This document is intended to provide information for NICE stakeholders and internal teams on the methods used by the resource impact assessment team in developing resource impact assessment commentaries, templates and other 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 each publication. It will also be reviewed internally by the Programme Director for Adoption and Impact and the Associate Director for Resource Impact Assessment again in a further 12 months’ time. This review will focus on external and internal factors that may require a change to the process or methodology, or where the accuracy, clarity or fairness of the process or methodology may be improved.

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 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.

Nothing in this document shall restrict any disclosure of information by NICE that is required by law (including, in particular but without limitation, the Freedom of Information Act 2000).
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Assessing resource impact methods guide
1 Introduction

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.

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.

NICE is accountable to our sponsor department, the Department of Health (DH), but operationally NICE is independent of government. Our guidance and other recommendations are made by independent committees. The NICE Board sets our strategic priorities and policies, but the day-to-day decision-making is the responsibility of the Senior Management Team (SMT).

The way NICE was established in legislation means that our guidance is officially England-only. However, NICE does 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, which have opportunities to be involved and consulted with in the development of NICE guidance.

NICE’s role is to improve outcomes for people using the health, public health and social care services. NICE does this by:

- Producing evidence based guidance and advice for health, public health and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
- Providing a range of informational services for commissioners, practitioners and managers across the spectrum of health and social care.

Guidance

- **NICE guidelines** – are evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health and managing medicines in different settings, to providing social care to adults and children, and planning broader services and interventions to improve the health of communities. They aim to promote integrated care where appropriate, for example, by covering transitions between child and adult services and between health and social care.

- **Technology appraisals** – assess the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also include 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.
• **Interventional procedures guidance** – recommends whether interventional procedures, such as laser treatments for eye problems or deep brain stimulation for chronic pain, are effective and safe for use in the NHS.

• **Medical technologies and diagnostics guidance** helps to ensure that the NHS is able to adopt clinically- and cost-effective technologies rapidly and consistently.

**Quality standards and other performance metrics**

• **Quality Standards** – are concise sets of statements, with accompanying metrics, designed to drive and measure priority quality improvements within a particular area of care. They are derived from the best available evidence, particularly NICE’s own guidance and, where this does not exist, from other evidence sources accredited by NICE.

• **Quality and Outcomes Framework (QOF)** – NICE’s role is to manage an independent and transparent process for developing indicators that are suitable for inclusion within the QOF; it does this by producing a ‘menu’ of QOF indicators. NHS England and the devolved administrations of Northern Ireland, Scotland and Wales will use the NICE QOF menu to help decide which indicators are included in the QOF within their countries.

• **Clinical Commissioning Group Outcomes Indicator Set (CCGOIS)** – working with the NHS England, as well as with professional and patient groups, NICE have developed some of the indicators of the framework for measuring health outcomes and the quality of care (including patient reported outcomes and patient experience) achieved by clinical commissioning groups (CCGs).

**Support to put NICE guidance into practice**

Putting NICE guidance into practice can be challenging, and the Health and Social Care directorate, across its teams, leads objectives to:

• Coordinate and operate a programme of external engagement, including with national and local organisations in relation to guidance and standards, and students and teachers in educational institutions.

• Publish support for the uptake and use of NICE guidance, including resource impact assessments, online learning modules for priority topics, shared learning examples and quality and productivity case studies.

• Provide an endorsement and quality assurance function to support implementation, which signposts support products provided by third party organisations that are in line with guidance and standards to broad and targeted audiences, as appropriate.

The purpose of this work is to benefit the public, patients, users of services and carers through supporting improvements in quality, and to support staff delivering those services to put recommendations into practice in a demanding financial climate and as health and social care systems undergo significant change.
The resource impact assessment team provides strategic advice and information about the resource impact of guidance to a number of national partner organisations including the Department of Health, NHS England, Monitor and Public Health England.

The resource impact assessments can be used locally by commissioners and providers as a framework for local agreement. The main outputs – commentaries and templates will look to provide indicative resource impact information that can be used locally. They may include supportive information to assist the development of business cases, consider risk sharing agreements, or provide direction to local health and social care economies on where integrated approaches should be considered.

The resource impact assessment team also provide input to a variety of NICE programmes. For example, the team produce the resource impact assessments related to QOF indicators and also local practice examples on quality and productivity. The team leads on partnership work with national stakeholders related to resource impact assessment issues.

Most work is focused on matters to do with supporting the direct use of guidance in practice and driven by the main guidance and quality standards outputs. The exception to this is the interventional procedures programme described above. Because the advice concerns safety and efficacy rather than clinical and cost effectiveness, we do not assess the resource impact of interventional procedure guidance.

As stated above the major outputs of the team are the products (defined in section 1.2.3) to assist those responsible for implementing guidance recommendations.

The NICE resource impact assessments contained within the products give advice on wide ranging issues such as the financial, workforce, capacity and demand, training, facilities and educational implications of the guidance being considered.

Advice is also given on where responsibility for implementation rests (who is the commissioner and who is the provider?) and whom the costs or savings fall upon (commissioner or provider).

The NICE resource impact assessment products are generally published at the same time as the related guidance and quality standards. Where products have a longer time for development, such as return on investment products covering several pieces of guidance, or when a small part of a guideline has been updated, essential information on resource impact will still be available at launch.

The team are also involved in the process for endorsement of guidance support resources produced by third party providers where the support resources involve understanding resource impact and/or advice for commissioners.

\[ 1.1 \quad \textbf{Aim of this guide} \]

This guide has been prepared primarily to support the resource impact assessment business analysts who are responsible for producing resource impact assessment...
General resource impact assessment principles

products and providing advice on resource impact for NICE guidance and standards. The guide:

- recognises that NICE guidance covers health and social care and highlights the importance of integrated working where possible.
- provides advice on the technical aspects that the business analysts need to consider when estimating resource impact.

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

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

**This guide in the context of national planning guidance**

When using this methods guide business analysts should also be aware of any relevant health and social care planning guidance as this can help to provide context and structure to guidance and preparing the resource impact assessment.

For example, the Department of Health has developed a number of long term planning guidance frameworks for commissioners and providers to develop 5 year plans to ensure the continuity of sustainable, high-quality care. The planning guidance typically would cover:

- Strategic plans covering a 5-year period, with the first 2 years at operating plan level.
- An outcomes-focused approach, with stretching local ambitions expected of commissioners, alongside credible and resource impact assessed plans to deliver them.
- Citizen inclusion and empowerment to focus on what patients want and need.
- More cooperation between providers and commissioners.
- More integration between health and social care.

**This guide in the context of local health and social care organisations**

Business analysts will need to assess how guidance and standards impact across whole pathways for health and social care and the effect on the different commissioners and providers (in local pathways) over a 5-year period. In addition to the main resource impact areas described in chapter 2 'General resource impact assessment principles', this could include providing details on the business planning changes that might be required to support key service planning changes.

The resource impact assessment focus is primarily on the national perspective and is 'whole population' based. NICE recognises that the local context cannot always be captured within the resource impact assessment but will look to highlight any evidence of local variation as part of the assessment. Furthermore, it is acknowledged that the resource impact template will provide commissioners with the ability to model the resource impact at a local level; when and where possible costs or savings that impact within providers will also be outlined.

Assessing resource impact methods guide
1.2 Resource impact assessment outputs

1.2.1 Strategic intelligence outputs from the resource impact assessments

The results of the resource impact assessment will be used for a variety of strategic purposes to inform and influence policy and activities in other national partner agencies. For example:

- Health Education England (HEE) and the regular transfer of information to them and discussion about guidance-related workforce planning, training and education needs. Accumulated information on workforce capacity across all guidance will be collated for HEE, for example impacts on GP numbers.
- The College of Social Work (TCSW), if guidance relates to social worker standards such as changes to training requirements.
- Monitor, holds specific responsibility for setting the NHS pricing policy and currencies with NHS England, and is interested in guidance and standards that may require system intervention and a change in a Healthcare Resource Group (HRG) price to improve uptake.
- Information provision to DH and NHS England relating to resource impact of selected guidance required for reviews, such as for Innovation Health and Wealth or the Pharmaceutical Price Regulation Scheme.

1.2.2 Practical planning products to accompany specific guidance outputs

The objective is to assist with the adoption and implementation of NICE guidance, and the use the quality standards (by embedding key information within them), through providing key planning information relating to the resource impact.

Clarifying the place of guidance within the pathway or organisation of care

The resource impact commentary will indicate where care pathways change for people receiving health and social care. Resource templates will set out current and future pathways for people receiving health and social care.

Resource impact perspectives

The resource impact may differ when it is viewed from either the commissioner or the provider perspective.

There could be a difference in the activity cost depending on whether the cost to provide activity or to commission activity is used; where possible both costs are stated. For example in the NHS, where acute activity falls mainly under Payment by Results (PbR) at a tariff rate, 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 than the commissioner to review what the change will mean in practice and assessing the actual cost of providing activity.
However it would be difficult to provide full cost details to providers, due to the structural resource variations between providers. At the same time the implications to providers will be highlighted where the information is robust and based on evidence. For example, if there is a need to expand or increase the workforce in the future.

The resource impact assessment usually covers a period of 3–5 years. Where implementation and the resource impact are anticipated to change over the course of 3–5 years, the resource impact over time should be analysed as well as the resource impact at full implementation.

There may also be occasions where the production of a resource impact assessment over a longer period such as 10 or 25 years could be produced. This would typically be where it is recognised that a longer period of change in service practice is required or where there is a longer return on investment required.

There will be an increased focus on producing a return on investment tool as part of the approach for developing resource impact assessments and accompanying tools. Return on investment approaches are seen as being an improved approach when considering the impact of guidance and standards.

Health and social care bodies should have a clear implementation plan linking operational and financial aspects and be integrated into mainstream financial planning and budgeting. Resource impact assessment products can be used to estimate the local cost of implementing NICE guidance in order to inform implementation plans and business cases.

The NICE resource impact assessments presented as commentaries, template or occasional other formats, should provide reliable and consistent national implementation estimates. Local circumstances can and will differ, so users are encouraged to consider local assumptions.

1.2.3 What are resource impact assessment outputs?
The main outputs relating to resource impact assessments are the:

- forward planner which is a record of, and quick reference to, all outputs produced or planned to be produced, (updated monthly),

- products that support the implementation phase for individual guidance, guidelines or standards, and are produced at or around the time of the launch.

The NICE forward planner

The forward planner helps people plan for and implement NICE guidance by:

- summarising published guidance, guidelines or standards that organisations may still be implementing.
- listing forthcoming guidance, guidelines or standards to help health and local authorities' bodies plan ahead.

Assessing resource impact methods guide
• including an indicative resource impact for England for forthcoming guidance, guidelines and standards based on the Institute’s draft guidance, where published.

**Resource impact assessment products for**

The products can take three broad formats:

1. Resource impact assessment commentary
2. Resource impact assessment template
3. Return on investment tool; produced for specific public health guidelines

These three main products are described below:

• **Resource impact assessment commentary** (in web viewer form).
  Summarises the resource impact in terms of financial, workforce, capacity and demand, training, facilities, educational and other implications of the guidance.
  - A national estimate is given where possible and discussion of the assumptions made when estimating the resource impact of implementing the guidance. This may be supported by a resource impact assessment template (see below).
  - Where cost is deemed not to be significant (see section 4.2) or cannot be estimated with any degree of certainty, a shorter narrative commentary is produced to discuss the costs or savings to be considered locally when estimating the cost of the guidance or why costs or savings are not significant. Examples of when a shorter commentary is likely because it is not possible within our available resources to estimate the national cost due to lack of readily available data or there is significant regional variation.

• **Resource impact assessment template** (a Microsoft Excel document).
  Provides users with the ability to estimate the local cost of the guidance using NICE standard assumptions or input their own local assumptions. Resource impact assessment templates are produced where it is possible to quantify the resource impact and the resource impact is considered to be significant. In some instances a blank template will be prepared with the major cost drivers for completion at a local level.
  - The national resource impact assessment template is based on the population of England; however local commissioners, such as CCGs or local authorities, can include their local population details in order to estimate local impact. National population figures are also provided for Wales and Northern Ireland so that the templates can be used in these countries.

• **Return on investment tool** (a web based tool).
  There will be an increased focus on producing a return on investment tool as part of the approach for developing resource impact assessments.
Return on investment approaches are seen as being an improved approach when considering the impact of guidance.

**Purpose and method of revision**

NICE scheduled a review of its ‘Assessing cost impact’ methods guide in 2014 and this revision fulfils that duty.

This revised methods guide reflects the change in responsibilities for NICE and the changing external environment in health and social care.

The methods guide revision has been led by a steering group, which advises the project and provided strategic support and guidance to ensure that the methodology and processes reflected other NICE processes where possible and include an external perspective.

The methods guide is subject to approval by the NICE Senior Management Team.

Chapter 2 lays out the principles for NICE resource impact assessment, and is followed by a more detailed explanation in chapter 3 of data sources to estimate population activity and activity costs and savings. Chapters 4, 5 and 6 focus on how products are created, and the quality assurance and updating process.

Further detail about the process of working with guidance producing centres is contained within separate documents although chapter 5 covers some of this ground. These micro processes will be reviewed with the teams concerned as part of the development and updating of this manual.
2 Resource impact assessment principles

NICE uses the following general principles to underpin the assessment of resource impact for guidance and subsequent updates. Section 2.1 identifies the approach to take for consideration of finance, workforce, capacity and demand, infrastructure, training and education, contractual and other key impacts.

Principles underpinning the development of NICE resource impact assessment outputs

Resource impact assessment will be based on the following principles:

- Only direct consequences of implementing guidance recommendations will be included.
- Resource changes will cover only those funded by the public sector.
- Assessments will be consistent with the economic analysis in the guidance.
- Standard accounting and workforce planning principles will be applied.
- The best available datasets will be used, supplemented with expert opinion if required.
- The timeframe required for full implementation will be taken into account.
- Key stakeholders will be consulted.
- National estimates will be provided wherever possible.

Additional note relating to the general principles

This information sets out to business analysts the key stakeholders how the assessments support guidance and standards implementation, and the key impact areas that the assessments are expected to take account of, such as the impact on finance and workforce. Key stakeholders are listed, noting the specific information requirements each type of stakeholder will require.

1. National health and social care organisations
   NICE will assess the resource impact consequences associated with the implementation of NICE guidance and standards at a national level. This could include informing national organisations such as Monitor where there may be changes required to the national tariff, or to highlight where additional focus may be needed to support implementation, or to confirm the impact assessment levels required to support the introduction of new technology.

2. Local commissioning organisations, and health and wellbeing boards
   NICE will assess the potential local resource impact that implementing NICE guidance or standards may require. This could include providing information relating to business planning processes and structures, as well as financial and workforce level changes.
3. Providers of health and social care organisations

NICE will highlight the key business planning information that could assist providers in understanding the resource impact of implementing NICE guidance and standards. This could include highlighting the workforce changes needed; or the initial investment plus payback period; or the activity changes that need to be understood before implementation.

The final outputs should be both realistic and consistent with the health and social care economic analysis on which the guidance is based (see section 2.1.3). The outputs do not form formal guidance to the health and social care or other bodies but aim to support implementation of NICE guidance and meeting the related quality standard. As such, the resource impact assessment is published as a resource rather than integral to the guidance in question and disseminated to the relevant audiences via the NICE website.

Key points related to resource impact may appear in the implementation section of NICE guidelines on clinical, social care or public health topics as they relate to key barriers or facilitators to putting the recommendations into practice.

Updates to guidance, guidelines and quality standards and accompanying resource impact assessment outputs

For guidance, guidelines or quality standards updates the following resource impact assessment principles apply:

- The focus should be on changes in the guidance or quality standard and to quantify the resource impact of service changes resulting from the guidance being implemented or meeting the related quality standard.

- Each change to the guidance or quality standard should be reviewed individually to determine whether the resource impact is significant.

- The update should not be a repeated resource impact assessment of the whole guidance or standard, except where there is clear evidence the existing resource impact assessment commentary/template is no longer applicable. For example, where clinical practice has changed.

- In circumstances where previous guidance or standards did not have a resource impact assessment template, or where it is considered that organisations may still be working toward implementation of recommendations in existing guidance, then a new resource impact assessment template may be prepared.

It is noted that resource impact information for quality standards will be integral to the quality standard itself and not presented as a stand-alone product.
Key impact areas that underpin the development of resource impact assessment outputs

Resource impact assessment should include, but is not limited to, the following key impact areas:

- Finance
- Workforce
- Capacity and demand
- Infrastructure
- Training and education
- Contractual
- Other (pertinent to the particular assessment)

Further details and examples relating to the impact areas are provided in remaining part of this chapter.

2.1 Finance

2.1.1 Accounting principles

The Government Financial Reporting Manual\(^1\) (FReM) is the technical accounting guide to the preparation of financial statements. It complements guidance on the handling of public funds published separately by the relevant authorities in England and Wales, Scotland and Northern Ireland. The manual is prepared following consultation with the Financial Reporting Advisory Board (FRAB) and is issued by the relevant authorities.

The FReM applies directly to:

- all entities ('reporting entities'), and to funds, flows of income and expenditure and any other accounts (referred to collectively as 'reportable activities') that are prepared on an accruals basis and consolidated within Whole of Government Accounts (with the exception of the accounts of any reportable activities that are not covered by an Accounts Direction);

But not to:

- Local Government, those Public Corporations that are not Trading Funds, and NHS Trusts and NHS Foundation Trusts. (The NHS Manual for Accounts, the NHS Foundation Trust Annual Reporting Manual and the CIPFA Code of Practice on Local Authority Accounting in the United Kingdom are compliant with the FReM manual other than for specifically agreed divergences.)

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Key issues that should be considered when developing the NICE outputs:

- Ensure costs or savings relate to the same time period, typically an annual period. Differences may arise where costs or savings 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 should be taken to recognise income and expenditure as soon as it is planned to be incurred. This is usually at the point an order is placed or contract signed.

2.1.2 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 resource impact assessment 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, or where effective social care in the community prevents admission to a care home. Savings from the avoided admission to the care home 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 resource impact assessment work.

2.1.3 Links between the commentary and template and the underpinning economic model

NICE’s approach to the economic analysis of cost–consequences considers all the health, care and non-health and care benefits, not just the direct costs or savings, of an intervention across different sectors and reports them in a disaggregated form. It accepts that different types of benefit cannot be gauged using the same units. The following cost consequences relating to the economic analysis can be included:

- direct costs and savings, including for health care, social services and transportation
- indirect costs and savings, including productivity losses and for criminal justice expenditure
- intangible costs and savings, including those related to quality-of-life and the impact of living with pain.

All impacts and costs or savings are considered (even if the impacts cannot be assessed) when deciding which interventions represent the best value. This distinguishes it from cost–benefit analysis.
The resource impact assessment commentary and template will concentrate on highlighting the direct cost or saving consequences in line with the economic analysis of the direct cost-consequences.

The resource impact assessment may also provide information relating to indirect costs or savings outlined in the economic analysis (but not the consequences) where it is considered to provide useful evidence of costs or savings and benefits, provide a more rounded view. The economic analysis will include cost consequences wider than the direct costs or savings.

Although focusing on the direct costs or savings, the resource impact assessment should be realistic and, wherever possible, should be consistent with the economic analysis on which the guidance is based. To achieve consistency, a two-way flow of information between business analyst and health and social care economist – or, for appraisals, the technical lead – will be encouraged when guidance is being developed.

Because the economic analysis is developed in advance of the recommendations being made, a two-way flow of information may not always be possible. However, the business analyst will be available to act in an advisory capacity on an ‘as required’ basis for health and social care economists or technical leads.

The guideline economic analysis may have looked at a variety of elements to determine the incremental cost per quality adjusted life year (QALY) gained. To calculate cost, the health and social care economist uses estimates of unit costs and levels of service use. The resource impact assessment will include, where relevant, the same costs, activity levels, workforce, risk identification and key assumptions to ensure consistency. However, there may sometimes be differences for which there may be legitimate reasons, resulting from the theoretical foundations of guideline economic evaluation.

There are ‘return on investment’ tools produced for specific public health guidance such as tobacco use, and these tools provide a link between the resource impact assessment commentary and template and the guideline economic model. The return on investment tool can be used by to consider the long term benefits relating to changes in service or provision that are required, and the initial investment required in order to facilitate those benefits.

### 2.1.4 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 or one care home manager and this fixed cost remains the same, but the staff required for outpatient clinics, or different levels of resident care, will vary depending on the 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, additional clinic accommodation may need to be built.
2.1.5 Recurrent and non-recurrent costs or savings

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

Recurrent costs or savings are usually the annual costs or savings of implementing a clinical or care intervention 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.

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 incident 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 specific recommendation or achieve best practice and care. Note that some training may need to be considered as a recurrent cost because of the need to offer refreshers or train new staff. This training is over and above that covered by existing training budgets.

2.2 Workforce planning

Each resource impact assessment commentary and template should consider the workforce implications of the guidance. Information relating to the impact of guidance for a particular workforce or profession type, such as GPs or social workers, will be considered and assessed, where there is evidence of specific strategic issues. The strategic information related to workforce planning, will also include the provision of education and training.

An example of this would be for safe staffing guidance where there is a need to train more nurses, or where the future supply of newly qualified nurses is planned to change. Discussion with HEE may provide insight to the issues that may arise during implementation of the guidance.

2.3 Capacity and demand

Each resource impact assessment commentary or template should consider the capacity and demand implications of the guidance. An example of this would be implementation of the NICE guideline on contraceptive services with a focus on young people up to the age of 25. This requires more GP appointments and is an increase in demand for services. In some areas there may not be sufficient capacity to meet the required demand, such as the provision of additional support for socially disadvantaged young people to help them access and use contraceptive services.
2.4 **Infrastructure**

Each resource impact assessment commentary or template should consider infrastructure implications of the guidance. Infrastructure covers such things as IT, facilities, premises, equipment and issues such as carbon footprint.

Implications that may need to be highlighted include the requirement for new equipment to carry out a new procedure or where a new computer system is required to support guidance implementation.

2.5 **Training and Education**

Each resource impact assessment commentary or template should consider the training and education implications and requirements of the guidance. This includes that, which can be undertaken from existing training budgets. The assessment should also highlight any new education programmes required to help guidance implementation.

2.6 **Contractual**

When guidance or standards note that there are clear areas for improvement relating to existing contractual issues, that could delay or restrict implementation, then the business analyst should consider the implications and state how the situation may be improved. This may be achieved by making reference to a specific national contract section, or it may be achieved by stating that a whole health and social care pathway contract should be introduced to assist all commissioners and providers.

2.7 **Other**

Notwithstanding the principles above, any other issues considered key to implementing the guidance should be highlighted in the resource impact assessment commentary or template.

2.8 **Assessment of equality impact**

The NICE guidance developers are responsible for ensuring that guidance takes appropriate account of equality considerations when making recommendations. With respect to implementation, the NHS, Local Authorities 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 resource impact of recommendations does not lead to unintended discrimination and this will be reviewed as part of the quality assurance process before publication of the NICE commentary or template.
3 Identifying: data sources, populations affected, activity levels and activity/ unit costs

The resource impact assessment process manual provides the business analyst with a comprehensive set of processes based on the identification of data sources, populations affected, activity levels and activity/ unit costs.

This section provides an outline of how the business analyst develops the resource impact assessment through identifying and appraising the appropriate:

- data source/s
- populations affected
- activity levels
- Activity/ unit costs.

3.1 Identifying data sources

The data used to establish the baseline or predicting future practice will vary depending on the topic of the guidance. In some cases a range of sources may be needed. Data used should be accurate and credible, and the underpinning source of data should be referenced.

The business analyst will determine the most relevant and useful data source by considering the guidance, guideline or standards topic, and then examining the key database/s available.

3.1.1 Establishing a data baseline

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

- Hospital data - such as Hospital episode statistics (HES)
- Prescribing data – such as Electronic prescribing analysis and cost tool (ePACT) system
- Primary care data – such as General practice medical databases – primary care data is available through sample GP practice systems (IMS Health or THIN)
- Public health and social care – such as the Health and Social Care Information Centre (HSCIC)
- Workforce – such as Health Education England (HEE), NHS employers, Health and Social Care Information Centre (HSCIC) social care workforce, Personal Social Services Research Unit (PSSRU).

3.1.2 Sources of data to establish future practice

Predicting future practice following the implementation of a recommendation poses significant challenges. When predicting uptake it is important not to rely only on one source. The validity of assumptions made in the draft resource impact assessment tool must be checked. This is subject to further scrutiny when the resource impact assessment tools are consulted upon.
The following sources of information (in addition to the commonly used sources in section 4.1.1) from the experts, developers or committee can be used to predict the uptake of guidance or the level of change needed for compliance:

- Previous uptake of similar drugs, or technologies or other interventions.
- Preference studies (although rarely available) – 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.
- 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 in the Local Practice Collection (for quality and productivity or shared learning) may be useful.
- Information used to inform the guideline economic models.

3.1.3 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?
- Specification of the sample frame – what elements are included in the sample?
- 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.
- 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.

Throughout the sampling exercise it is advised 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.

3.1.4 Use of decision models
There are occasions when the technology appraisal or guideline economic modelling used to help draft the guidance, or related research, will present the patient or care pathway in the form of a decision tree or Markov model. Health and social care economists use decision trees and Markov models to test which of several options is clinically and cost effective. For resource impact assessment purposes, only the section that describes either current or future practice will be relevant.
3.2 **Identifying the population affected**

A fundamental step in estimating the resource impact of implementing guidance recommendations is to identify the people affected by them. National estimates for England will be based on the relevant population for England to calculate the national resource impact of implementing the recommendations in England. The same assumptions can also be applied to a local population.

### 3.2.1 Population sources to use

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. The registered population is the number of patients registered with GP practices.

Where possible, the resident population should be used because the registered population may be overstated. The main reasons for the overstatement are; people leaving the country and not notifying their GP, the delay between a patient registering with a new GP, and patients being removed from the register with their original GP.

### 3.2.2 Incidence and prevalence data

Incidence and prevalence measure different aspects of disease or care need burden in a population, although they are related. The incidence of a particular condition is the number of new cases of the condition or care needs among a certain group of people over a certain period of time.

The prevalence of a particular condition or care need 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.

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 – a measure of the burden of disease or 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.

Both prevalence and incidence data may need to be considered within one resource impact assessment tool to enable accurate calculation of the resource impact of different significant recommendations. For example, the annual treatment cost for an acute or 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.
3.3 Identifying activity levels

Identifying the activity baseline and then predicting how this might change as a result of the guidance, guideline or standard is often one of the most challenging aspects of assessing the resource impact. Without a reliable, consistent and robust structured baseline, the ability to then predict the change in activity will be limited.

When considering what the current baseline is, the business analyst will need to identify if there are gaps in activity information sources, or the activity is not captured or coded in the same format as the NICE definition, or the care pathway is multi-provider and not currently shown in an integrated activity structure. Business analysts will need to consider as to what level of certainty and consistency they can place on the resource impact assessment if the baseline activity data or information cannot be relied upon. This may result in a resource impact commentary being produced but without a supporting template.

The activity being identified should also be clearly defined. Alternative definitions should be included because the same activity might be described using different names in different areas. The business analyst will use this to then consider how to predict the change in activity levels.

3.3.1 Identification of baseline activity levels

This is linked closely to the identification of data sources. The business analyst will consider the following key issues:

- Is the treatment or care clearly defined?
- Who is/are the professional group/s responsible for carrying out the activity?
- Where will the activity take place?
- What is the current average length time for the activity?

3.3.2 Predicting the impact of recommendations

Assessment the resource impact will include identifying the change required and can be estimated using the following formula:

\[(\text{predicted activity} \times \text{predicted cost}) - (\text{current activity} \times \text{current cost})\]

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 be realistic rather than optimistic (for example, expecting guidance to be implemented straight away in 100% of the population eligible is unrealistic). Experts can sometimes provide information on realistic levels and timeframes for implementing guidance to inform the resource impact over time.

Some changes can be effected with relatively little lead in time, whereas others may require more substantial system changes and cannot be achieved overnight. The availability of equipment, trained staff and premises, and the time to plan need to be considered.

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3.3.3 Implementation timeframe

Some changes can be effected with relatively little lead in time, whereas others may require more substantial system changes and cannot be achieved overnight.

The actual calculation of costs or savings over time can be straightforward once the resource impact assessment model has been defined. To calculate costs or savings over time for a constant rate of change, the same resource impact assessment 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 the 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.

3.4 Identifying activity/unit costs or prices

Where possible, the business analyst should check if the activity outlined in the guideline, guidance or standards has an identifiable cost or prices assigned to the activity spell or pathway or whether there are specific unit costs.

3.4.1 Healthcare

It is recognised that in the health service there are large parts of acute activity that the national tariff (price) or reference costs can be used when assessing the resource impact. However there are still some elements of acute care that fall outside tariff or where local agreements have been made to address local issues, thus making the identification of a national cost or price difficult to assign.

Furthermore, whilst there are the mental health cluster currencies and a number of mental health providers have implemented the Mental Health Minimum Data Set (MHMDS), there is too much variation in adoption to be able to use the prices or costs on a consistent basis nationally. There are also a number of health services where there are not specific national activity prices or costs, such as community, primary care.

Where it is not possible to use tariff or reference costs, unit prices could be obtained from NHS organisations currently providing the service. This is useful in the case of very new procedures that have not yet been included in the tariff. 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 resource impact assessment 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.
Most technology appraisals and some clinical guidelines have recommendations that relate to drugs. New drug prices are normally part of the manufacturer submission or are based on the list price if the drug is already used. For comparator drug prices, the following approach should be used:

Drug prices should be the latest available list price. The Medicines and Prescribing Centre (MPC) will give advice on the source of the latest price available. Drug prices should be taken from the following hierarchy of sources:

1. PPA Drug Tariff
2. Chemist and Druggist
3. Dictionary of Medicines and Devices

### 3.4.2 Public health costs

There is not a national tariff or national reference cost collection relating solely to public health services. Public Health funding transferred from PCTs to Local Authority control in April 2013. Nationally there is a mixture of block contract payments, based around historic budget transfers when the funding transferred from PCTs or a form of cost and volume approaches, based on historic agreements or recent tendering exercises. Public Health services are carried out by NHS, private or third sector providers (or sometimes a combination of these provider types).

When determining where to find examples of indicative unit cost information, analysts should review each public health topic and assess the appropriate information sources that are available at that time. These include the Health and Social Care Information Centre (HSCIC), the PSSRU, the Local Government Association (LGA), health economics, and guideline evidence. For example the PSSRU provides unit costs for counselling services for reducing the incidence of sexually transmitted infections and teenage pregnancy.

The Return on Investment (ROI) tools produced alongside guidance may also provide details of the assumed unit costs, along with the indicative range of activity that might be expected from the current baseline to the long term position. For example there is a ROI tool for tobacco, which provides Local Authorities with unit costs of smoking cessation intervention services along with unit costs of savings that could be achieved.

### 3.4.3 Social care costs

Resource impact assessment tools will be produced to support the implementation of social care guidance from the financial year starting April 2015. Resource impact assessment data from guideline economics will be used to help assess the resource impact of such guidance.
There is not a national tariff or national reference cost collection relating solely to social care. Social care is funded by Local Authorities, individuals or third sector. Local Authorities may pay for some services or all of support if individual needs meet eligibility criteria. Services Local Authorities fund include community equipment, minor adaption to the home or reablement. Business analysts should note that individuals will need to have an assessment carried out before services can be carried out. Many individuals will pay for some or all of the services required (known as self-funder).

When determining where to find examples of indicative unit cost information, analysts should review each social care topic and assess the appropriate information sources that are available at that time. These include the HSCIC, the PSSRU, the LGA, health economics, and guideline evidence. For example, the PSSRU provides unit costs across all the main social care services ranging from care packages, to social care staff.

When reviewing who funds costs, business analysts need to be aware of the different forms of personalisation funding of services as this will help assess how the unit costs will impact on individuals and local authorities, and where applicable, healthcare commissioners. The main types of personalisation funding for services are:

- personal health budgets (healthcare and support needs)
- personal budgets (social care and support needs)
- individual budget (social care and support needs plus other funding)
- direct payment (funds paid direct to individual) to buy agreed care.

Further work will be undertaken to refine appropriate sources of resource impact assessment data as the detail of the guidance emerges. Consultation with social care experts both internally and externally will further support the identification and application of assessment data and information.
4 Creating the resource impact assessment product/s

When is has been possible to identify and reliable and consistent population, activity and cost (or price) data relating to a guideline, guidance or standard then the next step for the business analyst is to determine whether a resource impact assessment commentary and template can or should be produced. There are a number of steps that the business analyst will take in order to determine how to produce the assessment and the assessment product.

Where there is a lack of data or where there are significant data gaps, then the business analyst should not produce a resource impact assessment template and a resource impact assessment commentary should be produced instead.

4.1 Identifying significant resource impact recommendations

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

There are several ways to approach the resource impact assessment, ranging from assessing the resource impact of every recommendation to just assessing selected specific recommendations. The concept of identifying those recommendations that are have a significant resource impact is used to ensure that resources are focused on the recommendations that are likely to require the greatest change to implement, and therefore may impact most on financial and resource planning.

It is acceptable to identify an area of resource impact that may cover several recommendations. Training is an example of this if a number of recommendations relate to care being provided by suitably trained staff. In this example costing a training course for staff working in this area is more logical than costing training elements from several recommendations.

When guidance is updated the resource impact assessment focuses on the revised or new recommendations arising from the update rather than producing an assessment for the whole guidance (For more information on updating resource impact assessment products see section 6). Where it is clear that the original recommendations have not been implemented the resource impact assessment commentary should highlight this issue. An example of this is the updated NICE guideline on fertility.

The return on investment tools enable the user to evaluate a portfolio of interventions in their geographical area (e.g. region, county or local authority) and models the economic returns that can be expected in different payback timescales. They have been developed in collaboration with Brunel University, LeLan Solutions and Matrix Knowledge.
There are currently three tools covering tobacco, physical activity and alcohol. The different interventions included in each tool can be mixed and matched to see which intervention portfolio or package provides the best 'value for money,' compared with 'no package of interventions’ or any other specified package.

Custom interventions can be created for interventions that have not been included in the model by default if data are available on the effect and cost of the intervention, as well as the percentage of the population that receives or would receive the intervention.

4.2 Definition of significant

There are various definitions of significant; therefore it needs to be defined to ensure consistency across the different NICE outputs. 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.
- the need to recruit a large number of additional staff or the need to change roles or responsibilities.
- the need to invest in large amounts of infrastructure, for example IT systems.

To achieve consistency on significance, limits on either the number of people affected or the cost or saving have been determined, as set out below.

The following impacts have been defined as significant:

- Where initial resource impact assessment work indicates that the national cost or saving is more than £1 million per year, it could be deemed significant: this is equivalent to just under £2000 per year per 100,000 population.
- Where the number of people affected by the guidance recommendations is estimated to be more than 300 per year, it is considered meaningful to produce a resource impact assessment template at a national level. In a clinical example this is equivalent to 1 patient per 185,000, and in practice smaller populations may have no patients or possibly no more than 1, particularly if it is a disease that runs in families and there is a cluster in 1 area.
- Where the scale of additional staff required as a result of the recommendations is more than 300 in total per year.
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 resource impact assessment work. Resource impact assessment work should also detail the impact of recurrent and non-recurrent costs or savings, for example the non-recurrent cost of installing new medical equipment to undertake scans that result 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 in the resource impact assessment commentary/template. For example, to provide reassurance that the cost 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 resource impact assessment team.

The decisions taken regarding significance also determine which NICE resource impact assessment products are produced, and this is presented in section 5.5 (see figure 1).

4.3 Methods of identifying resource impact

The process followed for identifying the resource impact can start as early as the current context process or scoping stage but the actual assessment usually begins at once draft guidelines have been developed. It also depends on the guidance being assessed. Technology appraisal recommendations may be fully resource impact assessed, whereas it may not be appropriate to assess every recommendation in a NICE guideline. The following methods to identify resource impact are recommended:

- Technology appraisals, medical technologies and diagnostics evaluations – the potential resource impact should be discussed with the technical lead for the topic, and documentation such as the draft guidance, assessment report, guideline economic evaluations, Evidence Review Group report or manufacturer’s submission may contain useful information.
- NICE guidelines – the potential resource impact should be discussed with the relevant group or committee as follows:
  - Clinical guidelines – Guideline Development Group (GDG) or Committee (CGAC)
  - Social care guidelines – GDG
  - Public health guidelines – Public Health Advisory Committees (PHACs) including topics
  - Safe staffing guidelines – Safe Staffing Advisory Committee (SSAC)

The project team at the relevant National Collaborating Centre (NCC) or internal development team, including the health or social care economist, is also involved as they may have useful background information.
The full draft guidance, guideline economic plan, guideline economic evaluations, draft guidance and responses to guidance consultation (when available) are also useful sources of information.

At least 4 months before a guideline is published, NICE business analysts should use a Systematic Categorisation of Recommendations (SCORE) to identify recommendations that may have a resource impact.

The SCORE involves looking at each draft recommendation and assessing whether there is a potential resource impact. In some instances it may be appropriate to group several recommendations together. This is useful when there are a large number of recommendations. For example, assessing the training costs across an entire guideline could be treated as one total cost rather than a cost for each individual recommendation.

Once the SCORE is complete it should be sent to members of the relevant group or committee developing the guideline to obtain a view as to whether there is a resource impact associated with individual recommendations.

There are a number of sources where useful information on costs or savings can be gained such as:

- NCCs
- the health and social care economist, both at NICE and NCCs
- the guideline economic plan
- evidence reviews
- guideline economic evaluations
- response to guidance consultation (when available)
- guidance, guideline and standards teams

The committee may not be able to identify all recommendations that have a significant resource impact. 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 to ensure that the impact is representative of the wider public sector and not skewed by the views of one individual.

Estimating the resource impact of implementing recommendations often carries a degree of uncertainty. Therefore the more effective approach is to identify all known areas to assess (which can be left out of final resource impact assessment products if subsequent consideration shows them to be insignificant) than to miss potentially significant areas.

4.4 Where the resource impact cannot be quantified

Occasionally, circumstances will be such that it is not possible to quantify the resource impact of implementing a guidance recommendation, quality standard or QOF indicator, given the resources available to the team.
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 2 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, for example the delivery of social care in people’s homes.

All resource impact assessments are subject to a level of uncertainty regarding the effect of recommendations. However, the resource impact assessment can usually be considered helpful in informing local decision makers about the magnitude of the resource change involved, even if the exact effect is likely to be different for each locality. 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.

For the sake of completeness, recommendations that cannot be quantified but are considered to have an impact on costs or savings should be discussed in the commentary. This flags the issue and allows local implementers to make judgements about the likely impact based on local circumstances.

Where it is deemed to be useful, a template should still be developed for local use in order to allow organisations to assess their position based on locally available data. Key unit costs should be provided to allow organisations to apply such costs to local activity data.

### 4.5 Assessing the population/activity/cost or price data

When the relevant population, activity and cost data have been identified and confirmed as being reliable, business analyst can then begin to combine the data using the standard resource impact assessment template. The data is input and checked to ensure that the initial calculations appear to be reliable and where possible consistent with the economic evidence.

The resource impact assessment 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 resource impact. This will give the first indication to the business analyst whether the resource impact is likely to be significant (see section 3.2 for advice on significance).
The style of resource impact assessment commentary and resource impact assessment template will depend upon the commissioner/s the commentary or template is being prepared for.

It is important to ensure that the estimated resource impact data and information relate to the relevant guidance, guideline or standards topic and not run the risk of being double counted with previous resource impact assessments. The business analyst will identify if related guidance has been published previously, and the type of resource impact assessment product that accompanied the related guidance.

Guidance, guidelines or standards may often refer to other relevant guidance that has been published and which may have resource impact assessment products to support it. Resource impact assessment products supporting related guidance should be referred to in the current commentary and template where they are relevant. However, it is not the intention to revisit previously resource impact assessed elements.

Where NICE commissioning and benchmarking tools (CAB tools), previously part of the NICE product portfolio are in existence, unit costs and activity data should be consistent and, if necessary, CAB tools should be updated for minor changes or removed as this product line form NICE has now ended. If for any reason this is not possible or desirable, the reasons for the difference should be stated but recognising the objectives of the CAB tools are different – they were used to estimate total cost to commission a service, rather than the incremental cost arising from implementing guidance recommendations.

4.6 Highlighting the benefits

Public services in the UK are facing significant financial challenges and, therefore, resource impact assessment products need to highlight the benefits of implementing NICE guidance or using standards for quality improvement.

A piece of guidance may be cost effective but still have a resource impact, or the timing of the impact may be different for costs or saving and benefits. It is important that the business analyst reviews the guideline economics supporting the guidance. The business analyst should understand both the cost per QALYs for the guidance and the incremental cost-effectiveness ratio (ICERs), where appropriate, for the guidance.

NICE states in the **Social value judgements: principles for the development of NICE guidance, second edition** (2008):

'NICE has never identified an ICER above which interventions should not be recommended and below which they should. However, in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. Where advisory bodies consider that particular interventions with an ICER of less than £20,000 per QALY gained should not be provided, they should provide explicit reasons (for example that there are significant limitations to the generalisability of the evidence for effectiveness). Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of resources will specifically take account of the following factors:

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• The degree of certainty around the ICER. In particular, advisory bodies will be more cautious about recommending a technology when they are less certain about the ICERs presented in the cost-effectiveness analysis.

• The presence of strong reasons indicating that the assessment of the change in the quality of life has been inadequately captured, and may therefore misrepresent, the health gain.

• When the intervention is an innovation that adds demonstrable and distinct substantial benefits that may not have been adequately captured in the measurement of health gain.

As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgement about its acceptability as an effective use of resources should make explicit reference to the relevant factors considered above. Above a most plausible ICER of £30,000 per QALY gained, advisory bodies will need to make an increasingly stronger case for supporting the intervention as an effective use of resources with respect to the factors considered above.'

A thorough review of the ICER will allow the business analysts to understand the benefits supporting the recommendations in approved guidance.

The business analysts should recognise that guidance economics are at a micro level, whereas resource impact is calculated at a macro level. A piece of guidance with a low value ICER but a large population may have a significant resource impact.

Work will be undertaken at NICE to better understand the implications of cost-effectiveness analysis for social care guidelines. Networks with internal social care leads and external social care networks have been established to further improve the understanding of social care resource impact issues.

There are existing examples of unit costs of social care, such as the PSSRU ‘Unit costs of health and social care’ annual report. There are a number of standard costs listed within the report that will be suitable for use when assessing a number of social care costs, such as care home costs and parenting programmes.

4.2 Discussion of initial draft

Informal discussions within the resource impact assessment team and with either the technical team within the guidance developer team or with GDGs is normally undertaken when the product/s 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 expert engagement; this will usually require sending a series of questions to professionals and practitioners involved in the development of guidance. For example, clinicians on the GDG 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. The use of the SCORE can facilitate this.
The 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 resource impact. This will focus attention on the activity assumptions as these tend to have more uncertainty than cost information.

Once the business analyst is satisfied that the draft spreadsheet or template represents the picture as accurately as possible, it is time to develop the resource impact assessment commentary and template.

4.3 **Publication formats**

The standard NICE style templates should be used for the resource impact assessment commentary and resource impact assessment template.

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

Occasionally, variation from the standard format may be called for and this will be decided at an early stage. For example, 1 resource impact assessment commentary and 1 template may be shares for 2 approved drugs covering the same population.

This can be achieved in 2 ways: firstly, by publishing 2 technology appraisals at the same time along with 1 commentary and 1 template; secondly, by updating the commentary and template of the first technology appraisal to publish when the second technology appraisal is published.

4.4 **Is a resource impact assessment 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 resource impact assessment product/s are appropriate (see section 3.2 for guidance on determining significance). There may be occasions where the costs or savings are less than £1 million, suggesting that a resource impact assessment commentary is appropriate, but other circumstances, such as local variation in practice, justify the production of a resource impact assessment template.

Figure 1 further depicts the considerations that determine whether a resource impact assessment commentary and Microsoft Excel template should be produced. It is intended to be a guide only, and there may be exceptions. For example, resource impact assessment work may indicate that the criteria for producing a resource impact assessment commentary are not met, but it is considered that full resource impact assessment product/s are appropriate.
4.5 **Constructing the resource impact assessment commentary**

This section applies to the resource impact assessment commentary that accompanies guidance. The template guides the developer towards which information should be included within the commentary. Depending on the complexity of guidance the resource impact assessment commentary may use an executive summary that notes the key factors but which does not include the discussion of the detailed assumptions. This is to help readers to determine whether they need to study the main body of the commentary in more detail.

When writing commentaries 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 3 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 3 or 4 variables for which the model is most sensitive to changes should be discussed within the main body of the commentary.

• Include a graph showing example of costs or saving over time, where appropriate.

• All costs or savings quoted in the resource impact assessment commentary should match the resource impact assessment template and following standard conventions such as: rounding errors should be eliminated; numbers in a table should appear as £000s; the letter ‘k’ should not be used in a narrative.

• National figures rounded to the nearest million should be used for services commissioned by NHS England and the cost per 100,000 population for services commissioned by CCGs or Local Authorities.

• Nothing should be presented in the executive summary that is not discussed in the main body of the commentary.

4.6 National or local template

Nationally, NHS England commissions specialised services, primary care (including co-commissioning with CCGs), offender healthcare and some services for the armed forces. CCGs commission local health services that fall outside the NHSE service commissioning, and GP prescribed drugs.

Commissioning of public health services is undertaken by Public Health England and local authorities, although NHS England commissions, on behalf of Public Health England, many of the public health services delivered by the NHS.

Commissioning of social care services is undertaken by local authorities but it is important to note that some services are commissioned and funded by the person requiring the care.

Whether a national template or local template should be used is determined by the commissioner of the service. For example, if a specialised service is commissioned by NHS England a national template should be used because services are the whole of England. If services are commissioned by CCGs a local template or a template where costs are expressed per 100,000 population should be used.

In some instances the local template may just be a template that needs to be completed at a local level to reflect local circumstances. For example, the template may identify the costs of interventions and the population affected is completed by
the local CCG. This is common where there is considerable variation in services across the country.

4.7 Sensitivity analysis

There are a number of assumptions in the resource impact assessment 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 resource impact estimation is most sensitive to. Ranges used for sensitivity analysis should reflect uncertainty 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.

Business 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 resource impact 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.
5 Resource impact assessment quality assurance process

All the resource impact assessment product/s produced are reviewed before publication. The review process involves an internal review and final sign-off.

Who should attend product reviews?

Meetings should be planned a minimum of 3 months in advance of the guidance publishing to allow full attendance.

The attendees are:

- associate director for resource impact assessment or deputy
- senior business analysts
- business analysts
- representative from the appropriate guidance producing centre and developer:
  - for clinical guidelines invite the guideline commissioning manager and NCC/internal health and social care economist.
  - for technology appraisals, medical technology and diagnostic guidance invite the technical analyst and technical advisor.
  - for public health guidance invite the associate director, technical lead and health economist.
  - for quality standards invite the quality standards analyst.

Papers for the meeting should be distributed:

- 5 working days in advance of the internal review meeting
- 3 working days in advance of the final sign-off meeting.

Because of the increased volume of guidance being published, the associate director for resource impact assessment 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 1 of the meetings, and their place at the other meeting will be undertaken by a senior business analyst who has not been involved in the resource impact assessment commentary/template development.

Other people involved may include a consultant clinical advisor and representative from the implementation support team, where appropriate. As part of the resource impact quality assurance process the group reviews the draft product/s the comments received and the responses from the guidance or standards developer. At this stage the product/s are either approved to go forward to the Publications Executive (PE) or the business analyst is requested to do further work.

Internal review

The internal review is an opportunity for the business analyst to check internally the assumptions included within the resource impact assessment commentary or template. This includes receiving comments from colleagues and peers within NICE to ascertain that all relevant and significant factors have been included within the product/s, that both the resource impact assessment commentary and resource impact assessment template follow a sensible and pragmatic approach and that all assumptions are corroborated.

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Consultation

After the internal review a limited consultation process takes place in which NICE invites external comments on the resource impact assessment product/s. Comments are invited on whether the assumptions made, format, presentation and usability of the resource impact assessment template are reasonable, where appropriate. The range of people approached to be part of this consultation includes:

- A minimum of 6 representatives from the NICE resource impact reference panel – a standing group from across health and social care including the finance profession
- Committee member’s clinical, public health and social care guidelines.
- QSAC
- NHS England for NHS England commissioned services
- DH
- Welsh Assembly Government, Representatives from Northern Ireland, Quality Improvement Scotland (only for multiple technology appraisals)
- Other contacts who have informed the development of the commentary/template, such as health and social care economists
- Manufacturer of the technology for technology appraisals; and 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.

In the event of an appeal, the resource impact assessment 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 resource impact assessment commentary or template. 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 resource impact assessment commentary or template, if necessary.

After consultation, all comments are collated and passed to the business analyst for review using a standard table format. The business analyst should note their response in the table alongside the comment in advance of the final sign-off.
Final sign-off

This is an internal process whereby the consultation comments and final proposed resource impact assessment product/s are reviewed. Comments that highlight significant variation with the draft product/s should be followed up with the commentator. Following discussions, further advice may be taken from other professionals to validate revised assumptions. Where necessary, the product/s should be amended and this response noted in the table.

5.1 Editing the resource impact assessment

The draft template and commentary are edited during the limited consultation phase. The editor checks for consistency between the resource impact assessment commentary and the guidance, and ensures that the product/s 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 there are substantial changes after consultation.

5.2 Publication

NICE has agreed to publish the following:

- For NHS England commissioned services: a short commentary stating the cost of the guidance. The resource impact assessment assumptions (the resource impact assessment template and commentary) are sent to NHS England; upon request, but not for wider circulation. These are also sent to the Northern Ireland Health & Social Care Board.
- For CCGs and Local authorities: the full resource impact assessment commentary/ template.

Publications on the website may vary, subject to agreement by NHS England and NICE.

NICE’s PE has the final decision about whether the resource impact assessment commentary/ template can be published.

The PE takes place every Monday and papers must be submitted to agreed timescales. Submission of a monthly schedule of products to be approved by the PE is requested in order to establish a place on PE agendas.

The business is required to submit a cover paper on the development of the resource impact assessment commentary/ template(s), any deviation from process or key issues to note.

In advance of submission to the PE the commentary and resource impact assessment commentary/ template is required to be signed off for submission by the:

- Associate director for Resource Impact Assessment before publication. The business analyst should complete the quality assurance checklist and this should be filed in the relevant work files. The business analyst should also ensure a final check is carried out, ideally by a senior business analyst but, if this is not possible, by another business analyst.
• Programme Director for Adoption and Impact for information and any observations pre-PE.

5.3 Post PE

At the completion of the resource impact assessment commentary/ template, the business analyst should ensure that all working papers are correctly filed. This is important because NICE can receive queries on a resource impact assessment commentary/ template a number of years after publication of the guidance.

The business analyst must ensure that the correct version of the product/s (as signed off by PE plus modifications) are sent to the publishing for upload. It is the business analyst’s responsibility to ensure that the product/s are uploaded correctly and within agreed timescales.
6 Making amendments post publication to the resource impact assessment product/s

6.1 Circumstances in which making amendments is appropriate

The resource impact assessment work is based on assumptions about current practice and predictions of future practice, at the time the guidance, guideline or standards are published. Sometimes issues concerning the resource impact assessment come to light that were not identified before publication. This can happen particularly during the post-publication engagement with stakeholders validating other implementation products. There are 2 ways of addressing this – to revise the original product/s or to issue a supplementary commentary.

Revising the resource impact assessment 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 – for example, a drug cost had been calculated on the basis of cost per kg, rather than cost per 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).
- There are issues with the related workforce information, which may require overall estimated numbers to be reconsidered.

The criteria against which a decision will be made about whether to update the resource impact assessment product/s are given below:

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

It is not considered appropriate to update the template in the following 2 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. 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 template on the website replaced with the amended one. This will be signed off by the associate director and advice sought from the programme director as to whether a report to the PE is required.

6.2 Life expectancy of the resource impact assessment

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

Furthermore, it is possible to amend the resource impact template to allow for national and local planning assumptions and this can include changes to estimated activity levels, income, costs and uptake.

6.3 Review of resource impact assessment commentary and template

The review and update of guidance will be a trigger for the consideration as to whether the related resource impact assessment commentary or template should also be reviewed. For guidance that is to be updated a resource impact assessment commentary or template to support the update – a commentary plus template or just a commentary – will be produced.

As NICE re-engineers its approach to surveillance and update of guidelines, the processes used by the resource impact assessment team may be modified.