Technical annex 1:

Guidelines on cost statement

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Purpose

These guidelines deal with cost statements when preparing recommendations from the Danish Health Technology Council on the use of health technology, including medical devices¹, but also other types of devices, such as diagnostic devices, as well as treatments, rehabilitation, prevention, and types of organisation and collaboration in the provision of healthcare services. In the following, 'health technology' is used as an umbrella term for all of these types of technology, etc.

The guidelines have been prepared by the Danish Health Technology Council in order to help applicants in their work on cost statements in connection with the economic analysis and budget impact analysis they have to submit in connection with an application to the Danish Health Technology Council. If an applicant is to provide evidence of cost neutrality or cost savings, the applicant should also use the guidelines in work on this. Please refer to the Danish Health Technology Council's process guide and methodological guidelines for further information relating to applications to the Danish Health Technology Council. The guidelines from the Danish Health Technology Council on cost statements are updated regularly and we recommend that you keep up to date on www.behandlingsraadet.dk.

These guidelines include a description of the approach applicants should take in costs statements, including examples of calculating unit costs, specific unit costs, as well as reference to the sources that the applicant can use when preparing an application. The contents of the guidelines should be considered as advisory, and applicants are recommended to use them as a basis for drawing up their economic analyses and budget impact analyses. However, the guidelines do not contain an exhaustive list of unit costs that may be relevant for an economic analysis and budget impact analysis. Applicants are responsible for ensuring they use the most accurate unit costs given the specific health technologies and evaluation situation. The Danish Health Technology Council is aware that there may be situations in which it makes sense to deviate from the recommendations in this document. In such cases, the applicant should account for reasons why a cost statement derogates from what is recommended.

In their cost statement, applicants should include an overall picture of the costs affected associated with use of the health technology under examination compared to its comparator(s). Generally, it is expected that cost statements in the economic analysis and budget impact analysis, respectively, are in line with the information the applicant has used in its evaluation proposal and associated outline of costs (the latter is only applicable if the applicant has to provide evidence of cost neutrality or cost savings). Such information concerns the health technology, its expected indication, patient population, impact and safety estimates, etc. The applicant may use other information than that provided in the evaluation proposal, if the applicant has compelling arguments for this, such as more recent data. If the expert committee prescribes something else in the evaluation design, the applicant should, however, follow this.

¹In this context, the term 'medical devices' denotes apparatus, software and *in vitro* diagnostic devices/materials used for diagnosing, preventing, monitoring, treating or alleviating diseases or injuries, for example, or used as assistive devices for injuries or disabilities. For a full definition, see Part 1 of the Medical Devices Executive Order (Bekendtgørelse om medicinsk udstyr <u>no. 1263 of 15/12/2008</u>).

1. Economic analyses and budget impact analyses

In general, economic analyses and budget impact analyses have two different purposes. The purpose of the economic analyses is to provide insight into the value for money of different health technologies. The results of economic analyses are often stated as costs per unit of outcome or the level of outcome per DKK spent. The unit of outcome may vary, depending on what is being examined. The focus of an economic analysis is not so much on how much treatment costs, but rather it is on what you get for the money spent [1,2].

A budget impact analysis is used to answer the question of how much it will cost to treat the whole of the relevant patient population with a specific health technology, for example. As the name suggests, a budget impact analysis indicates the financial consequences of using the health technology being examined rather that the technology in the existing budget. In other words, a budget impact analysis indicates how much it will cost to treat the patient population being examined; usually over a specific number of years. In contrast to economic analyses, however, budget impact analyses do not include the health effect² related to the use of different health technologies[1,2].

2. Framework for the economic analyses

In both economic analyses and budget impact analyses, it is necessary to describe how the health technology affects the overall pressure on resources in relation to the relevant comparator(s). If the pressure on resources is affected by the health technology being examined, this may lead to direct and/or derived costs in different sectors. For example, a health technology may affect the time hospital staff are occupied on a treatment, materials consumption, or the risks of complications in the treatment and disease. It may also put pressure on municipal resources, increased or reduced transport times for patients and relatives, etc. On the other hand, if the health technology being examined is expected to replace another technology without further impacts on the surrounding resource use, little or no impacts will be observed on these costs. Figure 1 illustrates how

Example

A health technology can change the diagnostics within a specific disease area so that patients can be treated earlier. For example, this could be earlier diagnosis of a treatable type of cancer. This will potentially affect all further resource use in connection with the treatment of the disease by influencing the size of the population treated, and potentially the type of treatment offered to patients. Altogether, this could lead to a new pattern in resource use and an overall change in treatment costs.

The 'earlier' a health technology is applied in a patient's care pathway (see figure 1), the greater its potential effect on the derived costs.

Text box 1: Example of how the position of a health technology in a patient's care pathway has consequences for the derived consequences of using the health technology.

² Health effects can be included in budget impact analyses, if there is an economic consequence of these, but the value of the *health* effect itself is not included. So, if a health technology can prevent blood clots, for example, this will be included because of the costs associated with treating a blood clot, while the health-related significance for the patient will not be included.

resource pressure can be influenced depending on the mode of action of the health technology and 'where' in a patient's care pathway the health technology is used (see also the example in text box 1).

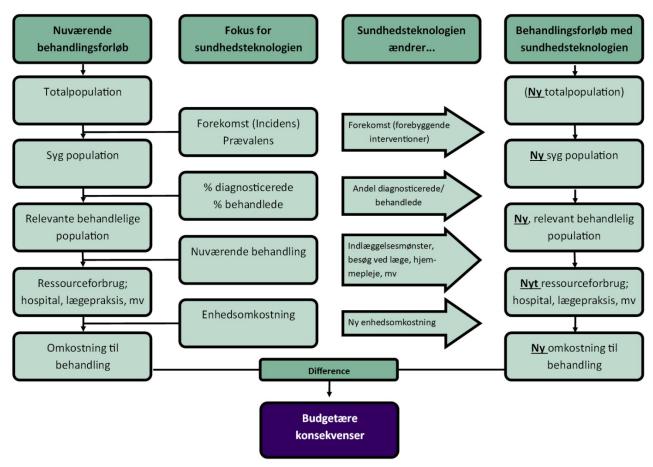


Figure 1 Visualisation of the derived economic effects that should be included in economic analyses. The comprehensiveness of an economic analysis and a budget impact analysis depends on where in the treatment pathway the health technology being examined is used. Inspired by[4].

In order to make it easier to understand how the health technology affects costs, applicants should follow the steps below to illustrate the relevant activities, resources and costs. This is relevant in relation to understanding economic analyses and budget impact analyses.

- 1. Preparation of a flowchart of the process in which the health technology is to be included
- 2. Identification of types of activities and associated resources
- 3. Calculation of the amount of resources consumed
- 4. Valuation of resources and/or units
- 5. Estimation of the total and average costs
- 6. Sensitivity analysis of the estimated costs.

The method to calculate costs in economic analyses is different from budget impact analyses, and the most important differences are outlined in table 1. The differences outlined in table 1 affect the results of the

analyses. However, for both economic analyses and budget impact analyses, applicants should never include:

- VAT
- · Productivity losses/gains
- Transfer incomes
- Future healthcare costs/savings that are not related to the current health technology and treatment situation.

VAT and transfer incomes are transfers, i.e. a reallocation of funds between different parties in society, and therefore they are not actual costs for society. There is no additional pressure on resources, and transfers therefore have no alternative cost³. For this reason, transfers should not be included in the economic analyses.

Productivity losses/gains constitute a loss or a gain for society, respectively, as they cover the productivity lost or gained from using a health technology. However, the productivity loss or gain should not be included in the economic analyses, as health technologies aimed at individuals who don't have a job, such as the elderly and children, would then be less likely to be cost-effective compared with interventions aimed at individuals in work.

Future healthcare costs/savings that are not related to the current health technology and treatment situation should not be included, as the causalities between the health technology being examined and future healthcare costs/savings are often associated with great uncertainty[3]. For example, it would not be easy, justifiable or reasonable to ascribe a health technology to treat type 1 diabetics with the future costs that could potentially arise if the diabetics were to develop a non-related disease, such as cancer, in the future. Therefore, these future healthcare costs or savings should not be included.

| Analysis element | Economic analysis | Budget impact analysis | Section |
|---|-----------------------------------|--|---------|
| Perspective | Limited societal perspective | Hospital perspective across Danish hospitals | 5.1 |
| Time horizon | Specified by the expert committee | 5 years | 5.1 |
| Comparator | Specified by the expert committee | Specified by the expert committee | |
| Inclusion in the calculations of size of patient population | No | Yes | |
| Cost level | Costs per patient | Costs for the total expected patient population in Denmark | |

³ In the context of economic analyses of health technology, the effects and costs that would have been incurred using one health technology rather than another are together referred to as 'alternative costs', even where both effects and costs are lost.

| Discount rate | Current socio-economic discount rate | 0 % | 4.4 5.2 |
|--------------------------------|--------------------------------------|------------------|-------------------------|
| Write-off of higher costs | Where relevant | No | 0 5.2 |
| Inclusion of overhead costs | Yes | No | 4.5.1 4.5.3 5.4.2 |
| Valuation, staff time per hour | Hourly pay (effective hrs.) | Gross hourly pay | 4.5.1 4.5.3 5.4.1 |
| Valuation, materials | Market price | Market price | 3.2.1 |

Table 1. Overall framework for economic analyses and budget impact analyses to be prepared in connection with applications to the Danish Health Technology Council.

For both economic analyses and budget impact analyses the applicant should submit documentation and references for the evidence submitted for resource use and valuation of unit costs. Expert sources may be stated, see the Danish Health Technology Council's methodological guidelines. A detailed and thorough description of how costs are calculated should be provided.

For a more detailed information about preparing cost-comparison analyses and budget impact analyses, see external references[1,4–6]. The approaches to calculating unit costs for both economic analyses and budget impact analyses are described in section 3.

3.Cost statement

3.1 Cost concepts

A number of concepts characterise work on cost statements in an economic analysis and a budget impact analysis, see table 2. Knowledge about the differences between these cost concepts, and how they are related, can help make the applicant's work on cost statements easier with regard to assessing the circumstances under which different costs will be affected and therefore when it is relevant to include them in the economic analysis and budget impact analysis, respectively.

| Cost concept | | includes |
|----------------|------|---|
| Total costs | (TC) | all costs related to production of a quantity of output $q: TC = FC + VC$ |
| Cost function | (TC) | Total costs as a function of the quantity of output (q) produced: $(f(Q))$ |
| Fixed costs | (FC) | Costs which in the short term do not change, irrespective of the size of production, e.g. rent, lease of the equipment, etc. Fixed costs (FC) may, however, change over time, and thus become variable costs. |
| Variable costs | (VC) | Costs which vary with the size of production, e.g. utensils, medicine, etc. |

| Average cost | (AC) | Average cost per unit of output produced: TC/Q |
|------------------|---------|---|
| Marginal cost | (MC) | Cost of producing one additional unit of output: TC for $q+1$ units of output - TC for q units = $\delta TC/\delta q$ |
| Incremental cost | (ICA-B) | The difference between the cost of two technologies (A and B): $IC_{A-B} = C_A - C_B$ |

Table 2. List of key cost concepts used to calculate costs in the economic analysis and the budget impact analysis[1,7].

3.2 Approach to cost statements

In cost statements in both economic analyses and budget impact analyses, applicants should identify, quantify and value the direct and derived resource use for the health technology being examined, as well as the chosen comparator(s). As far as possible, applicants should report costs as quantities consumed (activities and resources) and the related unit costs, see the steps on page 4. Examples of such cost components include time, utensils, etc[5,6].

In addition to the cost concepts described in table 2, in calculating costs it is also relevant for the applicant to consider whether there is a difference in costs for *all* of the cost components between the health technologies examined; that is, whether all cost components are relevant to include. It is only relevant to estimate costs if real and significant differences are expected between the interventions being examined in the analysis. If the applicant assesses and can explain why it is likely that there will be no difference in some cost components between the interventions being examined, it will not be necessary for the applicant to value these. Examples of where it is not necessary to value cost components are in text box 2.

Example

- 1. In its statement of the quantity of resources consumed, an applicant has identified that X utensils are consumed in connection with use of the health technology being examined, and this is the same as with the comparator(s). Therefore, it is not necessary to value the utensil as the difference in costs between the health technology and the comparator is effectively zero.
- 2. In its statement of the quantity of resources consumed, an applicant has identified cost components with only insignificant quantities used. The applicant considers that these will not significantly affect the total accumulated costs. Therefore, the valuation of these can be omitted. However, it is only possible to leave out valuation if it is assessed that the results would not be changed if the cost components had been included and valued.

Text box 2. Examples of cases where it is not necessary to value cost components.

There are different approaches to estimating unit costs. In general, applicants should apply a micro cost determination model when calculating costs affected by a health technology. In this context, it is important that all activities and resources are identified, quantified, and then valued. Where possible, the method should be used for both the health technology being examined and its comparator(s)[5].

However, there may be circumstances in which it is sufficient to apply rates, such as diagnosis-related group (DRG) rates or fees for remuneration of general practitioners, for example. If an applicant uses rates, the applicant is expected to account for whether and how the use of rates is likely to influence the results of the economic analysis and budget impact analysis (see example in text box 3). See section 0 for an

elaboration on use of DRG rates and section 4.5.2 for more details about using remuneration to value contact with general practitioners or medical specialists.

Example

In an economic analysis, an applicant has valued the incidence of serious blood clots in the brain, which is a late complication of disease *X*, by means of a DRG rate. The health technology being examined reduces the risk of these blood clots. The DRG rate for diagnostic evaluation of blood clots in the brain in a same-day package is 6712 DKK (code 01SP01, 2022 rates).

Basically, this rate, 01SP01, reflects the reimbursement received by the hospital for treating patients who, clinically and with regard to pressure on resources, are assessed to be largely similar, but therefore the rate also reflects an average value. For this reason, the DRG rate is used to reimburse hospitals for blood clots of different severities and with different aetiology.

It is possible that using this DRG rate to value the late complication may over- or under-estimate the actual resource use, as the severity of blood clots and their aetiology is not reflected in the amount.

Text box 3. Example of cases where use of a DRG rate may cause an over- or under-estimate of the costs associated with a late complication, the incidence of which can be influenced by use of the health technology under examination.

3.2.1. Valuation of unit costs

Applicants are responsible for estimating unit costs for the health technology under examination, its comparator(s), as well as derived costs such as materials and time consumption for health staff and patients/relatives. All materials should be valued if consumption of the material is assessed to be affected by the use of the technology under examination in relation to its comparator(s), see section 3.2. For example, consumption of utensils, or purchase requirements for equipment or software, etc. could be increased or reduced. There could also be changes in the time spent by health staff or patients and their families.

Valuation of unit costs in the economic analysis and the budget impact analysis should, as far as possible, endeavour to approximate market prices (excl. VAT) for the resources used.

Where appropriate, the applicant should state whether the costs are acquisition and start-up costs, such as installation and training, or actual operating costs, including maintenance, etc. For health technologies with multiple use and/or long lifetime, the applicant should indicate the costs associated with the lifecycle of the technology, including the expected unit price, implementation, regular servicing and repair, possible disposal costs, etc. In this connection, the applicant should state in the economic analysis how the health technology is treated with regard to depreciation and any costs allocation, where this is relevant (see section 0 and 4.3).

3.2.1.1. Estimate of costs, where prices are not publicly available. The Danish Health Technology Council recognises that certain costs data is not necessarily available to applicants. For example, in connection with public procurement, discounts can be offered for procurement of different materials, and these discounts may vary from procurement department for procurement department. Information about these discounts is generally not available to the applicant, and therefore the discounts cannot reasonably be incorporated in the analyses. Therefore, the applicant may take outset in publicly available market prices (excl. VAT) for the utensils. The Danish Health Technology Council will accept the applicant's best estimate for prices of comparator(s).

In its evaluation design, the expert committee may request specific sensitivity analyses, which applicants will have to carry out in relation to any uncertainty in cost estimates. The secretariat and the expert committee may also initiate additional sensitivity analyses on the basis of the material submitted by the applicant, to examine how any discounts and other assumptions affect the results of the analyses.

3.2.1.2. Use of foreign data and models

It is generally not possible to use foreign cost estimates, for example from economic analyses, directly in cost-comparison analyses related to Danish contexts, as these will reflect a different healthcare-system design (settlement system, inter-specialist collaboration, clinical practice, etc.) and pricing.

Data on estimates of activity and pressure on resources based on foreign data may, in the same way as the overall cost estimates, have limited transmissibility and relevance for Danish conditions because of differences in clinical practice, capacity and organisation of the healthcare system, etc. If the applicant uses foreign data on activities and resource use, the applicant should therefore confirm that the estimates are representative for Danish conditions[8]. For the same reasons, valuations of activities and resources should always use Danish unit costs. If the applicant does not do this, there should be a statement confirming that the estimates used are likely to reflect Danish conditions.

If the applicant applies an international health economic model in the economic analysis, the applicant should therefore also apply costs data based on a Danish context, including data on the expected resource use, in order to adapt the model to Danish conditions.

3.2.1.3. Price adjustments

In principle, cost estimates should always be calculated as current costs, and all cost estimates should reflect the same year. Therefore, as far as possible, applicants should use the most recent estimates of unit costs, for example by using the most recent lists of fees, DRG rates, etc. If an applicant applies older cost estimates, for example from published studies, these should be adjusted to reflect the present value. Price adjustments should generally be based on the net price index⁴, which can be found at <u>Statistics Denmark</u>.

There may be situations in which the requirement for present-value costs would require the majority of the unit costs to be adjusted, for example due to a delay in updating tables of rates. If the applicant considers it reasonable to state all costs in terms of a year that is *not* the year in which the analysis was prepared (e.g. 2020 instead of 2021), this may also be accepted. Applicants should state why estimates of costs have not been price-adjusted to present values.

4. Economic analyses

The purpose of the economic analysis is to provide insight into the value for money of the health technology under examination, including alternative costs; that is, the costs and effects 'lost' if the health

⁴ The net price index states changes in prices excluding changes in taxes and subsidies. The net price index is calculated on the basis of actual consumer prices, but excluding VAT and goods-specific taxes. The difference between the consumer price index and the net price index is the correction for taxes and subsidies in prices and weightings in the net price index.

The Danish Ministry of Finance recommends using the net price index in analyses in the public sector in the form of socio-economic impact assessments.

technology under examination is put into use. Irrespective of whether there is a full economic analysis, in which both costs and effects are calculated, or just a cost analysis (see the methodological guidelines from the Danish Health Technology Council), it is important to describe how costs accumulate, both for the health technology under examination and for its comparator(s) in order to make a comparison analysis possible.

According to the methodological framework from the Danish Health Technology Council, an economic analysis should use a limited societal perspective (see section 4.1.). Applicants should include all relevant treatment-related costs of using the health technology under examination. These include costs related to the treatment itself, and to any effect on the cumulative costs associated with implementation and administration of the technology, side effects and late complications from using the health technology compared with its comparator(s), etc.

Economic analyses should state the costs and effects calculated per patient. The results of the analysis are usually reported as cost per unit of outcome, for example X DKK per infection prevented or X DKK per quality-adjusted life year. As recommendations from the Danish Health Technology Council are applicable nationally, it should be possible to generalise analyses to reflect all potential changes that may be required, for example in infrastructure to support use of the health technology under examination, including changes in fixed costs (FC) such as rent, water, electricity, etc. For this reason, applicants should use the *full costing principle* and calculate costs as the average cost per patient, taking outset in the calculation of all the fixed and variable costs (AC = TC/Q, where AC = FC + VC and AC = FC + VC anall AC = FC + VC and AC = FC + VC and AC = FC + VC and AC

In situations where a health technology solution is used to treat several patients, such as ultrasound equipment or a monitor, possibly over a number of years, the costs associated with use of the health technology should be distributed over several patients using a cost-allocation key (see sections 0 and 4.3). If an economic analysis requires costs to be depreciated and/or distributed over several patients, the applicant should always state how and under what assumptions depreciation has been provided. The expert committee can describe how costs should be written off and allocated in its evaluation design.

4.1. Time horizon and perspective

In principle, the time horizon of an economic analysis should be sufficient to capture all differences in cumulative costs and effects between the health technology under examination and its comparator(s). However, in its evaluation design, the expert committee will specify the time horizon to be used by the applicant, and specify alternative time horizons to be used in sensitivity analyses. For example, the expert committee may deem that an applicant has to apply a shorter time horizon in an economic analysis than would otherwise be expected based on the characteristics of the technology, because it is likely that the technology will become out of date technologically, even though the technical lifetime of the technology is effectively longer. Text box 4 contains examples of the use of different time horizons for health technologies with different characteristics.

Example

- 1. A health technology is used in hospitals to reduce patients' post-operative pain while they are in hospital. There are no derived economic consequences in the form of increased/reduced readmission rates, increased/reduced consumption of medicines, or similar, in relation to using comparator(s) for the health technology. Therefore, compared with the comparator(s), the health technology under examination is unlikely to entail any changes in the patient care pathway, other than in connection with the primary admission.
 - In this case, a relatively short time horizon for the economic analysis will be adequate to capture the impact on costs and effects.
- 2. A health technology is used for continuous monitoring of patients with a chronic disease. The health technology is telemedical, so that after training at the hospital, the patient can take the technology home for daily use. The economic consequences of using the health technology include fewer visits to the hospital outpatient department and fewer admissions because of serious deterioration in the disease, but there will also be more contact with the patient's own GP compared with the standard treatment.
 - In this case, a long time horizon, probably lifetime horizon, will be necessary to capture all impacts on costs and effects.

As mentioned in the body text, in this case the expert committee may specify a shorter time horizon than the lifetime horizon. This may apply if the expert committee assesses that technological developments may cause the health technology to become out of date before its technical lifetime comes to an end.

Text box 4. Example of how the core outcome of health technologies can effect the time horizon deemed relevant in evaluation of the health technologies.

Applicants should apply a limited societal perspective in the economic analysis. This means that all costs for all parties concerned must be included, such as hospitals, general practice, specialist practice, home care, nursing homes and nurses and costs of aids and appliances, plus social care. Furthermore, the treatment-related costs of patients and relatives, such as time lost, transport costs and costs of prescription drugs should be included, as illustrated in figure 2.

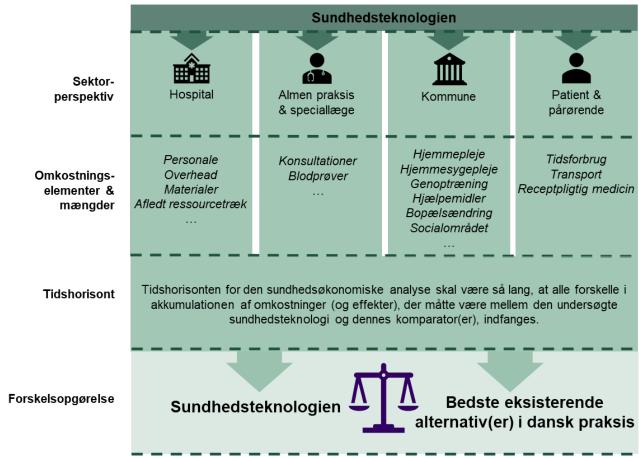


Figure 2 Illustration of the limited societal perspective to be used in economic analyses submitted to the Danish Health Technology Council. The limited societal perspective includes four sectors: the hospital sector, general practice and specialist practice, the municipal sector and the patient area, all of which will contain different cost components.

4.2. Depreciation and lifetime

If the health technology under examination or other relevant cost components have a lifetime likely to extend beyond one year, the one-off costs of these should be depreciated in the economic analysis over the whole expected lifetime of the technology. The annuity method should be applied[1,5]. For example, this may apply for large technological equipment such as scanners and robotic surgery equipment to treat several patients, as well as equipment that can only be used by one patient, such as an insulin pump or a pacemaker, but which also has an expected lifetime of more than one year. In the economic analysis, such one-off costs to procure the technology should be written off, as should any implementation costs associated with taking the health technology into use, including development⁵, procurement of supporting software, training health staff, administrative staff or patients in use of technology, etc.

⁵ Development costs should only be included if they are incurred in a realisation-close context. For example, development of an app to support use of the health technology under examination. Development costs do *not* include research-related costs, for example costs of completing a research study.

Formula to find the annual cost using the annuity method:

$$P = \frac{r(PV)}{1 - (1+r)^{-n}}$$

Where

- P is the annual cost
- r is the relevant annual socio-economic discount rate
- PV is the amount is to be written off
- n is the number of years over which the amount is to be written off the expected lifetime.

The relevant socio-economic discount rate from the <u>Danish Ministry of Finance</u> should be applied (see also section 4.4 on discounting). For more information regarding depreciation of health technologies, including use of the annuity method, see other texts[1,5].

Different cost components⁶ will probably have different lifetimes, see <u>The Agency for Governmental Management's provisions on bookkeeping</u>, and this should be taken into consideration in depreciation calculations. Table 3 shows an extract of the lifetimes of different cost components that may be relevant to include in economic analyses. There will be some cost components without an 'official' lifetime. In this respect, applicants should identify a reasonable lifetime in relation to the characteristics of the cost component. It is up to the applicant to justify the likely lifetime of the cost component being depreciated. Text box 5 contains an example of calculation of the annual costs associated with a health technology. Depreciation is provided using the annuity method.

Note that there may be differences between the relevant lifetime(s) for different cost components and the time horizon to be used in the economic analysis.

| Cost component | Lifetime |
|---|--|
| Adaptation or new development of applications for an existing standard system | 5 years |
| Licences etc. | 3 years |
| Land and property | No depreciation |
| Buildings | 50 years |
| Ordinary installations | 20 years |
| Special installations | 10-20 years |
| Fitting out rented premises | 10 years or the duration of the contract |
| Fixtures and IT equipment | 3-5 years |

Table 3. Example expected lifetimes of different costs that could be relevant to write off in an economic analysis (Agency for Governmental Management's bookkeeping provisions, 2021). This list is not exhaustive.

⁶ Including health technologies, implementation costs (such as training), development costs etc. When writing off costs associated with training in use of equipment etc. the applicant should consider how often the training will have to be repeated, as this will determine the expected 'lifetime' of the training.

4.3. Use of cost-allocation keys

If the health technology under examination is to be used to treat several patients, a cost-allocation key will be required to estimate the cost per patient of using the technology. This will usually be relevant in economic analyses of large medical devices such as scanners, monitors, etc., but it may also relate to training courses to upgrade staff skills that will benefit several patients.

Example

A scanner can be used for two different types of treatment, where the one type of scan takes 20 minutes, while the second takes 120 minutes. In this context, the two types of scan cause different levels of wear and tear on the monitor, and therefore minutes in operation could be a more appropriate cost-allocation key for the costs associated with the monitor distributed between the different types of scan than the more intuitive cost-allocation key of 'number of scans completed'.

Text box 5: Example of how several cost-allocation keys may be relevant for the same cost component, in this case, use of a scanner.

An obvious and commonly used cost-allocation key could be 'number of treatments completed' or 'number of patients treated'. An alternative cost-allocation key could be the number of minutes a technology is in use, as in the example in text box 5. It is not possible to describe a standard cost-allocation key, because the choice of cost-allocation key depends on what costs are to be allocated, and there may be situations in which several relevant cost-allocation keys can be identified, see the example above. Cost-allocation keys could be time, number of square metres, number of employees, etc[5].

It is up to applicants to identify, use and justify relevant cost-allocation keys in their economic analyses. For more information regarding use of cost-allocation keys, see other texts[1,5].

If an economic analysis includes cost components likely to have a lifetime of more than one year and to be used in treatment of several patients (scanners, operation robots, rehabilitation programmes, etc.), costs in connection with these should first be written off over a relevant period and then divided by the number of patients treated per year using an appropriate cost-allocation key.

4.4.Discounting

In connection with economic analyses, applicants should convert costs incurred more than one year in the future to present values. Thus, costs incurred during the first year of the analysis should not be discounted, but costs incurred after this should be discounted. If an applicant believes this principle should be deviated from, the applicant should provide reasons to support this.

Applicants should apply an annual discount rate corresponding to the current socio-economic discount rate from the <u>Danish Ministry of Finance</u>. For example, the discount rate for the first 35 years in an economic analysis would be 3.5% as at 7 January 2021 (actual discount rate as at 7 January 2021, <u>Ministry of Finance</u>). For further information concerning discounting, see other texts[1,5].

4.5. Unit costs

4.5.1. Hospital costs

If the health technology under examination is likely to influence cumulative hospital costs in direct connection with its use, the applicant should estimate these costs as accurately as possible. These costs may include staff time consumption, use of utensils, etc. In principle, it is expected that applicants apply micro cost determination for this, see 3.2 and [1,5].

It may also be relevant to price-set derived effects of the technology, such as the effects on risks of late complications that will have to be treated in hospital. If it makes sense in relation to the specific evaluation situation, an applicant may use DRG rates to value these, see section 0.

4.5.1.1. Staff time consumption

If use of health technology under examination prolongs or reduces the treatment time in hospital, this effect on staff time consumption comprises an alternative cost that has to be valued. Valuation of staff time is based on an assumed full-time equivalent of 1,924 hours (corresponding to 52 working weeks with weekly working hours of 37 hours), and in the economic analysis it should be calculated according to the concept of 'effective hours'[1,5].

The concept of 'effective hours' recognises that staff do not work effectively for all 1,924 hours in the full-time equivalent. In order to estimate the number of effective hours, vacation, public holidays, sickness, child sickness, other time off, lunch breaks, and non-patient-related tasks such as professional development, management, meetings, etc. have to be deducted. This is to endeavour to find an indication of the number of hours in which staff are working effectively on their core task, so that the valuation applies for effective time.

The number of effective hours within the healthcare sector is often somewhere between 1,100-1,500 hours per year[5,9]. The Danish Health Technology Council's calculation of the number of effective hours is as follows⁷:

| Full-time equivalent | 37 hours/week x 52 weeks | Ξ | 1,924 hours |
|--|---------------------------|---|-----------------|
| Holiday under the Holiday Act | 37 hours/week x 5 weeks | = | 185 hours |
| Extra holiday days in regions and municipalities | 7.4 hours/day x 5 days | = | 37 hours |
| • Public holidays[9] | 7.4 hours/day x 8.14 days | = | 60 hours |
| Own and child-related sickness, including child care | 7.4 hours/day x 14 days | = | 104 hours |
| days ⁸ | | | |
| This gives 208 working days | | = | 1,538 hours |
| Lunch breaks | 0.5 hours/day x 208 days | = | 104 hours |
| Non-patient-related tasks⁸ | 1.5 hours/day x 208 days | = | 312 hours |
| Effective hours per year | | Ξ | 1,122 |
| | | | <u>hours</u> |
| Effective hours per month | 1,122 hours/year /12 | = | <u>94 hours</u> |
| | months/year | | |

⁷ There is no single 'correct' calculation for the number of effective hours. The number of effective hours is likely to vary from one specialist group to the other. ⁸ Estimated.

Applicants should use the Danish Health Technology Council's estimate of the number of effective hours in their valuation of staff time.

To value resource spending on staff hours, applicants should use pay data broken down by specialist groups retrieved from the Municipal and Regional Pay Data Office (Kommunernes og Regionernes Løndatakontor). This data covers all relevant specialist groups employed in the regions and municipalities. Applicants should take outset in the latest available average gross annual pay including pension and supplements for the relevant specialist group to calculate staff-related costs. Applicants are responsible for using the most accurate pay data for the analysis and treatment situation in question.

Table 4 shows gross annual pay including pension and supplements, as well as the corresponding gross hourly pay and the cost of effective hours for selected specialist groups, calculated using the above method. The table is based on the average salary level for the gross annual pay for the selected groups in 2020. The list in table 4 is not exhaustive. It may be necessary for an applicant to find other gross annual pay figures on Municipal and Regional Pay Data Office (Kommunernes og Regionernes Løndatakontor) in order to estimate correct hourly pay per effective hour for the specialist group the applicant is to value. Text box 6 shows an example of the valuation of staff time using hourly pay per effective hour.

| Position | Gross annual pay*, DKK | Gross hourly pay, DKK | Hourly pay (effective hrs.), DKK |
|---|---------------------------|--------------------------|--|
| Lead consultant/professor | 1.202.424 | 625 | 1071 |
| Consultant, paid according to salary grade (not lead) | 1.164.298 | 605 | 1037 |
| Registrar, unspec. | 685.592 | 356 | 611 |
| Lead nurse | 678.979 | 353 | 605 |
| Lead bioanalyst | 636.706 | 331 | 567 |
| Lead occupational therapist | 632.965 | 329 | 564 |
| Lead physiotherapist | 653.386 | 340 | 582 |
| Lead midwife | 723.024 | 376 | 644 |
| Lead radiographer | 641.749 | 334 | 572 |
| Nurse, not lead | 511.025 | 266 | 455 |
| Bioanalyst, not lead | 455.974 | 237 | 406 |
| Occupational therapist, not lead | 451.264 | 235 | 402 |
| Physiotherapist, not lead | 457.571 | 238 | 408 |
| Midwife, not lead | 511.532 | 265 | 456 |
| Radiographer, not lead | 469.596 | 244 | 418 |
| Laboratory technician, not lead | 390.770 | 203 | 369 |
| Assistant nutritionist, not lead | 367.959 | 191 | 328 |
| Social and health care assistant | 475.769 | 247 | 424 |
| Hospital porter, unspec. | 413.774 | 215 | 369 |
| Specialist, IT staff | 612.568 | 318 | 546 |
| Medical secretary, unspec. | 430.519 | 224 | 384 |

Table 4. Staff costs for selected specialist groups employed at hospitals (regional), calculated as gross annual pay including pension and supplements, the corresponding gross hourly pay and the hourly pay per effective hour in 2021.

Further gross annual pay figures including pension and supplements are available at Municipal and Regional Pay Data
Office (Kommunernes og Regionernes Løndatakontor).*Including pension and supplements.

Example

If, on the basis of the figures in table 4, an estimate is to be calculated of savings in staff costs as the result of a 10-minute-shorter treatment time for consultation with a registrar and a non-lead nurse, the savings should be valued as $(611 \text{ DKK/hour } \times 10/60 \text{ hours} + 455 \text{ DKK/ per hour } \times 10/60 \text{ hours}) = 102 \text{ DKK} + 76 \text{ DKK} = 178 \text{ DKK}$.

Text box 6: Example of how time consumption can be valued using hourly pay per effective hour.

4.5.1.2. Overhead costs

When micro cost determination is applied, there will be some pressure on resources that is not directly attributable to the treatment in question, but which the treatment is likely to be a contributory factor in causing. 'Overhead costs' are costs that cannot be attributed directly to a specific treatment (and in this

respect the use of a health technology), but where the treatment nevertheless contributes to the cumulative costs, see the full allocation principle[5].

These indirect overhead costs include:

- Shared 'rent'
- Cleaning
- Administrative tasks
- Electricity, water and heating
- Equipment, including computers, monitors, etc. (not related directly to the health technology under examination)

Many overhead costs will usually be unchanged or only slightly affected by small changes in care pathways, and for this reason it is often not relevant to value these in an economic analysis (see section 3.2). If, in dialogue with the Danish Health Technology Council secretariat, an applicant judges that use of the health technology under examination will not, or will not significantly affect overhead costs relative to the specified comparator(s), and that it will not affect the results of the economic analysis, the applicant may omit the overhead cost from the cost statement. Examples of such situations are in text box 7. Applicants should justify omitting overhead costs from their valuation.

If, however, in dialogue with the Danish Health Technology Council secretariat, an applicant deems that overhead costs are affected by using the health technology under examination, the applicant should estimate these and include them in the economic analysis. For example, this situation may arise if the technology lowers time consumption of operating theatres to such an extent that in the longer term it enables use of the operating theatres for other purposes (see example 3 in text box 7). When valuing overhead costs, it is important to apply a cost-allocation key (see section 4.3, as well as[1] and [5].

If an applicant does not have data to support calculation of the overhead costs, but believes that there will be an effect on such costs, the applicant should estimate the overhead costs as 40% of the estimated staff costs. In the report, the applicant should state whether and how overhead costs have been included in the economic analysis.

Example

- 1. Overhead costs may be completely unchanged from using the health technology under examination. For example, this situation may arise if the health technology under examination does not affect the treatment time in connection with an operation compared with its comparator(s), which means there is likely to be the same pressure on resources in connection with 'rent', cleaning, administrative work, etc.
- 2. Overhead costs can be affected minimally from using the health technology under examination if they are not expected to contribute significantly to the total cumulative costs. This situation may arise if the time an operation takes is reduced by 10 minutes. In this case, the same administrative burden will be connected with the operation, and the costs of cleaning and water consumption will probably also be unchanged. In other words, the overhead costs affected are likely to be 'rent', electricity, heating, and possible equipment (depending on the cost-allocation key applied to apportion the costs). In this situation, the overhead costs will probably be small and insignificant in relation to the total cumulative costs. Therefore, there will be an argument to omit valuing these.
- 3. Overhead costs may be affected if, for example, by using the health technology under examination, the time for an operation is considerably reduced compared with the comparator(s). In this case, the 'rent' in connection with the operation is likely to be lower and could potentially be relevant to value. A relevant cost-allocation key in this context could be the area of the operating theatre in square metres compared with the total area of the hospital. In this example, it is relevant for applicants to assess whether all overhead costs are likely to be affected, or whether, for example, only 'rent', electricity and heating consumption or whether administrative work is also affected by use of the health technology. If an operation is likely to be less time-consuming, it cannot directly be assumed that this will lead to less administration in connection with performance of the operation.

In this situation, it is relevant to value overhead costs because, in the long term, it will be possible to use the operating theatre for other purposes in the time released. If the time for an operation is halved, for example, in theory one could perform twice as many operations in the theatre within the same time. The value of this alternative purpose should then be included as an alternative cost. To have a realistic possibility to use the operating theatre for an alternative purpose, however, savings should be of a certain size.

Text box 7: Examples of dealing with overhead costs in different situations. Examples 1 and 2 describe situations in which it is reasonable to omit valuing overhead costs as they 1) do not constitute relevant costs and 2) are not expected to be significant for the total cumulative costs. Example 3 describes a situation in which including overhead costs should be considered.

4.5.1.3. Derived effects on pressure on resources

Use of health technology can have derived economic effects which arise when the health technology is in operation, i.e. in the 'use situation'. There may be impacts on the pressure on resources in both the short and the long terms, as exemplified in text box 8:

Example

- 1. A health technology can have derived economic effects immediately after use. For example, this applies if the health technology has been used in an operating theatre and in the subsequent admission time there is a lower consumption of materials such as bandages, pain-relieving pharmaceuticals, etc. Similarly, the admission time itself may be shortened by using the health technology compared with its comparator(s).
- 2. A health technology can have derived economic effects for a long time after use. This may apply if a health technology reduces the risk of late complications from disease, such as admissions due to an infection or blood clots later in the care pathway, e.g. many years later. The derived economic consequences do not necessarily occur just in the hospital area, they may also include increased or reduced need for care at home over time.

Text box 8: Example of how a health technology can affect the pressure on resources shortly after, and a long time after use.

In an economic analysis, applicants are expected to estimate the impact of the possible resource use in direct connection with use of the health technology under examination. As far as possible, the Danish Health Technology Council recommends that applicants apply micro cost determination for this, see section 3.2.1. If the applicant only has overall estimates available, such as the impact on the length of admission, this can be valued on the basis of published data, if this is available, or the most recent long admission rate from the DRG rate system, if relevant (see table 5, and guidelines from the Danish Health data Authority on the rate system 2022). It is not relevant to estimate the costs associated with the primary admission using DRG rates or similar, because the rates do not consider the effects of the technology under examination on the pressure on resources from the admission[1,5,7].

It is often necessary to use a different approach to estimating the derived effects of the pressure on resources in the long term, as a micro cost determination model is rarely applied in this context. If it is not possible to apply a micro cost determination model to value such consequences, applicants may use rates, including DRG rates, rehabilitation rates and mental health services rates, etc. Overhead costs are included in the rates and therefore it is not necessary to calculate these separately.

Every year, the Danish Health Data Authority calculates new <u>DRG rates</u> for patients within the somatic and mental health services treatment areas. Where an applicant considers that DRG rates can be used for valuation, the applicant should, as far as possible, use the latest available rates.

Guidance on use of the DRG rates catalogue, DRG rates, rehabilitation rates and mental health services rates is available via the Danish Health Data Authority. Applicants should state which rate has been used, and what it has been used to value, as well as how the rate applied has been identified. Table 5 shows examples of rates with associated information.

| Name of rate | Used to value, for example | Rate, DKK | Code |
|--------------------|----------------------------|--------------|------|
| DRG, somatic rates | | | |

| Check of medicine pump | Outpatient examination, follow-up | 2.627 | 01PR03 | |
|--|-----------------------------------|--------|---------------------|--|
| Check-up examination | Outpatient examination, follow-up | 1.515 | 23MA04 | |
| Mammography, complex | Screening | 3.471 | 30PR13 | |
| MRI-guided radiotherapy | Treatment | 12.068 | 27PR03 | |
| Thrombolytic treatment of acute apoplexy | Late complication | 29.044 | 01MP11 | |
| Post-operative and post-traumatic infections, with comp. factors | Side effect | 41.506 | 18MA02 | |
| Complications from treatment, w/out comp. sec. diag. | Side effect | 30.549 | 21MA03 | |
| Rehabilitation | Late complication | 63.656 | 23MA01 | |
| Long admission rate | Change in length of admission | 2.185 | per day | |
| Mental health services rates, stationary and outpatient rates | | | | |
| Bed day | Side effect | 3.939 | Bed days | |
| Out-patient | Treatment | 1.971 | Out-patient | |
| Treatment completed | Treatment | 2.185 | Treatment completed | |

Table 5. Examples of DRG rates and mental health services rates (2022 rates), which can be used in connection with valuation of late complications of disease and side effects of treatment, for example. DRG: diagnosis-related group. The list is not exhaustive.

4.5.2. Costs in the context of general practice and specialist practice

If the health technology under examination affects the resource use in general practice and in specialist practice, this should be included in economic analyses.

Valuations of consultations and interactions with general practitioners should be with reference to the latest available collective agreement between the <u>Danish Medical Association</u> (PLO) and the <u>Regions' pay board (Regionernes Lønnings- og Takstnævn (RLTN))</u> for general practitioners. For consultations and interactions with medical specialists, valuations should refer to the latest available collective agreement between the medical specialists' association (<u>Foreningen af Speciallæger (FAS)</u>) and RLTN for the medical specialist area. Both collective agreements contain rates for services which applicants can use to estimate the costs associated with the specific types of visit and/or interaction with physicians.

Table 6 shows examples of basic services, supplementary services and laboratory tests that cover remuneration for general practitioners for consultations with patients in health insurance group 1 in accordance with the collective agreement between PLO and RLTN on 1 April 2022.

The latest available table of remuneration is available (in Danish) on læger.dk.

ı

| Service | Sec. 50 Basic service | Remuneration, |
|---------|-----------------------|---------------|
| no. | | DKK |

| 0101 | Consultation | 149 |
|------|---|-------|
| 0102 | Treatment of second insured in same home (sec. 66(1)) | 149 |
| 0105 | E-consultation (including with municipal nursing staff) | 47 |
| 0120 | Agreed specific preventative procedure ¹ | 400 |
| 0201 | Telephone consultation | 29 |
| 0411 | House call up to 4 km (zone 1) ² | 399 |
| 0421 | House call from start 5 km to 8 km (zone II) ² | 549 |
| 0431 | House call from start 9 km to 12 km (zone III) ² | 627 |
| 0441 | House call from start 13 km to 16 km (zone IV) ² | 709 |
| 0451 | House call from start 17 km to 20 km (zone V) ² | 1.096 |
| 0461 | House call from start 21 km to visit site ² | 1.418 |
| 2301 | For each additional commenced km above 21 km | 33 |
| | Sec. 51 Supplementary services | |
| 2101 | Blood test from a blood vessel per consignment | 51 |
| 2113 | Biopsy with subsequent microscopic exam. at pathologist incl. postage | 204 |
| 2117 | Removal of subcutaneous or deeper tumour, incl. possible postage | 305 |
| 2133 | Postage of biological material, excl. blood samples (also includes | 36 |
| | submission of urine for microalbuminuria exam. and swabs) | |
| | Sec. 60 laboratory tests | |
| 7101 | Urine test with test strip | 14 |
| 7115 | Machine leukocyte and differential count | 42 |
| 7120 | C-reactive protein (CRP) | 69 |
| 7126 | PP-INR (coagulation factors) | 125 |
| | | |

¹If the service is delivered at home, a mileage supplement and time supplement is also paid. See note 2.

Table 6. Extract of remuneration in general practice according to the collective agreement between the Danish Medical Association (PLO) and the Regions' pay board (Regionernes Lønnings- og Takstnævn (RLTN)) as at 1 April 2022 (applicable from 1 April 2022 - 1 Oktober 2022) for patients in health insurance group 1. The full, latest available tables of remuneration for general practitioners are available (in Danish) at læger.dk.

The collective agreement between FAS and RLTN covers the specialist areas:

- Anaesthetics
- Child and youth mental health services
- Dermato-venereology
- Radiology
- · Gynaecology and obstetrics
- Internal medicine
- Surgery
- Neurology
- Orthopaedic surgery
- Plastic surgery

²Kilometre limit applies up to the visit site.

- · Mental health services
- Paediatrics
- Rheumatology
- Assistance from an ophthalmologist, and
- Ear-nose-throat.

The collective agreement also covers the rates for general laboratory tests and are the same across specialist areas.

Table 7 shows the remuneration for medical specialists within dermato-venereology, neurology, assistance from an ophthalmologist, and rheumatology for a number of basic services according to the collective agreement between FAS and RLTN as at 1 April 2022. Rate cards for the individual specialist areas and for laboratory tests can be accessed (in Danish) on Rate cards for practicing medical specialists. There are large differences between the various specialist areas, as illustrated in table 7. Therefore, when making valuations of consultations and interactions with medical specialists, applicants should take outset in the relevant remuneration in the current collective agreement.

| Service no. | Dermatology sec. 1(1) | Remuneration, DKK |
|----------------|--|----------------------|
| 0105 | E-consultation | 77 |
| 0107 | Advice by telephone/counselling per EDIFACT for general practitioners | 269 |
| 0110 | 1st consultation | 538 |
| 0130 | Later consultation | 163 |
| 0140 | Tele-dermatology | 327 |
| 0201 | Telephone consultation | 81 |
| | Neurology sec. 1(1) | |
| 0105 | E-consultation | 77 |
| 0205 | Advice by phone for general practitioner | 375 |
| 0110 | 1st consultation - preliminary interview | 869 |
| 0130 | Later consultation | 532 |
| 0201 | Telephone consultation | 177 |
| | Assistance from ophthalmologist sec. 1(1) | |
| 0105 | E-consultation | 75 |
| 0205 | Advice by phone for general practitioner | 127 |
| 0110 | 1st consultation | 254 |
| 0130 | Later consultation | 113 |
| 0201 | Telephone consultation | 56 |
| 0111 | Diabetic eye examination | 785 |
| 0112 | Photo screening for diabetic eye disease | 523 |
| | Rheumatology sec. 1(1) | |
| 0105 | E-consultation | 76 |
| 0205 | Advice by telephone/counselling per EDIFACT for practicing medical specialists | 336 |

| 0110 | 1st consultation | 1.120 |
|------|---|-------|
| 0130 | Later consultation | 156 |
| 0140 | Telemedicine video consultation | 533 |
| 0201 | Telephone consultation | 74 |
| 0107 | Check-up for patients in DMARD-treatment by telephone or e-mail | 219 |

Table 7 Extract of remuneration for medical specialists within dermato-venereology (Rate card 21A), neurology (Rate card 20C), assistance from an ophthalmologist (Rate card 14b) and rheumatology (Rate card 28A) in accordance with the collective agreement between the medical specialists' association (Foreningen af Speciallæger) and the Regions' pay board (Regionernes Lønnings- og Takstnævn (RLTN)) applicable from 1 April 2022 for patients in health insurance groups 1 and 2. The full, latest rate cards for all specialist areas are available (in Danish) on læger.dk. DMARD: disease-modifying anti-rheumatic drugs.

If an applicant expects that the health technology under examination will affect resource use in general practice and/or medical specialist practice, but the applicant does not have data to this, the applicant should estimate the pressure on resources on the basis of well-justified assumptions. In this case, the applicant should account for how the estimate has been obtained. In sensitivity analyses, the applicant should also investigate the effect on the results of the economic analysis of excluding from the analysis costs in the context of general practice and/or medical specialist practice.

4.5.3. Municipal unit costs

If the health technology under examination affects municipal resource use, this should be included in economic analyses. Municipal costs include costs associated with home care, home nursing, nursing homes, health visitors, rehabilitation, the costs of any aids and appliances, as well as the social sector.

If an applicant expects that the health technology under examination will affect municipal resource use, but the applicant does not have data on this, the applicant can estimate the pressure on resources. In this case, the applicant should account for how the estimate has been obtained. In sensitivity analyses, the applicant should also investigate the effect on the results of the economic analysis of excluding municipal costs from the analysis.

4.5.3.1. Staff time consumption

If use of the health technology under examination affects patients' needs for care in the context of home care, home nursing, nursing homes, rehabilitation, and the social sector, the pressure on resources associated with these cost components can be calculated as described in section 4.5.1.1. Staff costs should be calculated on the basis of the average gross annual pay for the staff group calculated by Municipal and Regional Pay Data Office (Kommunernes og Regionernes Løndatakontor).

Table 8 shows gross annual pay including pension and supplements, the corresponding gross hourly pay and the cost of effective hours for selected municipal specialist groups. The table is based on the average salary level for the gross annual pay for the selected specialist groups in 2021.

| Position | Gross annual pay, DKK | Gross hourly pay, DKK | Hourly pay (effective hrs.), DKK |
|------------------------------------|--------------------------|--------------------------|--|
| Municipal physician, not specified | 1.078.757 | 561 | 841 |

| Nursing home assistant | 486.018 | 253 | 433 | |
|----------------------------------|---------|-----|-----|--|
| Social and health care assistant | 461.198 | 240 | 411 | |
| Social and health care helper | 434.258 | 226 | 387 | |
| Nursing aide | 474.100 | 246 | 422 | |
| Lead occupational therapist | 660.322 | 343 | 588 | |
| Lead physiotherapist | 663.046 | 345 | 591 | |
| Lead health visitor | 710.428 | 369 | 633 | |
| Lead nurse | 667.362 | 347 | 595 | |
| Non-lead ergotherapist | 483.380 | 251 | 431 | |
| Non-lead physiotherapist | 477.283 | 248 | 425 | |
| Non-lead health visitor | 521.785 | 271 | 465 | |
| Non-lead nurse | 512.790 | 267 | 457 | |

Table 8. Staff costs for selected specialist groups employed in a municipality, calculated as gross annual pay, gross hourly pay, and the hourly pay per effective hour as at February 2021. Further hourly rates stated as gross annual pay are available at <u>Municipal</u> and Regional Pay Data Office (Kommunernes og Regionernes Løndatakontor).

4.5.3.2. Overhead costs

Municipal overhead costs are not included in the calculation of the pressure on resources in connection with staff costs. Municipal overhead costs can relate to administrative costs, continuing training, etc. and they can be calculated as outlined in section 4.5.1.2[5]. If an applicant does not have data to support calculation of overheads, but believes that it is likely there will be an effect on such costs, the applicant should estimate the overhead costs as 40% of the estimated staff costs.

If, in dialogue with the Danish Health Technology Council secretariat, an applicant judges that use of the health technology under examination *will not*, or *will not significantly* affect cumulative municipal overhead costs, and that it will not affect the results of the economic analysis, the overhead costs may be omitted.

4.5.3.3. Transport costs

Transport to and from the municipal treatment and care of patients in their own homes should be included in the estimate of the total costs if the health technology under examination affects the needs for transport. For example, this may

be relevant if the health technology reduces the need to be present in person in the patient's home in connection with measurement of vital signs such as blood pressure and pulse.

The applicant should take outset in the actual road distance from the place of employment to the patients' address, where this is possible. Valuation of costs related to transport should apply the state government tax-free travel allowance (*befordringsgodtgørelse*) of 3.51/km DKK (2022 rate, Danish Tax Agency), to cover the costs of fuel, maintenance, vehicle tax, depreciation, financing and insurance. In their economic analyses, applicants should apply the rate relevant at the date of the analysis.

If an applicant judges that use of the health technology under examination will not, or will not significantly increase or decrease municipal transport costs, and that it will not affect the results of the economic analysis, this pressure on resources may be omitted.

4.5.3.4. Aids and appliances and other materials

If the use of the health technology under examination increases or reduces patients' needs for aids and appliances or consumption of other materials (e.g. in connection with care), these must be valued at the current market price, excl. VAT. (See also section 3.2.1).

4.5.3.5. Moving residence

If the health technology under examination is likely to affect patients' ability to take care of themselves, and it will be relevant to move to/from a nursing home or home for the elderly, this should be included in the economic analyses. This could be temporary relief or a permanent change of residence, for example in connection with adverse effects or (late) complications in connection with a disease and treatment.

It is not possible to indicate a standard estimate of the expected costs associated with temporary or permanent move of residence to or from a nursing home or home for the elderly. The estimate will depend on the specific disease area and the general care needs of the patient population under examination.

Applicants are responsible for estimating the costs in connection with citizens moving residence and for confirming that the estimates reasonably reflect the expected pressure on resources associated with a potential change of residence. The estimate should be made in dialogue with the Danish Health Technology Council secretariat.

4.5.4. Costs paid by patients and their families

Changes in resource use for patients or families arising in connection with use of the health technology under examination should be included in economic analyses. Relevant costs for patients and their relatives include costs related to

- Lost time (section 4.5.4.1)
- Transport to and from hospital (section 4.5.4.2)
- Prescription medication (section 4.5.4.3).

In connection with calculation of the costs for the family, the applicant may only include costs for one relative, such as a spouse, partner, child or one parent, per patient. Costs included for relatives should reflect the support a patient may need in connection with treatment, transport, consultations, etc. with respect to treatment by the health technology under examination and its comparator(s). For example, if two children of an elderly patient decide to accompany the patient to a medical consultation or other treatment, only one of the child's lost time should be included (see section 4.5.4.1).

If an applicant expects that the health technology under examination will affect the patient's and the relative's resource use, but the applicant does not have data on this, the applicant can estimate the pressure on resources. In this case, the applicant should account for how the estimate has been obtained. In sensitivity analyses, the applicant should also investigate the effect on the results of the economic analysis of excluding costs incurred by the patient and relative from the analysis.

If, in dialogue with the Danish Health Technology Council secretariat, an applicant judges that use of the health technology under examination *will not*, or *will not significantly* affect costs for the patient or the patient's relative, an estimate of the costs paid by the patient and the patient's relative may be omitted.

4.5.4.1. Lost time for patients and relatives

Use of the health technology can affect the time lost by the patient and relative in connection with treatment. For example, this could be if there are changed needs for contact with the hospital, or a lot of time is spent on treatment at home. Valuing the patient's and relative's time reflects that this time has a value, although in this context not necessarily in terms of the payment of a salary. Therefore, lost time should be valued, irrespective of whether the patients and relatives are likely to be in work.

In their valuation of lost time for patients and their relatives, applicants should take outset in the average hourly pay of an employee in Denmark before tax. The applicant should use the most recent estimates for the standard calculated hourly pay⁸ from <u>Statistics Denmark's StatBank Denmark</u>. The standard calculated hourly pay for 2021 (the most recent figures) was 271.80/hour DKK (<u>Statistics Denmark's StatBank Denmark</u>). An example of the calculation is in text box 9.

Unless it can be argued otherwise in the specific evaluation situation, valuation of lost time should be without breaking down job function, sector, type of pay, employee group, pay component, or gender.

Example

A health technology means that patients can be sent home from hospital earlier after treatment, as there is no need for further specialist treatment, but there is a certain degree of monitoring. In this connection, the patient has to spend time measuring and reporting vital signs using a telemedicine solution. It is likely that some patients will not be able to carry out such measurements themselves, but will need assistance from their family. On average, it is expected that measuring and reporting the vital signs will take one hour a day, every day, for a three-week period after being discharged from hospital.

As stated in the body text, the time should be valued, regardless whether the patient takes the measurements, or the patient's relative. The costs associated with the patient's and relative's time is estimated as 3 weeks x 7 days/week x 1 hour/day x 271.80 DKK/hour = 5.708 DKK for the three weeks in which the patient/relative has to take measurements.

Text box 9. Example valuation of patients' and relatives' time using the standard calculated hourly pay from Statistics Denmark.

4.5.4.2. Transport costs

Costs of transport for patients and their families to and from hospital should be included in the estimate of the total costs if the health technology under examination increases or reduces these costs. Where possible, the applicant should take outset in the actual road distance from the patient's residence to the treatment facility.

Unless otherwise stated by the applicant on the basis of existing evidence, the Danish Health Technology Council will assume that the distance to a hospital is 20 km by road, corresponding to transport costs to and from the hospital of 140 DKK[11]. If an applicant has data on the distance to the hospital for the patient, the valuation of costs related to transport should apply the government tax-free travel allowance (befordringsgodtgørelse) of 3.51/km DKK (2022 rate, Danish Tax Agency), to cover the costs of fuel,

⁸ The standard calculated hourly pay approximates to the pay agreed or the pay an employee receives for each normal hour worked. Applicants should base calculations on *LONS20* in Statistics Denmark's StatistikBank: Pay according to the job function, sector, type of pay, employee group, pay component and gender.

maintenance, vehicle tax, depreciation, financing and insurance. In the economic analysis, the applicant should select the rate applicable on the date of the analysis, irrespective of the choice of means of transport.

4.5.4.3. Prescription medication

If the health technology under examination affects how much prescription medication patients need, this pressure on resources should be included in the economic analysis. Such a situation may arise if the technology under examination reduces or increases the need for pain-relieving medication.

Consumption of a medicine should be valued in accordance with the current price of the medicine (pharmacy sales price) excluding VAT, which is available (in Danish) on medicineriser.dk. The applicant should value medicine consumption in relation to the lowest unit price available for the dose used, unless the applicant can reasonably argue for valuing medicine consumption using a higher unit price (will typically apply for generic versus original medicine).

5. Budget impact analysis

5.1. Perspective and time horizon

A hospital perspective should be applied in a budget impact analysis, showing the expected effect on the total regional hospital costs across Denmark of using the health technology under examination, as illustrated in the first column in figure 2⁹. The result of the budget impact analysis should indicate the expected total impact on hospital budgets over a five-year period if use of the health technology under examination is recommended. The budget impact analysis is not designed to support local budget planning.

5.2. Approach to calculation of costs

When preparing a budget impact analysis, the applicant should consider how the health technology will affect care pathways in practice.

The impact on regional hospital budgets should be estimated on the basis of existing Danish treatment practice without the health technology under examination, thus resulting in a comparison analysis. Applicants should therefore describe and compare the costs associated with two scenarios: treatment with and without the health technology under examination. The expert committee will specify what should constitute the scenario without the health technology under examination. In practice, the comparison basis for the budget impact analysis will often be the comparator(s) that the expert committee has specified for the economic analysis. The most realistic costs scenario will often be established by comparing a treatment scenario with and without the health technology under examination, where the scenarios basically consist of a treatment mix of several different health technologies. The treatment scenario with the health technology under examination takes over market shares (percentage of patients treated with the health technology under examination) from other technologies.

⁹ 'Using' in this context is meant very broadly and may include implementation of new health technology, as well as continued use or phase-out of an existing technology.

All relevant treatment-related costs associated with using the health technology under examination should be included in the budget impact analysis, provided they occur in the context of the hospital and within the five-year time horizon. This includes costs related to use of the health technology, but also any influence on cumulative costs associated with training in use of the technology, and administration of the technology.

Increased or reduced incidences of adverse effects as well as (late) complications as a result of use of the health technology compared with its comparator(s) should also be included.

When preparing a budget impact analysis, applicants should consider whether the size of the patient population will be affected by using the health technology under examination. This means the number of patients that it will likely be possible to treat with the health technology under examination compared with the number if the health technology were not used. For example, the size of the patient population treated may be increased or reduced by using the health technology, because it will likely be possible to treat more or fewer patients compared with the existing treatment.

When preparing a budget impact analysis, applicants should take outset in the following assumptions:

- Relevant costs include all expected hospital costs that affect the budget, including costs to procure
 the health technology, any training in its use, and all derived costs, both in the changed
 consumption patterns in connection with use of the technology and in any impact on the incidence
 of late complications and adverse reactions requiring treatment.
- The calculation of costs should be based on the technology's expected market share for the estimated patient population for each of the first five years after any recommendation as a possible standard treatment or part of a standard treatment.
- Costs of health technology etc. should be attributed to the time at which they are expected to occur and they should not be depreciated.
- Costs should be calculated in relation to their impact on the budget for the total relevant patient population across the Danish regions over a five-year period and not at individual patient level (see section 4.3).
- Costs over the five-year time horizon should be estimated without discounting.
- Any municipal co-financing should not be included.
- Costs should be reported broken down into each of the five years, and not aggregated.

Moreover, the applicant should consider and include the following, where the applicant considers relevant:

If sub-group analyses have been completed, the applicant should indicate the budget impacts if the
Danish Health Technology Council recommends the evaluated healthcare technology as a possible
standard treatment for the total population, as well as potential sub-groups.

For information on completion and good practice within the field of budget impact analyses, see Sullivan et al[4]¹⁰.

¹⁰ Sullivan et al. describes the approach to budget impact analyses of medicine, but the overall approach to the preparation of a budget impact analysis is also suitable for health technologies.

5.3. Presentation of the budget impact analysis

The budget impact analysis should be enclosed as an annex with the application to the Danish Health Technology Council, and the applicant should include a description of the assumptions behind the budget impact analysis.

In calculations made in the budget impact analysis, applicants can take their point of departure in the template budget impact analysis provided by the Danish Health Technology Council, although use of the template is not a requirement.

5.4. Unit costs

5.4.1. Staff time consumption

In reporting the budget impact analysis, applicants should state whether and how staff costs are included in the analysis. When valuing staff costs in a budget impact analysis, applicants should take outset in gross hourly pay including pension and supplements for staff employed at the hospital, as shown in table 4.

5.4.2. Overhead costs

It is not relevant to include overhead costs in the budget impact analysis. The time horizon for a budget impact analysis is relatively short (five years), and in the short term overhead costs will be classified as fixed costs (*FC*, see table 2 on page 7). The recommendation by the Danish Health Technology Council regarding the health technology and subsequent potential use of the health technology under examination is unlikely to affect fixed costs such as 'rent', water consumption, heating, administration, etc. to an extent that will have budgetary consequences within the time horizon examined.

If, nevertheless, in dialogue with the Danish Health Technology Council secretariat, the applicant deems that it is relevant to include overhead costs in the budget impact analysis, this can be done in accordance with the guidelines on the economic analysis (see section 4.5.1.2). The applicant should state this in their report.

5.4.3. Derived impacts

According to the framework for the budget impact analysis, applicants should include any derived impacts on the pressure on resources for a five-year period after the health technology has been taken into use, or phased out. In the calculation of the budgetary consequences of the derived impacts, the applicant should take the same approach as described for the economic analysis¹¹.

¹¹ DRG rates include overhead costs (see <u>guidelines on rates from the Danish Health Data Authority</u>), and this causes a certain over-estimation of the costs associated with the derived impacts, as the overhead costs will probably not be affected enough to cause budgetary impacts within the relevant time horizon.

6. Summary of key figures

Table 9 below is a collection of key figures that may be relevant for applicants in their applications. Generally, however, the Danish Health Technology Council refers to the guidance text above to ensure that the figures are up-to-date and for the unit costs that are relevant for the evaluation situation under examination.

| Hos | pital sector | | |
|---|-----------------------------|--|----------------|
| Staff | | | |
| Position | Gross hourly pay, DKK | Hourly pay (effective hrs.), DKK | Reference |
| Lead consultant/professor | 625 | 1.071 | <u>krl</u> |
| Consultant, paid according to salary grade (not lead) | 605 | 1.037 | <u>krl</u> |
| Registrar, unspec. | 356 | 611 | <u>krl</u> |
| Lead nurse | 353 | 605 | <u>krl</u> |
| Lead bioanalyst | 331 | 567 | <u>krl</u> |
| Lead occupational therapist | 329 | 564 | <u>krl</u> |
| Lead physiotherapist | 340 | 582 | <u>krl</u> |
| Lead midwife | 376 | 644 | <u>krl</u> |
| Lead radiographer | 334 | 572 | <u>krl</u> |
| Nurse, not lead | 266 | 455 | <u>krl</u> |
| Bioanalyst, not lead | 237 | 406 | <u>krl</u> |
| Occupational therapist, not lead | 235 | 402 | <u>krl</u> |
| Physiotherapist, not lead | 238 | 408 | <u>krl</u> |
| Midwife, not lead | 265 | 456 | <u>krl</u> |
| Radiographer, not lead | 244 | 418 | <u>krl</u> |
| Laboratory technician, not lead | 203 | 369 | <u>krl</u> |
| Assistant nutritionist, not lead | 191 | 328 | <u>krl</u> |
| Social and health care assistant | 247 | 424 | <u>krl</u> |
| Hospital porter, unspec. | 215 | 369 | <u>krl</u> |
| Specialist, IT staff | 318 | 546 | <u>krl</u> |
| Medical secretary, unspec. | 224 | 384 | <u>krl</u> |
| DRG rates | | | |
| Name of rate, somatic rates | Code | Rate, DKK | |
| Check of medicine pump | 01PR03 | 2.627 | DRG rates 2022 |
| Check-up examination | 23MA04 | 1.515 | DRG rates 2022 |
| Mammography, complex | 30PR13 | 3.471 | DRG rates 2022 |

| MRI-guided radiotherapy | 27PR03 | 12.068 | DRG rates 2022 |
|---|-----------------|-------------------|---|
| Thrombolytic treatment of acute apoplexy | 01MP11 | 29.044 | DRG rates 2022 |
| Post-operative and post-traumatic infections, with compl. factors | 18MA02 | 41.506 | DRG rates 2022 |
| Complications from treatment, w/out comp. sec. diag. | 21MA03 | 30.549 | DRG rates 2022 |
| Rehabilitation | 23MA01 | 63.656 | DRG rates 2022 |
| Long-term in-hospital stay | | 2.185 per day | DRG rates 2022 |
| Mental health services rates, stationary and ou | itpatient rates | | |
| Bed day | | 3.939 | Mental health services rates 2022 |
| Out-patient | | 1.971 | Mental health services rates 2022 |
| Treatment completed | | 2.185 | Mental health services rates 2022 |
| Gen | eral practice | | |
| Sec. 50 Basic service | Service no. | Remuneration, DKK | |
| Consultation | 0101 | 149 | <u>Table of</u> remuneration |
| Treatment of second insured in same home (sec. 66(1)) | 0102 | 149 | <u>Table of</u> <u>remuneration</u> |
| E-consultation (including with municipal nursing staff) | 0105 | 47 | <u>Table of</u> <u>remuneration</u> |
| Agreed specific preventative procedure ¹ | 0120 | 400 | <u>Table of</u> <u>remuneration</u> |
| Telephone consultation | 0201 | 29 | <u>Table of</u> <u>remuneration</u> |
| House call up to 4 km (zone 1) ² | 0411 | 399 | Table of remuneration |
| House call from start 5 km to 8 km (zone II) ² | 0421 | 549 | Table of remuneration |
| House call from start 9 km to 12 km (zone III) ² | 0431 | 627 | <u>Table of</u> remuneration |

| House call from start 13 km to 16 km (zone IV) ² | 0441 | 709 | <u>Table of</u> remuneration |
|---|------|-------|------------------------------|
| House call from start 17 km to 20 km (zone V) ² | 0451 | 1.096 | |
| House can from start 17 km to 20 km (zone v) | 0451 | 1.090 | <u>Table of</u> remuneration |
| House call from start 21 km to visit site ² | 0461 | 1.418 | Table of |
| Tiouse can from start 21 km to visit site | 0401 | 1.410 | remuneration |
| For each additional commenced km above 21 | 2301 | 33 | Table of |
| km | 2301 | 33 | remuneration |
| Sec. 51 Supplementary services | | | |
| Blood test from a blood vessel per | 2101 | 51 | Table of |
| consignment | | | remuneration |
| Biopsy with subsequent microscopic exam. at | 2113 | 204 | Table of |
| pathologist incl. postage | | | remuneration |
| Removal of subcutaneous or deeper tumour, | 2117 | 305 | Table of |
| incl. possible postage | | | <u>remuneration</u> |
| Postage of biological material, excl. blood | 2133 | 36 | <u>Table of</u> |
| samples (also includes submission of urine for | | | remuneration |
| microalbuminuria exam. and swabs) | | | |
| Sec. 60 Laboratory tests | | | Table of |
| | , | | <u>remuneration</u> |
| Urine test with test strip | 7101 | 14 | <u>Table of</u> |
| | | | <u>remuneration</u> |
| Machine leukocyte and differential count | 7115 | 42 | Table of |
| | | | remuneration |
| C-reactive protein (CRP) | 7120 | 69 | Table of |
| | | | <u>remuneration</u> |
| PP-INR (coagulation factors) | 7126 | 125 | Table of |
| | | | <u>remuneration</u> |

| Specialist practice | | | | |
|---|----------------|-------------------|---------------|--|
| Dermatology, sec. 1(1) | Service no. | Remuneration, DKK | | |
| E-consultation | 0105 | 77 | Rate card 21A | |
| Advice by telephone/counselling per EDIFACT for general practitioners | 0107 | 269 | Rate card 21A | |
| 1st consultation | 0110 | 538 | Rate card 21A | |
| Later consultation | 0130 | 163 | Rate card 21A | |
| Tele-dermatology | 0140 | 327 | Rate card 21A | |
| Telephone consultation | 0201 | 81 | Rate card 21A | |
| Neurology sec. 1(1) | Service no. | Remuneration, DKK | | |

| E-consultation | 0105 | 77 | Rate card 20C |
|--|-----------------------|-------------------------------------|---------------|
| Advice by phone for general practitioner | 0205 | 375 | Rate card 20C |
| 1st consultation - preliminary interview | 0110 | 869 | Rate card 20C |
| Later consultation | 0130 | 532 | Rate card 20C |
| Telephone consultation | 0201 | 177 | Rate card 20C |
| Assistance from ophthalmologist sec. 1(1) | Service no. | Remuneration, DKK | |
| E-consultation | 0105 | 75 | Rate card 14B |
| Advice by phone for general practitioner | 0205 | 127 | Rate card 14B |
| 1st consultation | 0110 | 254 | Rate card 14B |
| Later consultation | 0130 | 113 | Rate card 14B |
| Telephone consultation | 0201 | 56 | Rate card 14B |
| Diabetic eye examination | 0111 | 785 | Rate card 14B |
| Photo screening for diabetic eye disease | 0112 | 523 | Rate card 14B |
| Rheumatology sec. 1(1) | Service no. | Remuneration, DKK | |
| E-consultation | 0105 | 76 | Rate card 28A |
| Advice by telephone/counselling per EDIFACT for practicing medical specialists | 0205 | 336 | Rate card 28A |
| 1st consultation | 0110 | 1.120 | Rate card 28A |
| Later consultation | 0130 | 156 | Rate card 28A |
| Telemedicine video consultation | 0140 | 533 | Rate card 28A |
| Telephone consultation | 0201 | 74 | Rate card 28A |
| Check-up for patients in DMARD-treatment by telephone or e-mail | 0107 | 219 | Rate card 28A |
| Iv | Iunicipal sector | | |
| Staff | | | |
| Position | Gross hourly pay, DKK | Hourly pay (effective hrs.), DKK | |
| Municipal physician, not specified | 561 | 841 | <u>krl</u> |
| Nursing home assistant | 253 | 433 | <u>krl</u> |
| Social and health care assistant | 240 | 411 | <u>krl</u> |
| Social and health care helper | 226 | 387 | <u>krl</u> |
| Nursing aide | 246 | 422 | <u>krl</u> |
| Lead occupational therapist | 343 | 588 | <u>krl</u> |
| Lead physiotherapist | 345 | 591 | <u>krl</u> |
| Lead health visitor | 369 | 633 | <u>krl</u> |
| Lead nurse | 347 | 595 | <u>krl</u> |
| Non-lead ergotherapist | 251 | 431 | <u>krl</u> |

| | | · · · · · · · · · · · · · · · · · · · | |
|--|-----|---|---------------------------|
| Non-lead physiotherapist | 248 | 425 | <u>krl</u> |
| Non-lead health visitor | 271 | 465 | <u>krl</u> |
| Non-lead nurse | 267 | 457 | <u>krl</u> |
| Transport | | DKK 3.51/km DKK | Tax Agency |
| Patients and their families | | | |
| Time spent on treatment | | 271.80/Hour DKK www | w.statistikbanken .dk |
| Transport costs per hospital consultat | ion | 140/consultation DKK or 3.51/km DKK | www.sktst.dk www.kl.dk |

Table 9. Key figures

7. Changes log

| Version | Date | Subject |
|---------|------------|---|
| 1.0 | 24-09-2021 | |
| 1.1 | 23-03-2022 | Broken links, misspelling and typos |
| 1.2 | 16-05-2022 | Update of economic ratios and DRG-rates |

8. References

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