject to a confidential discount. Please note any agreed confidential discount price is always used in the cost effectiveness model.
- The technology price for comparator technologies prices is that used in the cost effectiveness model. Where this is not subject to a confidential discount. Please note any agreed confidential discount price is always used in the cost effectiveness model.
- The medicines evidence and advice team provides advice on the source of the latest price available. If prices are not confidential but have changed since the cost effectiveness model this is noted in the resource impact report.
- In some instances the Department of Health and the company agree that the technology will be available to the NHS with a patient access scheme, which makes the technology available with a discount. The size of the discount may be commercial in confidence. If this is the case, the reduced cost of the technology

is not included in the published resource impact products. However commissioners and providers will have the option to input confidential discount price into published resource impact template locally.

- Highly specialised technologies services may have bespoke tariff structures and these may need to be requested from NHS England.

4 Role of the resource impact team

This chapter defines resource impact and explains how it is calculated for technology appraisals and highly specialised technologies.

4.1 *What is resource impact?*

4.1.1 Resource impact is the financial change in the use of resources (cost or saving) as a result of implementing guidance. It can also be called the budget impact.

4.2 *Assessing resource impact*

4.2.1 The approach for estimating the resource impact is the same for technology appraisals and for highly specialised technologies. The process applies equally to multiple technology appraisals and single technology appraisals.

4.2.2 The resource impact is determined by estimating costs and savings as a direct consequence of implementing the guidance. Direct consequences are the changes in practice that will result from implementation. 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 – is also considered as a direct consequence.

4.2.3 The resource impact assessment looks only at the population recommended in the guidance. Where the technology is for multiple

indications (e.g. paediatric and adult) within the same TA, this will be clearly identified.

- 4.2.4 Value added tax (VAT) is included within a resource impact assessment where it is payable by the NHS. The resource impact work includes all costs of implementing guidance including VAT.
- 4.2.5 It is recognised that avoiding future admissions may not save money for the commissioner if the bed is used for other activity, but this is considered outside the impact of guidance and therefore not included in resource impact assessment.
- 4.2.6 An example of an indirect consequence is a scenario in which a person who has 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 recommendation for their original condition, this indirect consequence cannot be considered in the resource impact work.
- 4.2.7 Resource impact is based on accounting principles. These may differ from health economic principles used in the cost effectiveness calculation. For example the health economic analysis may include events avoided as part of considering the lifetime impact, whereas the resource impact tool focuses on the costs or savings for the first 5 years after the guidance is published.
- 4.2.8 The health economic analysis may use reference costs, which are the average costs to provide activity, whereas the resource impact tool could use the national tariff, which is the price to commission activity. This may result in differences between the unit costs but the activity classification should be consistent.
- 4.2.9 The resource impact team ensures that costs and savings relate to the same time period, usually a financial year. Differences may arise if costs are incurred earlier on that will result in savings in the

future. It is not acceptable to combine costs and savings to produce a 'net' cost saving if time periods don't match.

4.2.10 Resource impact tools do not form guidance to the NHS, but aim to support implementation of NICE guidance.

4.3 Process overview

4.3.1 To help the NHS plan for the resource impact of technology appraisal and highly specialised technologies guidance, the resource impact team forecasts the resource impact from initial referral to NICE through to publication of guidance.

4.3.2 If possible (namely if prices are not confidential) the resource impact team informs the NHS through the resource planner when a preliminary positive recommendation is made (in the appraisal consultation document) whether the use of a technology in the NHS is likely to be low, medium or high cost. The following definitions of resource impact are used:

- Below £0 – cost saving.
- Up to £5 million – low cost or not significant.
- £5 million up to £20 million – medium cost.
- £20 million and over – high cost.

4.3.3 The resource impact team uses a 'budget impact test' of £20 million, set by NHS England, to signal the need for a dialogue between NHS England and the companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. This is anticipated to apply to a small number of technologies that, once determined as cost effective by NICE, would have a high cost impact on the NHS budget.

4.3.4 NICE assesses the potential budget impact by estimating the net annual cost to the NHS. The test is regarded as having been met if

the budget impact is greater than £20 million in any of the first 3 financial years of a technology's use in the NHS.

4.3.5 To estimate whether the resource impact of technology appraisal guidance is significant the resource impact team undertakes the following:

- Reviews the company submission, including the section on impact on NHS resources
- Reviews the topic selection and block scoping work.
- Reviews professional, patient and commissioning group submissions
- Discussion with the company
- Discussion with clinical experts
- Discussion with commissioners
- Reviews the Evidence Review Group report
- Reviews the appraisal consultation document and the final appraisal document
- Discusses the guidance with the technical team from the technology appraisal or highly specialised technologies programmes.

4.3.6 At key milestones the resource impact team notifies the technology appraisal and highly specialised technologies teams of those technologies that will meet the budget impact test of £20 million in

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any of the first 3 financial years following implementation of the guidance.

Milestone	Maximum timescale
Company submission	10 working days from notification by technology appraisal or highly specialised technologies team that the company submission is available to review
Evidence Review Group (ERG) report	10 working days from notification by technology appraisal or highly specialised technologies team that the ERG report is available
Appraisal consultation document (ACD)	10 working days from committee meeting
Final appraisal determination (FAD)	10 working days from committee meeting

- 4.3.7 At each stage where those technologies that will meet the budget impact test of £20 million in any of the first 3 financial years following implementation of the guidance, consultation will take place with the company.
- 4.3.8 The resource impact team estimates the national cost for England of implementing positive guidance recommendations alongside the appraisal consultation document. This is reported in the resource planner if prices are not confidential.
- 4.3.9 For draft guidance with an estimated resource impact above the budget impact of £5 million at a national level, when the appraisal consultation document is produced a draft resource impact report and resource impact template are shared with stakeholders. No costs are quantified in the resource planner until after this consultation with key stakeholders including the company.
- 4.3.10 Stakeholders include the Department of Health, NHS England, NHS Improvement, the company, companies for comparator technologies (if they have completed the confidentiality agreement form) as defined in the scope, and commissioners. Only data that are not confidential are published as the Resource Impact

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Assessments, reflecting confidential net pricing will need to be shared confidentially with key stakeholders.

- 4.3.11 The resource impact team produces a resource impact report and template for all final technology appraisal guidance with a resource impact of more than £5 million at a national level and publishes the documents alongside the final guidance.
- 4.3.12 If costs and savings are not considered to be significant at final guidance (below £5 million at a national level), a statement is issued on the NICE website.
- 4.3.13 If technologies (technology appraisal or highly specialised technologies) are not recommended in the guidance, no resource impact tools are produced.

4.4 Confidential prices

- 4.4.1 Technologies being appraised or a comparator technology may have a confidential price, usually a patient access scheme. If so, a procedure is put in place between the technology appraisal or highly specialised technologies team and the resource impact team to protect the confidentiality of the price. This includes allowing

restricted access to the confidential price within the resource impact team.

- 4.4.2 Under no circumstances is a confidential price shared by a member of the resource impact team either within the team or externally, other than as specified in the procedure.

4.5 *Appraisal of Cancer medicines and the Cancer drugs fund*

- 4.5.1 A modified appraisal process for cancer drugs was introduced on 1 April 2016 and now allows NICE to make 1 of 3 recommendations:

- Recommended for routine commissioning – ‘yes’
- Not recommended for routine commissioning – ‘no’
- Recommended for use within the Cancer Drugs Fund (new).

- 4.5.2 The new recommendation available to NICE – ‘recommended for use within the Cancer Drugs Fund’ – can be used when NICE considers there to be plausible potential for a drug to satisfy the criteria for routine commissioning, but there is significant remaining clinical uncertainty.

- 4.5.3 The NICE appraisal process starts much earlier with the aim of publishing draft guidance before a drug receives its marketing authorisation, and then final guidance within 90 days of marketing authorisation whenever possible.

- 4.5.4 All drugs on the previous Cancer Drugs Fund as of 31 March 2016 will be reconsidered or appraised by NICE over the course of 18 months from April 2016. Until NICE is able to provide a commissioning recommendation, these drugs will continue to

receive funding from the Cancer Drugs Fund budget at current commercial terms.

4.5.5 The approach for estimating the resource impact for appraisals linked to the Cancer Drugs Fund is the same as for technology appraisals and highly specialised technologies but, if applicable, the resource impact report and template need to also identify the following:

- Previous Cancer Drugs Fund activity
- Impact on routine commissioning compared with current Cancer Drugs Fund activity and resource impac.
- Impact of new approvals for the Cancer Drugs Fund
- Impact of new approvals for routine commissioning
- The funding directive attached to the appraisal.

4.6 Timeframe

4.6.1 The resource impact report and template covers the 5 financial years after guidance publication. Both the report and template will identify separately the resource impact for each of the next 5 financial years. The report indicates the timeframe in which full implementation is assumed to be achieved.

4.6.2 The uptake of guidance over the first five years from approval is based on a number of sources; company submission, experts views, commissioner expectation and where applicable uptake of similar drugs.

4.6.3 The budget test of £20 million is regarded as having been met if it is projected to be reached or exceeded in any of the first 3 financial

years of a technology's use in the NHS. Only technologies which exceed £20 million in first 3 financial years will be notified to NHSE.

4.6.4 Forecasts may be updated following implementation - see chapter 7 for further details.

4.7 Sensitivity analyses

4.7.1 Several assumptions are made in estimating resource impact. These are subject to uncertainty, particularly predictions about future practice after the recommendations are implemented.

4.7.2 Reasonable minimum and maximum values of variables are recorded when gathering evidence. These inform sensitivity analysis that highlights which variables the resource impact estimation is most sensitive to.

4.7.3 Results are presented in tables and a short explanation included to describe the variables that have most effect on the total resource impact.

5 Resource impact products

This chapter describes resource impact products. The key outputs of the resource impact team are:

- the resource planner
- resource impact reports and templates
- resource impact statements.

5.1 Resource planner

5.1.1 Each month the resource impact team publishes the NICE resource planner on the NICE website. It is also sent to chief financial officers and other people who request it. The resource planner contains information on guidance published in the previous

financial year and guidance publishing in the current and next financial years.

5.1.2 The aim of the resource planner is to help organisations plan and implement NICE guidance by:

- summarising the resource implications of published guidance
- listing forthcoming guidance with indicative resource impact for England profiled over the next 5 years, based on draft guidance.

5.2 *Resource impact report*

5.2.1 A resource impact report is a Microsoft Word document that sets out the estimated resource impact of implementing the technology appraisal guidance. The report provides national estimates if possible and explains the assumptions made for estimating the resource impact.

5.2.2 Only published list prices of technologies are discussed in published resource impact reports. Confidential data is never disclosed in published resource impact reports.

5.2.3 A shorter version is prepared if the resource impact cannot be estimated or is likely to vary locally. This highlights the areas of costs and savings to be considered at a local level.

5.3 *Resource impact template*

5.3.1 A resource impact template is an Excel spreadsheet that enables users to estimate the local cost of implementing guidance using NICE assumptions or by inputting their own assumptions.

5.3.2 In some instances the Department of Health and the company agree that the technology will be available to the NHS with a patient access scheme, which makes the technology available with a discount. The size of the discount may be commercial in confidence. If this is the case the resource impact template is designed to allow those who have access to the confidential

price(usually commissioners and providers) to input the confidential price locally and therefore estimate the resource impact of the technology.

5.3.3 The national resource impact template is based on the population of England. However, local commissioners such as clinical commissioning groups can amend the template to their local population to estimate local resource impact. The template can also be amended to estimate the resource impact for the population of Wales and Northern Ireland.

5.3.4 Resource impact templates are produced if it is possible to quantify the resource impact and it is considered to be significant (over £5 million for England). In rare instances for technology appraisals for which costs cannot be quantified but are still considered to be significant, a resource impact template is prepared but with the major cost drivers identified for completion by users in their own local settings.

5.4 *Resource impact statement*

5.4.1 A resource impact statement is a web-based statement. This is used if costs and savings are not considered to be significant (less than £5 million for England).

6 Quality assurance process and publication

This chapter explains the process of quality assurance and publication of resource impact products. Resource impact products are all subject to a quality assurance process before either consultation or publication.

6.1 *Resource planner*

6.1.1 The resource planner is published once a month. Before submission for publication senior business analysts review the work of business analysts within their team. Once this process is complete the resource impact assessment manager reviews the

resource planner and submits it to the associate director for resource impact.

6.1.2 The accuracy of the planner is checked for consistency with the NICE website, and the resource impact forecasts are checked to ensure that the conclusions are supported by the evidence.

6.1.3 The associate director for resource impact then approves it for publication on the NICE website.

6.2 *Resource impact reports and templates*

6.2.1 Senior business analysts provide advice to business analysts on the production of resource impact reports and templates. This is before a formal internal review.

6.2.2 Senior business analysts are responsible for ensuring products are of a robust quality for formal internal review by checking patient pathways, reasonableness of assumptions made, sources of evidence and costing data used.

6.2.3 Before resource impact data are shared with external stakeholders an internal review takes place.

Internal review

6.2.4 The process for an internal review is described below:

- Meetings are planned at least 2 months in advance to allow full attendance.
- Papers are distributed 5 working days before the meeting.
- The following people are invited:
 - associate director for resource impact, or resource impact assessment manager
 - the business analyst and senior business analyst responsible for the guidance
 - the technical team for technology appraisal or highly specialised technologies.

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6.2.5 The internal review is an opportunity for the business analyst to check the assumptions used in the resource impact report and template. This includes receiving comments from colleagues and peers within NICE to make sure that all relevant and significant factors have been included in the products.

Consultation and sign-off

6.2.6 The documents are shared with the consultees for technology appraisals including:

- the company
- companies for comparator technologies who are participating stakeholders
- patient experts and clinical experts from the committee
- NHS England for NHS England commissioned services
- Department of Health
- a minimum of 3 representatives from the NICE adoption and impact reference panel

6.2.7 The external consultation runs for a minimum of 2 weeks.

6.2.8 Once consultation has closed all comments are collated using a standard table and passed to the business analyst for review. The business analyst notes their response in the table alongside the comment in preparation for final sign-off.

6.2.9 If a consultee's comment needs further clarification the business analyst contacts the consultee.

6.2.10 The process for final sign-off is described below:

- Meetings are planned at least 2 months in advance to allow full attendance.
- Papers are distributed 3 working days before the meeting.
- The same people are invited as to the internal review.

- All points raised at consultation are documented and actions agreed.
- The meeting concludes with the associate director for resource impact or the resource impact assessment manager signing off the products to proceed to Publication Executive.
- The associate director for resource impact or the resource impact assessment manager advises whether any key issues need to be shared with the Medicines and Technologies Programme director before submission to Publication Executive.

6.3 ***Editing***

6.3.1 The resource planner is not edited by NICE editors.

6.3.2 However, the resource impact reports, templates and statements are edited by NICE editors. Ideally this takes place after final sign-off. To ensure the products publish alongside the guidance, editing can place while they are being consulted on.

6.3.3 The editor checks for consistency between the resource impact report and the guidance, and ensures that the products are in the correct format, easy to understand and navigate, and in line with NICE style.

6.4 ***Approval for publication***

6.4.1 The resource planner is approved for publication by the associate director for resource impact.

6.4.2 The resource impact reports, templates and statements are approved for publication by the NICE Publication Executive, which

meets every week. Products are approved for publication once any queries have been answered.

7 Making post-publication amendments

This chapter explains the process for updating resource impact reports and templates after they have been published.

7.1 *New technologies for the same condition*

7.1.1 The resource impact team updates resource impact reports and templates if needed, to take into account new technologies for the same or similar conditions. For example, if a new technology becomes available for a condition that already has a resource impact report and template, any new publication will ensure consistency and that costs and savings are not double counted.

7.1.2 This may mean that existing resource impact reports and templates need to be updated and this will be part of the Publication Executive submission when the new guidance publishes.

7.2 *Annual review of the resource impact reports and templates*

7.2.1 Technology appraisals resource impact reports and templates are reviewed every year as set out below, when uptake data from NHS Digital, company data and other relevant sources are available.

7.2.2 An annual review between the resource impact team and the ABPI will review progress and introduce a feed.

7.2.3 The outcome of the review is 1 of the following:

- The report and template remain fit for purpose.
- The report and template need updating.
- The report and template are no longer necessary and are retired.

7.2.4 When the reports and templates are updated or retired, Publication Executive approval is needed before changes are made to the NICE website.

7.3 *Other circumstances in which amendments are needed*

7.3.1 Resource impact is based on assumptions about current practice and predictions of future practice, at the time the guidance is published. Sometimes resource impact issues emerge after the guidance is published that were not identified before publication. This can happen particularly during the post-publication engagement with stakeholders validating other implementation products.

7.3.2 There are 2 ways of addressing this:

- revise the original products **or**
- issue a supplementary commentary.

7.3.3 Revising the resource impact or issuing a supplementary commentary is considered in the following circumstances:

- A significant flaw is identified in 1 or more assumptions relating to current or predicted practice that is considered to be greater than local variation.
- The basis of the resource impact assessment is inconsistent with current practice or there has been an inaccurate use of costs.
- Feedback indicates that a recommendation will lead to nationally significant costs or savings that were not identified in initial work.

7.3.4 The criteria against which a decision is made about whether to update the resource impact products are given below:

- Revising the assumptions in the template affects the total resource impact by more than 10%.

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- Revising the unit costs in the template affects the net total resource impact by more than 10%.
- Estimated costs or savings arising from a new recommendation is considered to lead to a total resource impact change of £5 million per year or more for England.
- Revising the resource impact assessment template will correct obvious inaccuracies that, if left, will undermine user confidence in the template, even if the impact on the total net cost does not meet the thresholds above.

7.3.5 The template is not updated in the following circumstances:

- There are differences in baseline and predictions arising from natural variation in local circumstances.
- Unit costs that have been used for drugs and activity were correct at the time of publication but have since changed. Templates are not routinely updated for annual updates to activity costs, such as tariff changes.