# Evaluation proposal for the Danish Health Technology Council regarding <technology> for <treatment/use/diagnosis of/in patient population<

**Instructions for the applicant**

This template is used for submitting evaluation proposals to the Danish Health Technology Council in connection with the request of an assessment of new or existing health technology. Evaluation proposals are completed by the applicant and aim to provide the Danish Health Technology Council with a background for launching evaluations. Applicants are recommended to engage in a dialogue with the Danish Health Technology Council’s secretariat to receive guidance for proper completion.

The template covers the following main topics:

* Information about the applicant
* Information about the health technology
* Information about the evidence base for the health technology

The Danish Health Technology Council defines health technologies broadly as any use of medical devices, procedures, or processes applied in the treatment or diagnosis of patients. Evaluations of health technologies by the Danish Health Technology Council are always conducted with the consideration of four perspectives: Clinical Effectiveness and Safety, the Patient Perspective, Organizational Implications, and Health Economics.

Evaluation proposals that are considered by the Danish Health Technology Council will be published on the Danish Health Technology Council’s website. If there is confidential information in the evaluation proposal, it must be clearly marked using yellow text highlighting ("example").

The evaluation proposal should be kept as concise as possible and be in either Danish or English. At the end of the document, there is an example of a completed evaluation proposal that applicants can use for inspiration.

If questions arise during the preparation of the evaluation proposal, applicants may contact the Danish Health Technology Council's secretariat for elaboration or clarifications.

In addition to the evaluation proposal, companies, regions, and hospital administrations can complete and include a cost outline that provides an overview of the total costs associated with the use of the health technology. The Danish Health Technology Council’s secretariat provides a cost outline template that can be accessed on the Danish Health Technology Council’s [website](https://behandlingsraadet.dk/).

The completed evaluation proposal is the applicant's product.

## **Information about the applicant**

Name of the applicant (company name or the name of the hospital/region)\*:

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\* If you are a public applicant, the Danish Health Technology Council refers to the requirement that the evaluation proposal in its entirety must be approved by the hospital or regional management.

Contact person (name, position):

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Date of submission of the evaluation proposal:

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## **Information about the health technology**

Briefly describe the health technology to be evaluated:

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Provide a rationale for why it is relevant to conduct an evaluation of the health technology:

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What is the classification of the health technology?

[ ] Medical device, which is CE marked\*

 [ ]  Class I

 [ ]  Class IIA

 [ ]  Class IIB

 [ ]  Class III

[ ] Diagnostic technology, which is CE marked\*\*

 [ ]  Class A

 [ ]  Class B

 [ ]  Class C

 [ ]  Class D

[ ] Procedure (workflow related to diagnostics, treatment, rehabilitation, and/or with a preventive purpose)

If the procedure involves the use of one dominant health technology, describe it, and provide its CE marking and classification

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\* The Danish Health Technology Council only evaluates medical devices that are CE marked or otherwise meets the legal requirements for medical devices.
\*\* Diagnostic technology utilizing medical equipment for *in vitro* diagnostics.

[ ]  the applicant hereby declares under penalty of perjury that the above information is accurate and complies with the relevant legislation concerning CE marking.

Briefly describe the current status of the use of the health technology in Denmark and abroad.

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Proposed PICO specification (Population, Intervention, Comparator, Outcome) for framing the evaluation question:

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| Population – The patient group in/for which the health technology is utilized and which the evaluation focuses on, including the annual number of patients in Denmark: |  |
| Intervention – The specific health technology to be evaluated: |  |
| Comparator – The health technology or treatment that is natural to compare with and currently used as the best and most widely adopted alternative to the intervention in Denmark (I):  |  |
| Outcome – The clinical effectiveness measures that would be relevant to assess the health technology compared to the comparator are: |  |

 \* PICO is a tool utilized by the Danish Health Technology Council to formulate precise issues and is crucial in the planning and execution of an evaluation by the Danish Health Technology Council. PICO is further detailed in the Danish Health Technology Council's methods guide, available on the Danish Health Technology Council's [website](https://behandlingsraadet.dk/).

Provide a brief description of the proposed comparator and whether the suggested health technology (intervention) is suggested to replace or to be an add on to the current alternative:

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Is the health technology mentioned in professional clinical guidelines from institutions like the Danish Health Authority or medical scientific societies? Specify which ones:

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Has the health technology been evaluated by other HTA institutions (e.g. NICE, Nye Metoder)? Specify which ones:

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Provide the names of manufacturers/suppliers of the health technology, if relevant:

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**Information about the evidence base for the health technology:**

Indicate whether the health technology (compared to the current alternative) aims to improve treatment/diagnosis of the patient group as perceived from one or more of the following perspectives (indication of the primary impact of using of the health technology):

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| [ ]  Clinical effectiveness and safety | [ ]  Patient preferences and experiences |
| [ ]  Organizational aspects, such as changes to workflows | [ ]  Costs associated with treatment/diagnostics |

\*For the evaluation of health technologies, the Danish Health Technology Council employs four perspectives: Clinical Effectiveness and Safety, the Patient Perspective, Organizational Implications, and Health Economics. For further elaboration on these perspectives, refer to the Danish Health Technology Council Council's methods guide for the evaluation of health technologies, available on the Danish Health Technology Council Council's [website](https://behandlingsraadet.dk/).

State the expected impact of the health technology within the indicated perspectives above:

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Provide references\* for documentation of the health technology's effects (if possible, include up to 2 key references per perspective):

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| Clinical effectiveness and safety | 1.2. |
| The Patient perspective | 1.2. |
| Organizational Implications | 1.2. |
| Health Economics | 1.2. |

\* Reference to published, ongoing, or unpublished data.

Indicate whether the health technology is expected to incur additional costs, cost reductions, or be cost-neutral compared to the current alternative. Briefly describe how the costs are expected to be distributed across sectors (hospital, general practice, municipalities, patients, etc.), and what is considered to drive the potential addition or reduction in costs. The Danish Health Technology Council encourages applicants to complete and include the Danish Health Technology Council's cost outline, accessible on the Danish Health Technology Council's [website](https://behandlingsraadet.dk/).

[ ]  Additional costs

[ ]  Cost reductions

[ ]  Cost-neutral

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Free-text field (optional additional information, max 300 words):

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# \*\*\*Example\*\*\*

Evaluation proposal to the Danish Health Technology Council regarding non-operative treatment of distal radius fractures in patients over 65 years of age.

## **Information about the applicant**

Name of the applicant (company name or the name of the hospital/region)\*:

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| The evaluation proposal has been prepared by the Danish Health Technology Council’s secretariat. |

\* If you are a public applicant, the Danish Health Technology Council refers to the requirement that the evaluation proposal in its entirety must be approved by the hospital or regional management.

Contact person (name, position):

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| Anders Andersen, Health Science Officer, the Danish Health Technology Council’s secretariat |

Date of submission of the evaluation proposal:

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| June 5 2023 |

## **Information about the health technology**

Briefly describe the health technology to be evaluated:

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| Non-operative treatment in the form of applying a cast for distal radius fractures.In cases of distal radius fracture, the application of a cast can be utilized to stabilize the fracture and promote proper healing. |

Provide a rationale for why it is relevant to conduct an evaluation of the health technology:

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| New evidence indicates that the clinical effectiveness of surgical treatment and non-invasive treatment with a cast is comparable in terms of outcomes such as physical function and complications (see references for Clinical Effectiveness and Safety). Despite the lack of evidence supporting surgical treatment over casting in this patient group, there is a reported increase in the number of surgeries for distal radius fractures, which could be associated with greater resource consumption than conservative treatment (see references for Health Economics). Therefore, applying a cast for distal radius fractures in patients over 65 years of age might be a cost-effective alternative if the clinical effectiveness is comparable to surgical treatment. |

What is the classification of the health technology?

[ ] Medical device, which is CE marked\*

 [ ]  Class I

 [ ]  Class IIA

 [ ]  Class IIB

 [ ]  Class III

[ ] Diagnostic technology, which is CE marked\*\*

 [ ]  Class A

 [ ]  Class B

 [ ]  Class C

 [ ]  Class D

[x] Procedure (workflow related to diagnostics, treatment, rehabilitation, and/or with a preventive purpose)

If the procedure involves the use of one dominant health technology, describe it, and provide its CE marking and classification

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| Not relevant |

\* The Danish Health Technology Council only evaluates medical devices that are CE marked or otherwise meets the legal requirements for medical devices.
\*\* Diagnostic technology utilizing medical equipment for *in vitro* diagnostics.

[x]  the applicant hereby declares under penalty of perjury that the above information is accurate and complies with the relevant legislation concerning CE marking.

Briefly describe the current status of the use of the health technology in Denmark and abroad.

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| Currently, casts are used both in Denmark and abroad. The application of casts is performed across all age groups for various types of fractures. |

Proposed PICO specification (Population, Intervention, Comparator, Outcome) for framing the evaluation question:

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| Population – The patient group in/for which the health technology is utilized and which the evaluation focuses on, including the annual number of patients in Denmark: | The patient population includes individuals over 65 years of age with distal radius fractures. Data from the National Patient Register reveals that in 2022, there were 7,120 patients over 65 years old with fractures at the distal end of the radius (advanced extraction). According to ‘Lægehåndbogen’, distal radius fractures encompass fractures in the lower part of the radius bone, most commonly Colle's fractures with dorsal displacement. |
| Intervention – The specific health technology to be evaluated: | The treatment approach under investigation involves non-operative treatment in the form of applying a cast. |
| Comparator – The health technology or treatment that is natural to compare with and currently used as the best and most widely adopted alternative to the intervention in Denmark (I):  | The alternative to applying a cast is surgical treatment. |
| Outcome – The clinical effectiveness measures that would be relevant to assess the health technology compared to the comparator are: | The patients' physical function, complications, mobility, grip strength, and quality of life. |

 \* PICO is a tool utilized by the Danish Health Technology Council to formulate precise issues and is crucial in the planning and execution of an evaluation by the Danish Health Technology Council. PICO is further detailed in the Danish Health Technology Council's methods guide, available on the Danish Health Technology Council's [website](https://behandlingsraadet.dk/).

Provide a brief description of the proposed comparator and whether the suggested health technology (intervention) is suggested to replace or to be an add on to the current alternative:

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| As alternatives to cast treatment for distal radius fractures, several surgical methods are used, including volar locking plate fixation, external fixation, or percutaneous pinning, as indicated by ‘Lægehåndbogen’. These three surgical methods involve different health technologies aimed at maintaining fracture stability. According to ‘Patienthåndbogen’, the choice of surgical method depends on the specific fracture, bone quality, and other patient-specific factors. ‘Lægehåndbogen’ notes that in certain cases, it might be necessary to combine different surgical methods.It is expected that cast treatment could replace surgical treatment for distal radius fractures in a portion of the patient population. |

Is the health technology mentioned in professional clinical guidelines from institutions like the Danish Health Authority or medical scientific societies? Specify which ones:

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| The Danish Health Authority published a National Clinical Guideline in 2013, which is no longer in effect:Sundhedsstyrelsen. National Klinisk retningslinje for behandling af håndledsnære brud (distal radiusfraktur). 2013.The American Academy of Orthopaedic Surgeons released an evidence-based clinical practice guideline on the management of distal radius fractures in 2020:American Academy of Orthopaedic Surgeons. Management of Distal Radius Fractures Evidence-Based Clinical Practice Guideline. 2020. |

Has the health technology been evaluated by other HTA institutions (e.g. NICE, Nye Metoder)? Specify which ones:

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| In 2017, SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) investigated the treatment of arm fractures, including distal radius fractures, in patients over 60 years of age:Swedish Agency for Health Technology Assessment and Assessment of Social Services. Treatment options of arm fractures in the elderly. 2017. |

Provide the names of manufacturers/suppliers of the health technology, if relevant:

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| There are several manufacturers of medical casts. |

**Information about the evidence base for the health technology:**

Indicate whether the health technology (compared to the current alternative) aims to improve treatment/diagnosis of the patient group as perceived from one or more of the following perspectives (indication of the primary impact of using of the health technology):

|  |  |
| --- | --- |
| [ ]  Clinical effectiveness and safety | [ ]  Patient preferences and experiences |
| [x]  Organizational aspects, such as changes to workflows | [x]  Costs associated with treatment/diagnostics |

\*For the evaluation of health technologies, the Danish Health Technology Council employs four perspectives: Clinical Effectiveness and Safety, the Patient Perspective, Organizational Implications, and Health Economics. For further elaboration on these perspectives, refer to the Danish Health Technology Council Council's methods guide for the evaluation of health technologies, available on the Danish Health Technology Council Council's [website](https://behandlingsraadet.dk/).

State the expected impact of the health technology within the indicated perspectives above:

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| Organizational aspects:* Reducing the number of surgical procedures for distal radius fractures can lead to decreased resource consumption and specialized healthcare personnel (Navarro et al, 2019).
* Fewer surgical procedures can have a positive impact on hospitalization and operation room capacity.
* Reduced surgical procedures may decrease the demand for physiotherapy and home care (Hassellund et al, 2021).

Health economics:Treatment with casts is cost-effective compared to surgical treatment. This holds true for both short and long-term perspectives. |

Provide references\* for documentation of the health technology's effects (if possible, include up to 2 key references per perspective):

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| --- | --- |
| Clinical effectiveness and safety | 1. Li Q, Ke C, Han S, Xu X, Cong Y-X, Shang K, et al. Nonoperative treatment versus volar locking plate fixation for elderly patients with distal radial fracture: a systematic review and meta-analysis. J Orthop Surg Res. juli 2020;15(1):263.
2. Thorninger R, Wæver D, Tjørnild M, Lind M, Rölfing JD. VOLCON: a randomized controlled trial investigating complications and functional outcome of volar plating vs casting of unstable distal radius fractures in patients older than 65 years. Journal of Orthopaedics and Traumatology. 2022;23(1).
 |
| The Patient perspective | 1. Healy S, Dorflinger E, Michaleff ZA, Marks D. Patient preferences and decision‐making when considering surgery for musculoskeletal disorders: A mixed methods systematic review. Musculoskeletal Care. 15. november 2022.
 |
| Organizational Implications | 1. Navarro CM, Brolund A, Ekholm C, Heintz E, Ekström EH, Josefsson PO, et al. Treatment of radius or ulna fractures in the elderly: A systematic review covering effectiveness, safety, economic aspects and current practice. PLoS One. 2019;14(3):1–28.
 |
| Health Economics | 1. Navarro CM, Brolund A, Ekholm C, Heintz E, Ekström EH, Josefsson PO, et al. Treatment of radius or ulna fractures in the elderly: A systematic review covering effectiveness, safety, economic aspects and current practice. PLoS One. 2019;14(3):1–28.
2. Hassellund S, Zolic-Karlsson Z, Williksen JH, Husby T, Madsen JE, Frihagen F. Surgical treatment is not cost-effective compared to nonoperative treatment for displaced distal radius fractures in patients 65 years and over. Bone Jt Open. december 2021;2(12):1027–34.
 |

\* Reference to published, ongoing, or unpublished data.

Indicate whether the health technology is expected to incur additional costs, cost reductions, or be cost-neutral compared to the current alternative. Briefly describe how the costs are expected to be distributed across sectors (hospital, general practice, municipalities, patients, etc.), and what is considered to drive the potential addition or reduction in costs. The Danish Health Technology Council encourages applicants to complete and include the Danish Health Technology Council's cost outline, accessible on the Danish Health Technology Council's [website](https://behandlingsraadet.dk/).

[ ]  Additional costs

[x]  Cost reductions

[ ]  Cost-neutral

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| Treatment with casts is cost-effective compared to surgical treatment. This holds true for both short and long-term perspectives. The cost reduction is primarily driven by the primary treatment costs (Hassellund et al, 2021). The costs associated with the primary treatment incur in the hospital sector, while subsequent treatment-related costs might also be affected the municipal sector and general practice.The cost components in the identified studies have been validated in the Danish Health Technology Council's cost outline and do not significantly change when using Danish key figures. |

Free-text field (optional additional information, max 300 words):

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