Template/Guidance for submission of documentation for Single Technology Assessment of medical device, diagnostic methods and procedures

1. Introduction

The national system for the introduction of new health technologies within the specialist health service will involve the rapid assessment of health technologies in relation to the introduction of medical devices, diagnostic methods, procedures and pharmaceuticals.

Two templates for Single Technology Assessment (STA) have been prepared:

1. Template for submission of documentation for the STA of medical devices, diagnostic methods and procedures
2. Template for submission of documentation for the STA of pharmaceuticals

**The desciprition of the system found on the website nyemtoder.no is the main document. We refer to it for information about the national system, and description of various types of Health Technology Assessments (HTAs) Nettside- klikk her

**This template will be for submission of documentation to the Norwegian Institute of Public Health (NIPH) for Single Technology Assessment (STA).

The actual template should only be used by the manufacturers that are asked to send in documentation. The template is to be used after RHA Forum (Regional Health Authorities Forum for the commissioning of HTAs) requests (through the use of a proposal order) the Norwegian Knowledge Centre for the Health Services to carry out a STA. The Norwegian Knowledge Centre for the Health Services will then ask for documentation by the actual manufacturer in accordance with the guidance in this template.

Questions concerning this template or any requests for assistance, meetings, etc. in regard to submission of documentation should be sent to: Metodevurdering@niph.no

The economic analyses in the health technology assessments that are to be conducted are based on the recommendations in the Norwegian Directorate of Health's guideline for health economic analyses, which in turn follow the recommendations in the Ministry of Finance's guideline for economic analyses

NIPH is currently developing its own guidelines for submission of single technology assessments of medical devices and diagnostic interventions. These will be published in 2020.

NIPH asks manufacturers to ensure that the documentation is presented systematically as proposed in this template. Deviations from the template and elements that are considered by the manufacturer not to be relevant must be justified. Documentation may be submitted in either English or a Scandinavian language. The documentation should be submitted electronically in Word format. **If a health economic model has been used to calculate cost-effectiveness, it should accompany the submission in either Excel or TreeAge format. Web-based models are not permitted.**

If the documentation contains confidential information (commercial secrets or data awaiting publication), which cannot be published by NIPH, this must be agreed in advance. NIPH will publish completed reports on its website.

The template has been prepared by NIPH in collaboration with the national working group for the introduction of New Health Technologies in the Specialist Health Service.

Contents

2. Technology to be appraised

Briefly present the commission as outlined by the Commissioning Forum that this STA responds to

3. Information about the manufacturer's / manufacturer' representative

State your contact information (e-mail/ postal address and telephone number).

4. Background

4.1 Description of the health technology

4.1.1 What type of health technology is involved?

- Medical devices? (If yes, outline category)
- Diagnostic methods?
- Procedures?
- Other methods? Please specify

4.1.2 How does the health technology work? State the principle.

4.1.3 Is the health technology new or a further development of an existing health technology?

4.1.4 Is the health technology or procedure already in use for other patient groups or for other indications?

4.1.5 *What is the status of the health technology concerning any certification, CE-marking, use or approval in* a) Norway and b) other countries (internationally)?

4.1.6 Describe briefly the development process for the health technology or procedure

4.1.7 List ongoing studies or other documentation which may become available for assessment during the next twelve months and subsequent years

4.2 Description of the context for use

4.2.1 What patient groups/conditions are to be helped using the health technology or procedure?

- Describe the most relevant patient group(s), including current and anticipated developments in prevalence/incidence.
- Describe the disease(s) for which the health technology is indicated, including consequences of the disease in the short and long term, as well as severity of the disease

4.2.2 What advantages is the health technology intended to give compared with the current health technology?

4.2.3 Which treatment(s), including other health technologies will be displaced – either partly or entirely- by the new technology?

- What place is the health technology thought to have in the everyday clinical set-up/health service?

4.2.4 How many patients will be affected?

4.2.5 Describe any Norwegian national clinical guidelines for the condition which could be affected by the health technology

4.2.6 Will the health technology or procedure result in changes in the patient patwhay with ith regard to diagnostics and/or treatment?

4.2.7 Will the introduction of the new technology result in changes of the infrastructure (organisation of the health service, spatial requirements, training, monitoring, follow-up, administration or costs)?

4.2.8 What are the key groups for comparison? Justify the choice on the basis of Norwegian clinical practice.

4.2.9 Could introducing the new technology have negative consequences for vulnerable patient groups?

4.2.10 Describe the current Norwegian treatment tradition / practice

5. Clinical effect

What clinical documentation is available to demonstrate that the health technology is effective and safe?

In cases where the actual health technology has been through clinical studies, a certification and/or an approval process in Norway or abroad, the information should be included.

Additionally, systematic searches for studies involving the new technology and comparison alternatives must be performed in relevant databases detailing relevant outcome objectives. For information about systematic searches see the Norwegian Knowledge Centre for Health Services health technology manual «slik oppsummerer vi forskning" (In Norwegian).
http://www.kunnskapssenteret.no/verkt%C3%B8y/slik-oppsummerer-vi-forskning

5.1 Description of the study identification

5.1.1 Inclusion and exclusion criteria

- Describe what has been done to identify relevant clinical data, both published and unpublished.
- In connection with searches for published studies, describe the selection of electronic databases, which databases were searched, state the date and time of the search and enclose complete search strategies with the number of hits (may be in enclosures). The search will be checked by an employee of the National Knowledge Centre for the Health Services.
- Describe the inclusion and exclusion criteria in the studies:

Inclusion criteria	Population/patient group/indication Intervention Comparison Endpoint Study design Linguistic limitations *Study quality*
Exclusion criteria	Specify whether there were any special exclusion criteria

5.1.2 Selection of studies

- Describe the process for the selection of studies and create a flow chart for the process.
- If possible, state the number of studies of each type/design that were available during each stage in the process. If appropriate, adapt the flow chart developed by PRISMA (http://www.prisma-statement.org/statement.htm)
- Specify whether data from a single study has been published in several publications.

5.1.3 Relevant studies

- Prepare a complete list of relevant studies.

Study (acronym, ID no.) Type of design	Reference	Population	Intervention	Comparison
Study 1				
Study 2				
Etc.				

- If any of the identified studies will not be used further as part of the documentation basis, this must be stated and justified.

5.2 Description of studies included

5.2.1 Studies included

- Give a brief summary in text and describe details from each study in table form. Specify any important differences between the studies.

Study (acronym, ID no.)	Study 1	Study 2	Etc.
Location/place conducted/country			
Design/study type			
Duration of the study			
Randomisation method			

Blinding method (investigator, patient, outcomes assessor)			
Intervention (n=)			
Comparison/control (n=)			
Primary outcome (including measurement tools and measurement times)			
Primary outcome (including measurement tools and measurement times)			
Follow-up time			

5.2.2 The patients/participants in the studies

- Describe the patients/participants in each study
- Give a brief summary in text and describe details from each study in table form. Specify any important differences between the studies.

Study (acronym, ID no.)	Inclusion criteria	Exclusion criteria
Study 1	Important inclusion criteria such as age, gender, diagnosis, severity, etc.	
Study 2		
Etc.		

- Present an overview table of important baseline characteristics of the patients in the studies included.

Study (acronym, ID no.)	Intervention	Comparison
Study 1 (n=)	(n=)	(n=)
Age		
Gender		
etc.		
Study 2 (n=)	(n=)	(n=)

5.2.3 *Endpoints*

- Describe the endpoints in each study
- The choice of endpoints should be in line with the guidelines by EUnetHTA. . Describe the selections for this research issue. When appropriate, state whether the tools used have been validated and are valid in Norway.

Study (acronym, ID no.)	Primary outcome	Validity in current practice	Secondary outcome, including side effects	Validity in current practice
Study 1				
Study 2				
etc.				

5.2.4 Statistical analyses and definition of study groups

- Describe the research hypothesis that was investigated and the statistical analyses that were used.
- Specify the strength calculation and sample size calculation, including the assumptions that have been made.
- State clearly whether the analyses include patients that withdrew/had missing measurements and, if so, how this was handled.

Study (acronym, ID no.)	Hypothesis	Statistical analysis	Sample size, strength calculation	Handling of data (withdrawals, missing measurements, etc.)
Study 1				
Study 2				
etc.				

5.2.5 Flow chart

- Present a flow chart of the patient's progress through the study (randomised patients, withdrawal from the groups, replacement of groups, etc.). See for example Consort's chart.

5.3 Detailed description of included studies

5.3.1 *Give a detailed description of all included studies included.*

- See the Norwegian Knowledge Centre for Health Service's health technology manual "Slik oppsummerer vi forskning" (in Norwegian).
  A complete quality evaluation of all studies must be enclosed.
  The evaluation will be checked by an employee of the National Knowledge Centre for the Health Services.

5.4 Presentation of results

5.4.1 *Present results for all relevant endpoints.*

- Where possible, data must be presented as "intention-to-treat" analyses (analyses where all the patients are analysed in the group in which they started). Depending on the study design and type of endpoint, other types

of analysis may also be relevant (e.g. “on-treatment” and “safety-on treatment”).
- Always define which patients are included in the analysis and, where applicable, the reasons why any patients were not included in the analyses.
- State clearly whether the analyses include patients that withdrew/had missing measurements and, if so, how this was handled.
- Data should be presented in the form of text, table and graphics where possible.

5.4.2 Meta-analyses

- If there is more than one study, consideration must be given to performing meta-analyses. Clearly present the assessment behind the decision regarding whether or not meta-analyses are suitable.
- In cases where meta-analyses are included, provide at least the following: selection method (random or fixed effects model, choice of effect parameter, sensitivity analyses) and test for heterogeneity.

5.4.3 Indirect comparisons

- If there are no directly comparable studies (head-to-head studies), consideration must be given to the execution of indirect comparisons. See the EUnetHTA’s guidelines for indirect comparisons.
- Present clearly the assessment behind choices made, how the studies for indirect comparison were identified, how the data was extracted and the method adopted for analysis.

5.5 Summary of the key findings

- Briefly summarize key findings of presently available clinical documentation, with a focus on effects and side effects of the new health technology (the device or procedure).
- Give a brief summary of the strengths and weaknesses inherent in the documentation available for the new health technology (the device or the procedure).

5.6 Relevance to Norwegian conditions

- Briefly discuss how and to what extent the provided documentation is relevant for the Norwegian context.
- Identify factors which could be of significance for the external validity of the study results when applied in normal clinical practice.

6. Cost-effectiveness

6.1 Previously published cost-effectiveness analyses

6.1.1 Identification of other relevant published analyses

If published health economic analyses that are relevant to the case exist, the Norwegian Knowledge Centre for Health Services wishes that such analyses are enclosed.

Fill in the following table summarizing identified studies.

Study	Year	Country in which the study was conducted	What type of model analysis?	Patient population (age, gender, state of health, etc.)	Incremental QALY* benefit	Incremental costs	ICER**	Comparison
Study 1								
Study 2								
Etc.								

* QALY: Quality-Adjusted Life Years

** ICER: Incremental Cost-Effectiveness Ratio

6.1.2 Previously published mini-HTA?

- Enclose the search results from the relevant mini-HTA (can be found in the MedNytt database).

6.2 In-house cost-effectiveness analysis

- The recommendations in the table below specify a standard analysis for evaluations of the cost-effectiveness of different measures. 'Standard analysis' means health technologies, assumptions and unit values that are preferably to be common. The column on the right specifies the section in the Norwegian Directorate of Health's guideline in which each of the elements in the analysis is discussed.

Element in the analysis	*Standard analysis*	*Section in the Norwegian Directorate of Health's guideline*
Comparison alternative	**The measure or measures which the new measure will essentially replace.**	2.4
Analysis perspective	**The health service's perspective for both health benefits and costs If applicable, the social perspective too**	2.5
Time horizon	**Sufficiently long to ensure that all important future differences in costs and consequences between the alternatives are identified**	2.6
Analysis method	**CUA***	2.8
Objectives for health and indicators for health benefits	**QALY and life years**	2.7
Method for measurement and personal valuation of health benefits	**Generic MAU** instruments,preferably EQ-5D**	2.7
Inclusion of production effects	**May be included in separate results if relevant. Method selection must be justified. The results should be shown with and without production effects.**	2.9
Discounting	**4% per year for both costs and health effects.**	2.10
Method for handling uncertainty	**PSA***, one-way sensitivity analyses (shown in tornado diagram) and scenario analyses**	2.12

** CUA: Cost-Utility Analysis*
*** MAU: Multi-Attribute Utility*
**** PSA: Probabilistic Sensitivity Analysis*

6.2.1 The patient group in the analysis

- Describe the patient group at which the analysis is aimed. Does it differ from the target group as defined in 4.2.1, and if so, how?

6.2.2 The structure of the analyses

- Describe and explain the structure of the analyses.
- Is the analysis based on modelling or based directly on costs and health effects collated as part of a comparative efficacy study (piggyback analysis)? Or a combination of these?
- If modelling is used, state how the course of the disease with the current treatment is modelled and the new treatment. State the reasons for the choices made during construction of the model.
- If the analysis is based directly on a comparative efficacy study, please describe the collation of costs and health effects in detail, such as choice of target group,

determination of how the data (costs, quality of life data) is to be acquired and analysed, and choice of time interval/time frame for data acquisition.

6.2.3 *Concerning the methods: the intervention(s) and comparator(s)*

- In connection with the selection of comparison alternative, follow the recommendations in the Norwegian Directorate of Health's guideline (section 2.4) and in the EUnetHTA's guidelines on how to carry out a health technology assessment.
- Is use of the method in the analysis in accordance with the use investigated in the clinical studies? If not, explain why.

6.2.4 The perspective and time horizon of the analyses

- In STAs for health technologies, the analysis must be carried out using both the societal perspective and the health care perspective.
- The Norwegian Knowledge Centre for the Health Services refers submitters to the Directorate of Health's guidelines and its recommendation 5, in addition to section 2.5 about perspective:
- Societal perspective: The analyses should at the first hand be carried out using the societal perspective, and should give an overview of the consequences for all involved actors. It is recommended that the analyses should be carried out using the societal perspective where all significant costs and consequences are included, regardless who it involves, e.g. the public health service, municipality, companies, patients, relatives.
- Health care perspective: In analyses on new efforts in the health service, the most important costs will most often be from the health and care services, and the most important health effects will be related directly to the patients. We recommend to rely on a broad perspective related to consequences.
- The time horizon of the analysis should be sufficiently long to ensure that all important differences in costs and health effects between the comparison alternatives are identified. This will often result in a need for a life-cycle perspective.

6.2.5 Use of efficacy data in the model

- It is recommended that clinical efficacy data from the included studies, should be included in the model in the form of hazard ratios (or alternatively relative risks or odds ratios) for an event or condition applied to a background risk taken from Norwegian epidemiological data (see the section below).
- Describe all the stages in the calculation of probability for different events in the model.
- Clinical, hard endpoints (e.g. number of cases of relapse, infarction, death, etc.) are preferred in the modelling. If intermediate (surrogate) endpoints are to be used in the model instead of clinical endpoints, this must be justified (e.g. HbA_{1c}, LDL-c, SBP, PSA, etc.). Please also give references and discuss the available evidence which supports the ratio between the chosen surrogates and the relevant clinical endpoints. See the EUnetHTA's guidelines on the use of surrogate endpoints in health technology assessments for more details.

- For how long time period was the efficacy data applied? If this extends beyond the period for which clinical documentation is available, this must be justified and assumptions must be described thoroughly. Show the results in diagram form, e.g. using the Kaplan-Meier curve.

Variable	Value	95% confidence interval	Probability distribution (type and parameters)	Reference
Outcome 1				
Outcome 2				
Etc.	…	…		…

6.2.6 Use of epidemiological data in models

- The analysis should preferably be based on Norwegian epidemiological data as the source for background risk. If Norwegian epidemiological data are not available, data from countries that are considered to be as similar as possible to Norway in terms of the occurrence of diseases should be chosen.
- On occasions, a balance must be struck between study quality and transferability (internal vs. external validity). In such cases, advantages and disadvantages in connection with the various choices should be discussed. The control arm from an RCT can be used as a last resort, if it is not possible to find other sources of epidemiological data.
- Please complete the following summary table of the key epidemiological parameters used in the analysis:

Variable	Value	95% confidence interval	Probability distribution (type and parameters)	Reference
Probability of event X				
Probability of event Y				
Etc.	…	…		

6.2.7 The patient's quality of life

- Quality-Adjusted Life Years (QALY) is the preferred objective for health. If QALY is not used in the analysis, this must be justified.
- How does the disease affect the patients' quality of life? How is the patients' quality of life expected to develop over time, with and without the currently established treatment? How do these developments compare with the developments for the rest of the population?
- Was quality of life data acquired in connection with the studies from which clinical data was obtained? If yes, describe in detail the method for valuing the patients'

quality of life and for acquiring this data. Include the time of measurement and the confidence intervals concerning the measurements.

- Specify the quality of life weightings which were used in the submission in the following format:

State of health/health situation	Quality of life weighting	CI (95 %)	Source	Reason for the selection
State of health 1				
State of health 2				
Etc.				
Event 1				
Event 2				
Etc.				

6.2.8 *Identification, measurement and valuation of resource use in the model*

- This section is based on section 2.9 of the Norwegian Directorate of Health's guideline.
- The submitter must also report the costs linked to each of the states of health and the events in the model:

State of health/health situation	Cost item	Unit cost	Quantity	Total cost	Sources
State of health 1	Cost item 1				
	Cost item 2				
	Etc.				
	TOTAL				
State of health 2	Cost item 1				
	Cost item 2				
	Etc.				
	TOTAL				
Etc.					
Event 1	Cost item 1				
	Cost item 2				
	Etc.				
	TOTAL				
Etc.					

6.2.9 Discounting

- It is recommended that both health effects and costs be discounted at the rate recommended by the Ministry of Finance for measures with a low to moderate systematic risk, currently 4% p.a. (see FIN 2005). See section 2.10 of the Norwegian Directorate of Health's guideline for more details.

6.2.10 Base case cost-effectiveness results

- Overview of all treatments assessed in the analysis in ascending order with regard to total costs in the tables below. State the incremental cost effectiveness ratio (ICER) for each of the treatments in relation to the relevant comparator (see section 2.4 of the Norwegian Directorate of Health's guideline for a description of the criteria for selection of the comparison alternative).

Measure	Total costs (NOK)	Total number of life years	Total number of QALYs	Incremental costs	Life years gained	QALY gained	ICER vs. relevant comparator (QALYs)	NHB (Net Health Benefit)
Treatment alternative 1								
Treatment alternative 2								
Treatment alternative 3								
Etc.								

6.2.11 Sensitivity analyses

- The uncertainty concerning the results of the analysis must be investigated, described and discussed via one-way and probabilistic sensitivity analyses, as well as scenario analyses. See section 2.12 of the Norwegian Directorate of Health's guideline for a more comprehensive discussion of these methods.

6.2.12 Sub-group analyses

- Is data available which indicates that the efficacy and/or costs associated with the health technology under consideration differ between sub-groups?
- If so and the measure has indication/CE marking for the treatment of these sub-groups, state whether the sub-groups were identified before the clinical study was conducted (a priori) or after the results of the study became available (a posteriori); describe the sub-groups' characteristics; and finally report the model's results for these sub-groups.

6.2.13 Interpretation of the analysis results

- What does the submitter consider to be the key strengths of the analysis? And the key weaknesses?
- Are the results of the submitter analysis in accordance with the results of previously published analyses? If not, state the possible reasons behind the differences.

7. Budget impact of the new technology

The manufacturers/submitters must provide/present an analysis of their technology's budgetary consequences. The Norwegian Knowledge Centre for the Health Services will then evaluate and possibly carry out own calculations where necessary.

The submitter must calculate and provide the budget implications for the specialist health services (i.e. progamme category 10:30 of the Nafion<l Budget) . The budget impact/impact is defined as the additional costs incurred i.e. the total costs of introducing the new technology minus the total costs of not doing so.

These calculations/analyses are intended for the national level.

The time horizon in relation to budget analyses of pharmaceuticals is five years. This is because it is assumed that the broad usage of new pharmaceuticals is well established after five years. For other technologies, the time horizon may vary depending on the economic lifespan and/or depreciation of the technology. Provide a justification if the time horizon deviaties from five years.

Calculation of the additional costs shall be based on the following factors:

1. Costs incurred by the specialist health service during the calculation/analysis period.
2. The estimated market share of the new technology, in relation to the patient group the technology targets, in each of the relevant years after the decision to use the technology is made.
3. Deductions of: costs of competing technologies that will be completely or partially replaced by the new technology, any increases in patient payments and increments in user fees during outpatient treatment.
4. Other costs related to the technology assessment (change in bed-days, commodity costs, personnel costs, nursing costs, depreciation, travel expenses covered by the specialist health care service, administrative expenses, etc.) should only be included if there are significant differences between the competing technologies and/or if the differences constitute a large proportion of the additional costs.

Budget calculations/analysis should cover both the new technology and coompeting competing technology(ies) if the extent of use is affected by the possible introduction of the new technology. This will in turn make it possible to calculate a total budget impact. The budget impact is the difference between the two scenarios in each of the relevant years of the analysis (tables below). Year 1 is the first full calendar year after a decision is made about introducing the new technology into the specialist health care service.

The budget impact calculations must show the following:

1 What proportion of the total additional costs is the result of an increase in patient numbers and what proportion is due to the transition to a more expensive technology
2 The basis for key assumptions in the calculations.

Additionally, the following calculations may apply in special cases:

1 Subgroup analyses such as in cases where it is prudent to prioritize giving the new technology to only a subset of the total population.
2 Analyses with added costs/impact on other patient groups not targeted by the new technology but whom none the less use the technology.
3 Sensitivity analyses where key assumptions and data are tested in order to check to what extent results and estimates used are sensitive to changes. This is particularly relevant if critical assumptions in the analyses are very uncertain.

There is a distinction in financial terms between small medical devices that can be allocated to patients separately and devices that might be fixed in a location and that patients will share over a given period. The former will be dependent on patient volume, while tha latter is not (and may involve a larger investment with a longer lifespan.) Two methods of presenting budget impact will depend on these two categories and are discussed below.

7.1 Implamntable/wearable and other non-shared medical devices tiveness

First, estimate the market share of the intervention and comparator(s), in terms of number of patients over the next five years. The costs of the intervention and comparator are then applied to the respective numbers to obtain an estimate of annual budget impact. Expenditure must not be calculated cumulatively for the first five years.

The cost of a medical device should be based on the expected retail price including VAT (if expenditure must be calculated without discounting)

Patients' co-payment must not be included.

The tables below show how the calculation of budget impact for the specialist health care services should be presented

Number of patients

Table 1 shows the number of patients expected to be treated with the intervention, and the comparator in the first five years in scenarios with and without the intervention being implemented in the specialist health care sector.

Table 1 Number of patients expected to be treated over the next five-year period – if the intervention is implemented

	Year 1	Year 2	Year 3	Year 4	Year 5
Intervention					
Comparator 1					

Comparator 2					

Table 2 Number of patients who are expected to be treated during the next five-year period – if the interventionl is NOT implemented

	Year 1	Year 2	Year 3	Year 4	Year 5
Intervention	0	0	0	0	0
Comparator 1					
Comparator 2					

Expenditure per patient

Calculate the expenditure per patient per year for the different treatments. The estimates should be consistent with the corresponding calculations in the CUA. If you choose to use the health economic model for these calculations, note that they should be inclusive of VAT and the relevant costs, as set out in the various sections in this chapter, but without discounting.

Budget impact

Multiply the expenditure per patient per year by the number of patients per year for the intervention and comparator(s). Total these costs for each year and enter this figure into the table below. In the bottom row of the table, present the estimated budget impact of adopting the intervention.

Table 3 Expected budget impact of adopting the intervention for the relevant indication.

	Year 1	Year 2	Year 3	Year 4	Year 5
The intervention is adopted	X1	X2	X3	X4	X5
Minus: The intervention is not adopted	Y1	Y2	Y3	Y4	Y5
= budget impact	X1 - Y1	X2 – Y2	X3 -Y3	X4 – Y4	X5 –Y5

Expenses may be linked to treatment monitoring and consultations, laboratory tests, admissions, personnel requirements etc. Only include the types of expenses that are expected to be different in the two scenarios in your calculations. Your estimates should be consistent with the corresponding calculations in the cost-utility analysis.

The budget impact is the difference between the two scenarios in each of the first five years.

7.2 Fixed and other shared medical devices

Medical devices or equipment which are used by several patients over a period of time (located in a hospital or in a mobile unit) should be included in the budget impact analysis in a manner similar to that described above for small devices and implants.

As in the above case, first estimate the market share of the intervention and comparator(s). However, rather than quantify the number of patients, estimate the number of shared devices for both intervention and comparator(s) that is likely be in use in the specialist care sector each year in the next five years. If a comparator is not a shared device, refer to the section below for details. Do this for scenarios with and without the intervention. Again, as in the above case, the costs of the intervention and comparator are applied to the respective numbers to obtain an estimate of annual budget impact. If the comparator is a drug or a non-shared device, the method in 13.1 should be used to estimate the annual costs for this comparator.

The cost of a shared medical device should be based on the expected retail price including VAT (if expenditure must be calculated without discounting)

The tables below show how the calculation of budget impact for the specialist health care services should be presented

Number of shared devices

Table 1 shows the number of patients expected to be treated with the intervention, and the comparator in the first five years in scenarios with and without the intervention being implemented in the specialist health care sector.

Table 3 Number of shared devices expected to be in use during the next five-year period – if the intervention is implemented

	Year 1	Year 2	Year 3	Year 4	Year 5
Intervention					
Comparator 1					
Comparator 2					

Table 4 Number of shared devices expected to be in use during the next five-year period – if the intervention is NOT implemented

	Year 1	Year 2	Year 3	Year 4	Year 5
Intervention	0	0	0	0	0
Comparator 1					
Comparator 2					

Expenditure per device

Calculate the annual expenditure per device per year for the different devices. The estimates should be consistent with the corresponding calculations in the CUA. If you choose to use the health economic model for these calculations, note that they should be inclusive of VAT and the relevant costs, as set out in the various sections in this chapter, but without discounting.

Budget impact

Multiply the expenditure per device per year by the number of devices per year for the intervention and comparator(s). Total these costs for each year and enter this figure into the table below. In the bottom row of the table, present the estimated budget impact of adopting the intervention.

Table 5 Expected budget impact of adopting the intervention for the relevant indication.

	Year 1	Year 2	Year 3	Year 4	Year 5
The intervention is adopted	X1	X2	X3	X4	X5
Minus: The intervention is not adopted	Y1	Y2	Y3	Y4	Y5
= budget impact	X1 - Y1	X2 – Y2	X3 -Y3	X4 – Y4	X5 –Y5

8. References

1. Cochrane Handbook for Systematic Reviews of Interventions, http://handbook.cochrane.org/
2. Consort statement website, http://www.consort-statement.org/consort-statement/flow-diagram0/
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