HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH

AIHTA final research programme 2025

The following projects will be processed in 2025:

- 3 Programme lines (continuation of ongoing work)
- 8 Individual projects Shareholders
- Appraisal board work
- 5 Self-initiated projects
- 6 Third-party funded projects

Content

Programme Lines

1. Horizon Scanning in Oncology: Early Assessment of New Oncologicals

https://aihta.at/page/horizon-scanning-in-der-onkologie-berichte/de

Project lead: Sabine Geiger-Gritsch
Project team: flexible
Duration: ongoing since 2009; new concept from 2025 (9.7 PM)
Language: English

Subject: Early assessments of new oncologicals have been carried out since 2009 to support decision-making by (regional) drug commissions and payers. As part of the HSO project, early assessments (n=91) of selected new oncologicals were prepared by the end of 2019, for which significant financial and/or therapeutic consequences were predicted. Due to the changing European environment, fact sheets on all new drug-based cancer therapies have been prepared monthly since 2020 (n=190) and categorised using the ESMO scale (magnitude of clinical benefit/MCBS). From 2025, all new oncology drugs will be assessed in European cooperation as part of the HTA regulation and the assessments will be available just 1-2 months after authorisation.

For this reason, the existing programme line will be changed:

Method:

- Contextualisation of the European HTAs on oncologicals
- Advance planning of the notified oncologicals for budgeting

Timetable: January to December 2025

2. Evaluation of Individual Medical Procedures/Devices (MEL)

https://aihta.at/page/bewertung-medizinischer-einzelleistungen-mel-berichte/de)

Project lead: Gregor Götz
Project team: different AIHTA researchers for individual MELs
Duration: since 2009, always from November to March (17.5 PM)
Publication: July15th, 2025
Language: English (with German summary)

Subject: Every year, numerous new medical interventions are proposed to the Federal Health Agency (BGA) for reimbursement in the catalogue of services (so-called individual medical services/ MEL). The task of the AIHTA is to systematically assess the effectiveness and safety of these new interventions. The topics are prioritised jointly by the Ministry (BMASGPK), the federal states and social insurance in a working group of the Federal Health Agency.

Method: Systematic reviews (evidence analyses, approx. 6-8 per year) on individual interventions in individual indications or individual interventions in several indications. Recommendation for inclusion/non-inclusion based on GRADE.

Timetable 2025: January to March 2025 and November to December 2025

3a. (Timely) Information Service for the Austrian Social Insurance Funds, time slots for ÖGK and BVAEB

https://aihta.at/page/hta-information-service-rapid-reviews/de

Project lead: Reinhard Jeindl
Project team: Reinhard Jeindl, Julia Mayer-Ferbas, Sabine Ettinger, Doris Giess
Duration: ongoing (7 PM 2025)
Publication: continuously
Language: German

Subject: The scientific support of the Austrian social insurance organisations requires a rapid, agile and timely response to enquiries. As the content of the enquiries is not known in advance, processes (registration, etc.), formats (data fields, etc.) and methods (transparent procedure, etc.) were defined so that a rapid and prompt evidence-based response is possible. The project is being carried out in the form of a framework agreement for a limited number of ad hoc questions/assessments (depending on the scope of the topics).

Topics already registered for 2025 are:

1. Ongoing supervision of DiGA work (DVSV)
2. Serum eye drops (ÖGK)
3. Telemedical interventions to support sport and exercise in people with chronic (back/joint) pain (BVAEB)
4. …..

Method: Short systematic summaries

3b. Timely Information Service for Hospitals - 1 time slot (WIGEV)

https://aihta.at/page/hta-information-service-rapid-reviews/de

Project lead: Reinhard Jeindl
Project team: Reinhard Jeindl, Sabine Ettinger, Julia Mayer-Ferbas, Doris Giess
Duration: ongoing (1 PM 2025)
Publication: continuously
Language: German

Subject: The scientific support of service departments in hospitals includes, on the one hand, the rapid, agile and timely response to enquiries and, on the other hand, the methodological support of the employees of these service departments in their preparations for various commissions in hospitals (drug commissions, equipment investments, service planning).

Topic 2925: Combination therapy (chemotherapy + immune therapy vs. Chemotherapy only) in metastatic non-small-cell-lung cancer (NSCLC)

Method: Short systematic summaries

Individual Projects (Shareholders)

1. Telecardiology for heart failure patients: Benefit assessment and evaluation concept for telemedicine-supported care programs in Austria

Project lead: Michal Stanak
Project team: Michal Stanak, Michaela Riegelnegg
Internal review: Gregor Goetz
Duration: April to November 2025
Language: English (with German summary)

Background:

Cardiovascular diseases (CVDs) are one of the leading causes of premature death worldwide [1]. The WHO 2024 report states that in the European region alone, more than 40% of all deaths were due to CVDs [1]. Heart failure (HF) constitutes a subset of this group and is the most common cause of hospitalisation in patients over 65 years of age [2]. HF is a chronic disease characterized by reduced capacity of the heart to pump enough blood and oxygen to supply the organs of the body. This can be associated with deterioration of physical performance [3].

Various approaches have been developed for the treatment of heart failure. In addition to usual care (outpatient visits or hospitalisation), integrated care approaches are becoming established for HF patients through disease management programs (DMPs), which coordinate fragmented care after hospital discharge [4]. These programs aim to improve survival rates, reduce hospital readmissions, and improve quality of life [5]. DMPs are increasingly being supplemented by telemedicine (invasive or non-invasive, e.g., via an app). Due to the complexity and heterogeneity of such additional telemedical interventions, European projects such as the ASSESS-DHT are working on methods to facilitate the assessment of added value of such care programs [6].

As an addition to DMPs, patients with HF can be monitored at distance via the means of telemedicine, i.e. through the use of information and communication technologies. Telemedicine is not a standalone discipline, but it encompasses a variety of digital working methods used within a discipline, in this case cardiology [7]. Telemedicine covers a range of interventions from simple ones, such as s telephone call, to more complex ones, such as an app that may or may not be connected with other stand-alone technologies. An example of a comprehensive telemedical program is HerzMobil Tirol, which uses, among other things, a mobile app for daily documentation and transfer of information such as blood pressure, heart rate, weight, well-being, and drug intake [4]. Based on this information, early signs of deterioration may be detected, relevant therapy adjustments may be considered more quickly, and adherence to medication may be better monitored, thus preventing additional complications and potential hospital readmissions [8].

In Austria, the situation regarding the care of HF patients is currently inconsistent. While selected federal states already have DMPs for HF patients, a nationally uniform care model for HF patients does not exist and is still under development [9]. Some of these federal state-specific DMPs already include telemedical components, while others consist of a series of individual home visits by trained medical professionals without telemedical care components [10]. The actual effects of telemedical care in addition to DMPs on clinical and organisational outcomes remain unclear and will therefore be investigated in this project.

Project goals:

The project aims to:

- systematically assess the evidence on clinical care effects (effectiveness and safety) and organizational care effects (utilization) of an additional non-invasive telemedical component to DMPs/integrated care/structured care models for HF patients compared to DMPs without a telemedical component, or, in case of the absence of evidence,
    - assess the clinical and organizational care effects of telemedicine with DMPs compared to standard care, and
- develop an evaluation concept for the assessment of added benefit of digital health technologies as part of DMPs, and
- investigate the practical applicability of the ASSESS-DHT manual for the assessment of digital health technologies.

Non-objectives:

The project does not aim to:

- systematically assess the added benefit of DMPs without telemedicine (e.g. only home visits) and
- systematically assess the cost-effectiveness of the telemedical component in DMPs.

Research questions:

The following research questions (RQ) will be answered in the course of the report:

RQ1: What evidence is available for the clinical and organizational care effects of a non-invasive telemedical component to DMPs/integrated care or structured care models for patients with heart failure compared to DMPs/integrated care or structured care models without this component?

If no evidence is available to answer the question above, the following question with be assessed: What clinical and organizational care effects does telemedicine demonstrate in combination with DMPs/integrated care or structured care models compared to standard care?

RQ2: How can the clinical and organizational care effects of digital health technologies in DMPs be assessed?

Methods: Systematic review of literature for non-invasive telemedical components to DMPs for HF patients using the EUnetHTA Core Model 3.0 or ASSESS DHT manual.

RQ1: systematic review of literature

- conduct a systematic search to identify available literature on non-invasive telemedical components to DMPs for HF patients,
- document the identified publications in a table,
- extract the predefined data from the publications or systematic reviews, and
- synthesise the findings.

RQ2: development of an evaluation concept based on RQ1

- analyse previously conducted studies (e.g., which study designs have been used internationally to evaluate comparable interventions),
- compare with the ASSESS-DHT manual (e.g., what evidence should be available, how should it be collected, which study designs should be used)
- document the results in narrative form.

Inclusion criteria:

	Inclusion	Exclusion
Population	HF patients after hospitalisation	-
Intervention	Non-invasive telemedical intervention in addition to DMPs	Telemedical interventions not combined with DMPs
Comparison	DMPs without a telemedical component/ if there is not evidence: Standard care	-
Outcome	▪ All cause mortality and HF mortality, ▪ All cause hospitalization and HF hospitalization, ▪ Length of stay ▪ Quality of life, ▪ Adherence, ▪ Utilization, ▪ Benefits for healthcare professionals, ▪ Quality of collaboration between professional groups (physicians, nurses, etc.)	-
Language	English, German	Other languages
Publication Type	RQ1: Prospective randomised controlled trials, Systematic reviews, HTA reports, all from 2010 onwards RQ2: no limitation	-

All steps including study selection, data extraction are performed by two researchers. The results will be reviewed by an AIHTA reviewer (internal review) and at least one external peer reviewer.

Timetable and milestones:

Period	Tasks
April 2025	Scoping and finalising the project protocol.
May 2025	-
June-July 2025	Identifying literature for application areas: systematic literature search and hand search. Data extraction.
August – September 2025	Development of an evaluation concept, drafting the report
October 2025	Internal and external review
November 2025	Layout and publication

References:

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[2] Benjamin EJ et al (2017) Heart disease and stroke statistics-2017 update: a report from the American Heart Association. Circulation 135:e146–e603

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[5] Egelseer-Bruendl, T., Jahn, B., Arvandi, M. et al. Cost-effectiveness of a multidimensional post-discharge disease management program for heart failure patients—economic evaluation along a one-year observation period. Clin Res Cardiol 113, 1232–1241 (2024). https://doi.org/10.1007/s00392-024-02395-5.

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2. Artificial Intelligence in Health Care: Evaluation of the Clinical and Organizational Impacts of selected AI Applications in Hospitals

Project lead: Judit Erdos
Project team: Judit Erdos, Lena Grabenhofer
Internal review: Gregor Goetz
Duration: Mid- April to Mid- November 2025 (6 PM)
Language: English (with German summary)

Background:

Artificial intelligence (AI) is a field of computer science that aims to imitate human cognitive abilities. It is becoming increasingly important and is expected to have a significant impact on various areas of society, such as education, research, and medicine [1]. AI is already being used in various areas of healthcare [2]. In the majority of healthcare applications, AI can be conceptualized as a digital health technology (DHT), functioning either as a standalone medical device (software as a medical device) or as software integrated within a medical device (software in a medical device) [3]. As healthcare continues to digitalise, AI-enabled DHTs are expected to be integrated across various medical applications, especially in the hospital sector [4].

The Austrian Institute for HTA (AIHTA) published a report [4] on the methodological approaches for evaluating the benefits and risks of AI-enabled DHTs in hospital procurement decisions and provided an overview of assessments conducted by various international HTA organisations on such technologies. AI-enabled DHTs were used across a wide range of medical specialties. Most assessments (90%) focused on radiology and internal medicine, with diagnostics as the main application. Across the analysed 27 assessments in diagnostics, 134 individual AI-enabled DHTs were identified. In Austria, a 2022 report by the Austrian Health Institute (Gesundheit Österreich GmbH/ GÖG) identified 43 AI-enabled DHTs deployed either as pilot projects or already in routine hospital operation [5]. These were grouped into three main categories: risk prediction, treatment improvement and diagnostics. In this report most AI projects fell into the diagnostics category (54%), followed by treatment improvement (27%), and risk prediction (18%). Hence, the focus at both the international and national level lies primarily on the diagnostic use of AI.

Regarding the methodological aspect, the AIHTA report recommended to use existing frameworks for DHTs, supplemented with AI-specific components [4]. The ASSESS-DHT project, a European initiative, was highlighted as a structured starting point for such evaluations [6].

Based on the GÖG report [5] and the AIHTA report [4], AI-enabled DHTs in diagnostic imaging and in documentation/administration support were selected by the decision-makers for further assessment. Administrative AI tools, such as automatic notetaking, have already been implemented in several countries and show potential for improving efficiency by freeing up clinicians' time. Meanwhile, diagnostic imaging AI-enabled DHTs continue to gain ground as technologies that have the potential to enhance diagnostic accuracy. Despite their considerable potential, these technologies also pose notable risks—such as documentation errors or hallucinations, and the potential for overdiagnosis and overtreatment in imaging diagnostics—that must be carefully weighed through a thorough benefit-risk assessment prior to clinical implementation [7].

While AI-enabled DHTs hold great promise for improving efficiency, accuracy, and accessibility, their use also raises critical questions. The adoption of AI is expected to affect many aspects of care, including resource allocation, staffing, patient outcomes, and the

organization of health systems. Ethical and legal aspects such as data privacy, equity of access, and legal responsibility in AI-supported decisions represent additional considerations that may apply to certain use cases [7].

Project goals:

The aim of this project is:

1. to provide an overview of AI-enabled DHTs in the field of documentation support and diagnostic imaging and prioritise those currently in use or considered most relevant in Austrian hospitals, and
2. to evaluate the clinical and organisational impacts, as well as the types of resources to be considered, of two AI-enabled DHTs selected from this overview by Austrian healthcare experts.

Non-goals:

These are **not** within the scope of this project:

- To systematically evaluate AI-enabled DHTs other than the selected ones,
- To conduct a systematic search or comprehensive market analysis of AI systems (DHTs, products) in diagnostic imaging or documentation support,
- To systematically analyse ethical and legal aspects and cost impacts in monetary terms.

Research questions:

The following research questions (RQ) will be answered in the course of the report:

RQ1: Which AI-enabled DHTs in the fields of documentation support and diagnostic imaging are considered most relevant in Austrian hospitals by Austrian healthcare experts?

RQ2: What is the clinical and organisational impacts and what types of resources are needed for the implementation of selected AI-enabled DHTs in documentation support and diagnostic imaging? Specifically, sub-questions for the selected applications:

RQ2 A: *Documentation support*:

- How do the selected AI-powered documentation support systems affect the time healthcare providers spend on administrative tasks in hospitals?
- What are the potential benefits and challenges of AI documentation systems from the perspective of healthcare providers in terms of usability, accuracy, satisfaction, and possible disadvantages?
- What types of resources are needed related to acquisition and setting up the new technology?
- How does the technology modify the need for other technologies and use of resources?

RQ2 B: *Diagnostic imaging*:

- How do the selected AI applications in diagnostic imaging affect the accuracy and efficiency of diagnoses in hospitals, including any potential risks, limitations, or unintended consequences?
- What are the organizational impacts of integrating AI into diagnostic imaging practices in terms of workflow, staff training, and resource allocation?
- Which types of resources are affected by processes related to acquisition and setting up the new technology?
- How does the technology modify the need for other technologies and use of resources?

Methods:

RQ1:

- An overview of AI systems for diagnostic imaging and documentation support will be compiled using the AIHTA and GÖG reports as primary sources.
- A structured expert survey will be conducted with selected Austrian stakeholders (i.e., experts from the GÖG report, members from an internal expert pool, and selected representatives from Austrian hospital operators). Experts will be asked to prioritise AI applications of the long list based on criteria such as clinical relevance (novelty of the technology, addressing clinical need, potential to improve patient outcomes or clinical workflows, and availability of evidence), resource implications (frequency of use, costs, expected impact on healthcare resource use), and feasibility of implementation (including potential barriers such as organisational resistance, infrastructure limitations, data security concerns) and potential risks or unintended consequences (e.g. diagnostic errors, increased workload, ethical concerns).

  Survey design (TBD): point allocation system (i.e. we provide each respondent with a fixed number of points (e.g., 100 points) and ask them to distribute these points among the list items based on their perceived relevance or importance. Items that are considered most important would receive more points.) OR Top N selection (Instead of ranking all items, ask respondents to select their top 3, 5, or 10 items from the list).

RQ2:

- Clinical and organisational evaluation, including the impact on types of resources of the selected AI-enabled DHTs using the EUnetHTA Core Model [8] as an established European evaluation framework. The AIHTA recommendations [4] and the new European HTA methodology [6] (currently under development by ASSESS-DHT) will be applied as complementary resources. These assessments will serve as a pilot implementation of the ASSESS-DHT methodology.

The final protocols for RQ2 (A+B) will be developed once the prioritisation is complete, and these will be made public in June via OSF.

All steps (literature screening and selection, data extraction, and quality control) will be conducted by two researchers. Results will undergo an internal review by an AIHTA reviewer and an external peer review by at least one subject matter expert.

Timetable and milestones:

Period	Tasks
April 2025	Scoping und finalising the project protocol
May 2025	Compiling the overview of the AI-enabled DHTs in diagnostic imaging and administration support, followed by a structured expert survey to prioritise the listed DHTs
June-July 2025	Conducting the assessment of clinical and organisational impacts and related resources of two selected AI-enabled DHTs
August – September 2025	Evidence synthesis
October 2025	Internal and external review
November 2025	Layout und publication

References:

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3. Human Genetic Testing in Austria: An Overview of Reviews of Massive Parallel Sequencing (MPS) - Application Areas, Clinical Evidence, and Implications for Healthcare

Project lead: Gregor Goetz
Project team: Gregor Goetz, Reinhard Jeindl, Alba Colicchia
Internal review: Sabine Geiger-Gritsch
Duration: April 2025 – November 2025 (7 PM)
Language: English (with German summary)

Background:

Human genetic testing encompasses various methods for analysing human genetic material. Massive parallel sequencing (MPS) – including Next Generation Sequencing (NGS/Short-Read) and Third Generation Sequencing (TGS/Long-Read) – has emerged as a key technology. These methods enable simultaneous analysis of numerous DNA fragments, making genetic diagnostics faster while significantly expanding applications in medical care. This development creates new possibilities in diagnostics and therapy planning but also raises complex questions regarding evidence assessment, integration into standard care, and ethical implications. The increasing availability of these technologies requires evidence-based decision-making foundations for healthcare systems [1].

The benefit assessment of human genetic testing is complex. On one hand, primary studies and systematic reviews on genomic data showed methodological weaknesses and limited evidence regarding patient-relevant endpoints [2, 3]. On the other hand, genomic medicine offers potential for more meaningful study designs through targeted patient selection strategies and validated surrogate markers for more efficient and adaptive study designs [4].

A recent, unpublished review by GÖG (Gesundheit Österreich GmbH) analysed human genetic services, including organisational aspects, in selected countries (Belgium, Netherlands, Germany) [5]. The analysis focused on service catalogues, reimbursement systems, and access pathways to genetic diagnostics, identifying significant differences between countries regarding structure, level of detail, and scope of genetic service catalogues. Additionally, a recent AIHTA Rapid Review provided an overview of sequencing technologies already in use and under development, as well as their application fields [6].

Both the GÖG report [5] and the AIHTA Rapid Review [6] identified a broad spectrum of application fields for human genetic testing, primarily aiming at personalised medicine through genetic diagnosis of rare diseases and metabolic disorders, molecular pathology testing in oncology (tumor profiling, liquid biopsy), or pharmacogenetics. Both reports particularly emphasised requirements for genetic counseling, quality assurance systems, and cross-national cooperation models for rare genetic diseases. The challenges in implementing MPS technologies were also addressed: large data volumes, high costs, complex result interpretation, and ethical questions regarding incidental findings.

Building on this preliminary work, the present project aims to systematically map clinical indications categorised by application fields, evaluate the clinical evidence of selected MPS technologies, particularly as Austrian social insurance providers (SV) are planning a benefit catalogue for human genetic testing.

Project Objectives:

This project aims to systematically review evidence from systematic reviews on human genetic testing with a focus on MPS technologies for decision-makers in the Austrian healthcare system. Specifically:

1. Identification of clinical indications structured by application fields of human genetic testing from systematic reviews/HTA reports.
2. Assessment of evidence on the benefits of selected MPS-tests, considering diagnostic accuracy as "linked evidence" as well as reported clinical consequences and patient-relevant endpoints.

3. Structured presentation of organisational, economic, and ethical implications of selected MPS tests.
4. Provision of a basis for prioritising human genetic services with a focus on MPS for possible inclusion in the benefit catalogue.

Non-Objectives:

The following aspects will not be addressed in the project:

- Complete de novo assessment of all available human genetic tests
- Detailed cost analyses or budget impact analyses of individual tests
- Legal assessment of data protection and liability issues
- Systematic evaluation of primary studies on individual genetic tests

Research Questions:

RQ1: Which clinical indications structured by application fields for human genetic testing are evaluated in systematic reviews and HTA reports?

RQ2: What evidence exists on the benefits of prioritised human genetic testing regarding:

- diagnostic accuracy as "linked evidence"
- clinical consequences and patient-relevant endpoints (e.g., therapy changes, morbidity, mortality, quality of life)

RQ3: What organisational, economic, and ethical implications are reported in the literature in connection with the prioritised human genetic tests?

Methods:

Study Design

Overview of Reviews with multi-stage approach:

1. Initial scoping: Comparison of an SV list of human genetic services with international literature
2. Short-list: Prioritisation of 3-5 tests/indications in coordination with the umbrella organisation of Austrian Social Insurance Providers (DVSV). Economic implications (e.g., estimated quantities, costs) will be assessed together with the Social Insurance providers to create the short-list.
3. Evidence analysis: Systematic synthesis for prioritised MPS/indications

PICO: Literature inclusion criteria:

	Inclusion	**Exclusion**
Population	Persons with clinical indication for human genetic testing	Healthy subjects, animal models
Intervention	Human genetic testing using MPS technologies (Short-Read/NGS, Long-Read/TGS)	Non-genetic diagnostics, genetic tests without MPS technology
Control intervention	Relevant comparison interventions (other diagnostic tests, no test, other human genetic testing other than MPS) or no comparison intervention	-
Outcomes	RQ1: Clinical indications structured by application fields RQ2: Effectiveness Diagnostic accuracy (sensitivity, specificity, etc.) and/or Clinical consequences/patient-relevant endpoints Safety:	Studies with exclusively technical parameters without clinical reference

	False-positive rate False-negative rate Psychological harm from false-negative test results Psychological harm from false-positive test results Number Needed to Harm (NNH) RQ3: Organisational, economic, and ethical implications	
Publication type	Systematic reviews, HTA reports, reviews with modeling studies on benefits/harms	Narrative reviews, scoping reviews, primary studies, conference abstracts, editorials, commentaries
Language	English, German	All other languages
Publication period	From 2020	Before 2020

Abbreviations: HTA...Health Technology Assessment; NGS...Next Generation Sequencing; TGS...Third Generation Sequencing

Information Sources & Search Strategy

Systematic database search:

- PubMed/MEDLINE
- Embase
- Cochrane Library
- International HTA Database
- PROSPERO (for ongoing reviews)

Hand search:

- Reference lists of identified reviews
- Websites of relevant HTA agencies (e.g., NICE, IQWiG, CADTH)
- Websites of relevant professional societies

Search strategies will be carried out using keywords and validated filters for systematic reviews.

Literature Selection and Data Extraction:

Screening: Two independent authors will screen titles/abstracts and full texts according to pre-defined criteria. The selection process will be presented in a PRISMA flow diagram.

Data extraction: Relevant information on study characteristics, methods, and main results (PICO) will be extracted using piloted data extraction tables. Extraction will be performed by one author with verification by a second person.

Quality Assessment:

The quality of included systematic reviews will be assessed using ROBIS [7] by two independent authors. The results will be considered in the data synthesis.

Data Synthesis:

RQ1: Narrative description of identified clinical indications structured by application fields with tabular overview.

RQ2: Narrative synthesis of evidence on diagnostic accuracy and clinical consequences according to the EUnetHTA Core Model for diagnostic tests [8].

RQ3: Structured summary of reported organisational, economic, and ethical implications.

All work steps will be conducted using the four-eyes principle and quality-assured through internal and external review.

Timeline:

Period	Task
April 2025	Protocol finalisation, scoping,
May – June 2025	Systematic literature search, abstract screening, comparison with SV list, development of short-list proposal
July-August 2025	Full-text screening, DVSV coordination, data extraction, quality assessment of studies
September 2025	Evidence synthesis and writing
October 2025	Creation of a first draft of the report, internal review
November 2025	External review, finalisation, publication

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4. Transition from Child and Adolescent to Adult Mental Health Services: Analysis and Comparison of International Models

Project lead: Romy Schönegger
Project team: Romy Schönegger, Yui Hidaka
Internal review: Reinhard Jeindl
Duration: February 2025 - September 2025 (5 PM)
Language: English (with German summary)

Background:

The transition from child and adolescent mental health services (CAMHS) to adult mental health services (AMHS) is a critical period. However, the transition period remains fragmented, often leading to discontinuities in care through inadequate coordination and barriers to access [1]. Studies show that up to 45% of CAMHS patients require further care in adulthood [2], yet approximately half experience discontinuity in services, and only a small proportion experience an optimal transition [3-5].

Despite international efforts such as the MILESTONE project, which identified key components for successful transitions - including early planning, collaboration, service integration, and continuity of care [3]- implementation remains inconsistent. The MILESTONE survey of 28 countries found that in 2018, only two countries, Denmark and the UK, had national or regional transition guidelines, highlighting widespread policy and structural gaps in transitional psychiatry [1].

Existing research confirms these challenges in Austria: 98.8% of professionals rate the system as inadequate, and only 16.3% report having structured transition protocols at their workplace [2]. In addition, 70.9% feel that it is not easy for patients to cope with the transition [2]. Experts emphasise the importance of integrated care approaches, improved communication between CAMHS and AMHS, adequate resource allocation or generation and statutory guidelines [2, 6, 7]. Finally, a practitioner review published in 2024 highlights that there is still much to learn about making service transitions as effective and efficient as possible, with only preliminary evidence regarding the cost-effectiveness of transition protocols [8].

Project aim and research question:

The aim of this project is to systematically analyse and compare international strategies and models addressing transitional psychiatry for differences and similarities in structural processes, characteristics, implementation strategies, and resource allocation, as well as to identify factors that promote and hinder successful implementation. Based on this analysis, the project aims to derive recommendations for the implementation, evaluation and further development of transitional psychiatry in Austria.

The aim of this study is <u>not</u> to develop a detailed implementation plan or carry out an impact analysis for specific interventions or a budget-impact analysis. Instead, the study will focus on structural comparisons and provide a knowledge base for decision-making.

> Q1: What international and cross-national strategies and models of transitional psychiatry exist, and what are their similarities and differences?
>
> Q2: What are the particular challenges and considerations for transitioning young adults with specific mental health conditions?
>
> Q3: How does Austria's current approach to transitional psychiatry compare with international models? What recommendations can be derived to harmonise Austria's transitional psychiatry with these models and strategies?

Methods:

The following methods are used to answer the research questions:

Q1: Country and cross-national organisations selection; structured hand search for international transitional psychiatric care models/strategies; adapted version of the AGREE II (Appraisal of Guidelines for Research & Evaluation) framework to assess the quality of the included reports; identification of experts (policymakers / healthcare professionals / researchers) through purposive sampling; expert consultations (oral or written) for further insights through (semi)-structured questionnaires; structured data extraction on key information (including basic model information, scope and target population, service integration and coordination, treatment approach, workforce and training requirements, implementation and governance, cost and resource allocation, and evaluation); thematic content analysis based on extracted data to identify patterns and gaps; narrative synthesis and data visualisation based on the identified themes

Q2: Mental health condition selection; structured hand search for indication-specific models in the selected countries; expert identification and consultations (oral or written) for further insights through (semi)-structured questionnaires; data extraction on key information (including indication-specific transition challenges and considerations, existing policies, specialised transition services, gaps & limitations); thematic synthesis

Q3: Needs assessment; structured hand search for overview of current care situation in Austria; expert identification and consultations (oral or written) for further insights through (semi)-structured questionnaires; data extraction; contextual comparative analysis (synthesised Q1 results) for structured policy mapping analysis (to define key policy dimensions and identify specific gaps); comparative table presentation; derivation of recommendations for every identified category to improve continuity of care and ensure sustainable personnel resources and qualifications, considering enabling and constraining factors and contextual conditions; structured framework to categorise recommendations; visualisation

Databases for Search Strategy (RQ 1-3): Google/Google Scholar, WHO MiNDbank, Europe's Encyclopedia of National Youth Policies, national websites of ministries of health, public health and guideline institutions, TRIP Database, Guidelines International Network, website resources of cross-national organisations

Inclusion criteria for country selection (Q1):

Criteria	Inclusion Criteria	Exclusion Criteria
1. Similar Healthcare System	Bismarck-based health systems with existing guidelines for transitional psychiatry	Countries with highly centralised or heterogeneous health systems (unless adopted a psychiatric transition policy at early stage (see criteria 2))
2. Established/Early Implemented Guidelines for Transitional Psychiatry	Countries with firmly established/early adopted national strategies/models on transitional psychiatry according to MILESTONE [1] or WHO report [9]	Countries without structured policies or transition frameworks
3. Research and Documentation	Countries with accessible data, published reports	Countries with limited or unavailable policy documentation
4. Population Size	Countries with a population over 5 million	Countries with a population under 5 million
5. Geography	European countries	Non-European countries unless they provide robust policy insights and were early adopting countries (e.g., Australia)
6. Human Development Index	Countries with an HDI equal to or higher than Austria's (larger/smaller 0.926, 2022 [10])	Countries with an HDI below 0.926

The following countries are used for analysis: **Australia, Belgium, Denmark, Germany, Netherlands, Switzerland and the United Kingdom.**

The selected countries represent best practice models in transitional psychiatry due to their high Human Development Index (HDI), which ensures comparability of health system capacity, workforce availability, and overall socio-economic conditions, and their structural similarity to

Austria's Bismarckian health system, which ensures policy relevance or their early introduction of structured strategies in transitional psychiatry, which provide long-standing, well-documented examples of transitional care. This selection ensures that the study results are applicable, implementable and informative for policy development in Austria.

Furthermore, as cross-national organisations, we included **WHO, UNICEF and OECD** because of their central role in shaping global (youth) mental health policies.

Inclusion criteria for the Selection of Mental Health Conditions (RQ2):

1. High Dropout Rates or Low Referral to AMHS, as reported by Reneses et al. [4] and/or Singh et al. [3, 11]
2. High Burden of Disease or Prevalence in Adolescents (15-19), according to the Global Burden of Disease Study (GBD) [12]
3. Emerging/Occurring Diseases during late adolescence Age, based on data from the Global Burden of Disease Study [12]

We will limit RQ2 to conditions that meet at least two of the above criteria. Therefore, we will focus on **Anxiety Disorder, Attention Deficit and Hyperactivity Disorder (ADHD), Conduct Disorder**, **Depressive Disorders, Eating Disorders and Substance Abuse Disorder.**

Inclusion criteria for relevant transitional psychiatry models (Q1):

Criterion	Inclusion	Exclusion
1. Type of Model	National or transnational strategies/models for transitional psychiatry, published by government bodies, health organisations, or academic institutions	Regional strategies or models (if national models exist), informal or unofficial policies
2. Scope of Transition	Covers transition from child and adolescent mental health services to adult mental health services	Policies addressing transitions in other sectors (e.g., school-to-work) or policies limited to children or adults only
3. Publication Language	Policies available in English, German, or national languages (if no official translation exists, neural machine translation will be applied for key policy documents)	Policies published only in languages, where neural machine translation is not feasible for interpretation
4. Publication Period	No restriction – all historical and current policies are included if they are still applicable	Policies that are outdated or replaced, unless they provide relevance for transitional psychiatry development
5. Model Characteristics (Preliminary)	Models must describe relevant characteristics (e.g. age range, target groups, treatment approaches, professional roles, service coordination and responsabilites, and implementation)	Policies that fail to specify key characteristics

This study prioritises national models where they are available. However, in cases where national frameworks are absent or insufficient, regional models will be considered to prevent (data) gaps. Regional models will only be included if no national model in the selected countries is found and will be identified through an unstructured hand search. These models will be subjected to the same inclusion criteria as national models to ensure consistency in analysis.

Timetable/Milestones:

Period	Tasks
February – March 2025	Scoping and project setup; Hand search; Literature selection and acquisition; Document analysis;
April – May 2025	Document analysis; Planning and preparation of expert consultations (identification of participants, development of interview guide); Expert consultations; Data extraction;
June – July 2025	Expert consultations; Thematic and comparative analysis of international models (RQ1 & RQ2); Structured analysis of policy mapping and derivation of recommendations (RQ3); Draft report;
August – October 2025	Analysis of results/development of policy recommendations (Q3); Visualisations, internal and external review; Revision; Finalisation;

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5. Systematic Review of the Long-Term Effectiveness and Safety of Enzyme Replacement Therapy in Mucopolysaccharidoses Disorders and Pompe Disease

Project lead: Sabine Geiger-Gritsch
Project team: Ana Pantovic; Eva Malikova, Sabine Geiger-Gritsch
Internal review: Judit Erdos
Duration: April to September 2025 (5 PM)
Language: English (with German summary)

Background:

Lysosomal storage disorders (LSD) include rare inherited metabolic disorders involving impaired functions of specific enzymes located within the lysosomes. These disorders can be further categorized into four groups, two of which are known as glycogen storage disorders (GSD) and mucopolysaccharidoses (MPS).

Pompe disease belongs to the GSD group of lysosomal storage disorders and is known as glycogen storage disease type 2. This is a rare, inherited, progressive muscle disorder that affects mobility and breathing. It is caused by a deficiency of the enzyme acid alpha-glucosidase (GAA), leading to lysosomal glycogen accumulation and muscle damage, including the diaphragm and skeletal muscles. Incidence rates vary, with one Austrian study estimating a combined early- and late-onset incidence of 1 in 8,686 [4], and a more recent study estimated the prevalence of 1 in 350,914 [5]. Two types of Pompe disease exist. Infantile-onset Pompe disease (IOPD) involves little to no GAA activity and typically occurs in early infancy with cardiomyopathy and hypotonia, often resulting in fatal cardiorespiratory failure within the first year if untreated [6]. In contrast, late-onset Pompe disease (LOPD) retains some enzyme activity, leading to a milder but progressive course with muscle weakness and respiratory issues emerging later in life.

MPS are a group of rare inherited lysosomal storage disorders characterized by a reduced or complete inability to break down complex sugars known as glycosaminoglycans. There are several types of MPS, classified based on the specific enzyme deficiency and the resulting clinical manifestations. The project focuses on the following three types of MPS disorders:

- **Mucopolysaccharidosis Type I (MPS I**) results from a deficiency in the enzyme alpha-L-iduronidase, preventing lysosomes from breaking down dermatan sulphate and heparan sulphate. There are three MPS I sub-types:
  - Hurler syndrome: Most severe type, presenting in the first year of life with varied symptoms like cardiomyopathy, recurrent ear-nose-throat issues, and coarse facial features, including short stature, bony deformities, developmental delay, hepatosplenomegaly, and corneal clouding develop later. Untreated, it results in death by adolescence.
  - Hurler-Scheie syndrome: Intermediate severity.
  - Scheie syndrome: Least severe, children are intellectually normal but may face disabilities from degenerative bony disease, corneal opacity, and valvular heart disease.

  The estimated prevalence is 1 in 100,000, with Hurler syndrome comprising 57% of cases, Hurler-Scheie syndrome 23%, and Scheie syndrome 20% [1].
- **Mucopolysaccharidosis type II (MPS II, Hunter syndrome)** is a rare X-linked disorder caused by a deficiency of the enzyme iduronate-2-sulfatase (I2S). Beyond neurological involvement, one of the major challenges in MPS II is the significant impact

of progressive physical abnormalities on quality of life. Bone disease reduced respiratory function, and cardiac impairment lead to chronically low endurance. As the disease advances, many lose the ability to walk even short distances and eventually require a wheelchair. By the second decade of life, most individuals with central nervous system (CNS) involvement experience severe cognitive decline and are fully dependent on caregivers [2]. The incidence of MPS II ranges from 0.38 per 100,000 live births in Brazil to 1.09 per 100,000 in Portugal. In general, European countries report lower incidence rates compared to East Asian countries, where MPS II can represent up to 50% of all MPS cases [3].

- Mucopolysaccharidosis **IVA (MPS IVA, Morquio A syndrome or Morquio–Brailsford syndrome**) is a lysosomal storage disorder inherited in an autosomal recessive pattern. It results from a deficiency of the enzyme N-acetylgalactosamine-6-sulfatase which leads to the accumulation of the glycosaminoglycans keratan sulfate and chondroitin-6-sulfate in various tissues, bones, and organs [7]. The reported prevalence of MPS IVA varies: 1 in 323,000 in Denmark, 1 in 599,000 in the UK, 1 in 926,000 in Australia, and 1 in 1,872,000 in Malaysia. Birth prevalence ranges from 1 in 71,000 in the United Arab Emirates to 1 in 500,000 in Japan [8,9]. Clinical features include waddling gait, skeletal abnormalities, genu valgum (knock knees), bell-shaped chest, joint hypermobility, spinal deformities, enlarged elbows and wrists, short stature, and short neck. Other possible symptoms include mild hepatosplenomegaly, hearing loss, respiratory issues, cardiac abnormalities, corneal clouding, and enamel hypoplasia. Unlike other forms of MPS, Morquio A typically does not involve the brain or cause significant cognitive impairment [10].

Currently, enzyme replacement therapy (ERT) represents the standard of care in treating Pompe disease and MPS disorders. ERT is a systemic approach, which involves administering recombinant enzymes intravenously to replace the deficient enzyme in affected individuals. By targeting the underlying enzymatic deficiency, ERT aims to alleviate symptoms, slow disease progression, and improve quality of life for patients with LSDs. Diagnosis and initiation of ERT in Austria is usually carried out in specialized centres in hospitals. As patients require lifelong monthly infusions this significantly impacts on quality of life for patients and their caregivers. In some countries and so in Austria, eligible patients are allowed to receive their infusions at home rather than in the clinic. Home infusion of ERT has been approved for several LSD, resulting in a positive impact on the quality of life for both patients and their caregivers.

In general, ERT has demonstrated efficacy depending on the disease in improving various clinical outcomes including reductions in organ enlargement, improvements in blood counts, mitigation of skeletal and neurocognitive symptoms, and improvement of quality of life. Despite its effectiveness, ERT has limitations: it may not be effective in reversing tissue damage that has already occurred prior to treatment initiation, it requires lifelong administration, it may result in anti-drug antibodies, and its requirement for regular infusions can pose logistical challenges for patients and caregivers [12]. In addition, ERT's limited ability to cross the blood brain barrier (BBB) reduces its capacity to reach the CNS. In addition, current knowledge about the long-term effectiveness and safety of these treatments in real-world settings is limited, highlighting the need for a systematic review. The present project focuses on real world evidence of the following selected therapies for four different LSD:

- avalglucosidase alfa and alglucosidase alfa for Pompe disease
- laronidase for Mucopolysaccharidose Type I (MPS I)
- idursulfase for Hunter Syndrome (MPS II)
- elosulfase alfa for Mucopolysaccharidose Type IVA (MPS IVA; Morquio A syndrome)

Objectives of the project:

The aim of this project is to perform a systematic search and qualitative evidence synthesis of published studies that assess the long-term effectiveness and safety of the five ERTs (laronidase, idursulfase, alglucosidase alfa, avalglucosidase alfa, elosulfase alfa) in the treatment of Pompe disease and three types of MPS disorders (MPS I, MPS II, and MPS IVA).

Non-objectives:

These are not within the scope of this project:

- to evaluate short-term efficacy and safety (less than 2 years of follow-up)
- to evaluate other ERT than the five selected treatments

Research questions (RQ)

- **RQ1**: What is the long-term effectivness and safety of alglucosidase alfa and avalglucosidase alfa intervention in the treatment of Pompe disease?
- **RQ2**: What is the long-term effectivness and safety of laronidase in the treatment of MPS I?
- **RQ3**: What is the long-term effectivness and safety of idursulfase in the treatment of Hunter syndrome (MPS II)?
- **RQ4**: What is the long-term effectivness and safety of elosulfase alfa in the treatment of MPS IVA?

Methods:

A preliminary search was conducted to identify the most recent systematic reviews that meet the present assessment's scope. The identified systematic reviews will be evaluated based on their scope, inclusion and exclusion criteria, and methodological quality using the Risk of Bias Assessment Tool for Systematic Reviews (ROBIS). High-quality systematic reviews that align with the scope of the current research question will be updated by conducting a systematic literature search for studies published after the original search date of the respective systematic reviews. If no high-quality review is identified, or is not available, a systematic literature search of several databases for primary studies will be performed, as well as a manual search of the references of relevant published systematic reviews and journal articles. In addition, a manual search is carried out for registers and publications from these registers. Abstract and full-text screening will be performed by two authors independently. In case of a disagreement, a third author will be contacted. A hierarchical approach will be applied when selecting studies by giving preference to RCTs, Non-RCTs and observational studies with a prospective design.

Data will be extracted in a pre-defined tabulated form, which will contain the following information: details about the study design, the intervention (dosage, duration period), the comparator (if applicable), the duration of the follow-up, losses to follow-up, details about the patient population (age, gender, severity of the disease, disease manifestation / symptoms / conditions), and the main findings related to the outcomes of interest. The risk of bias of included studies will be assessed with Cochrane Risk of Bias 2.0 tool for randomized controlled trials (RCTs) and with the Risk Of Bias In Non-randomized controlled Studies - of Interventions (ROBINS-I) for non-randomized studies (NRSs). The certainty of the evidence will be assessed using the GRADE approach [13].

PICO - Inclusion criteria for relevant literature:

Alglucosidase alfa and avalglucosidase alfa for infant-onset Pompe disease (IOPD)

Population	Patients of all ages with infantile-onset Pompe disease. *Alternative terms*: type II glycogenosis, glycogen storage disease type II, acid maltase deficiency, acid α-glucosidase deficiency, infant-onset Pompe disease (IOPD).
Intervention	Alglucosidase alfa Avalglucosidase alfa *Alternative terms*: enzyme replacement therapy, ERT
Control	Any kind of control intervention will be included
Outcomes	
Efficacy	▪ Respiratory function (ventilator-free survival) ▪ Cardiac function (ECG, echocardiography, LV mass) ▪ Musculoskeletal outcomes (motor function, swallowing) ▪ Quality of life
Safety	▪ Mortality ▪ Adverse events
Study design	▪ Systematic reviews ▪ RCTs with a minimum follow-up of 2 years. ▪ NRCs with a minimum follow-up of 2 years. The minimum sample size should be 5 patients. In case of a sufficient number of studies, only studies with a larger sample size (n>10), will be included. Excluded: in vitro, animal, case studies, conference abstracts, letters to the editors and authors responses.

Abbreviations: ECG = Electrocardiogram, LV = left ventricular, ERT= Enzyme replacement therapy, IOPD= Infant-onset Pompe disease, n= Number of patients, NRCs= non-randomized comparative studies, RCTs= randomized controlled trials

Alglucosidase alfa and avalglucosidase alfa for late-onset Pompe disease (LOPD)

Population	Patients of all ages with late-onset Pompe disease. *Alternative terms*: type II glycogenosis, glycogen storage disease type II, acid maltase deficiency, acid α-glucosidase deficiency, late-onset Pompe disease (LOPD).
Intervention	Alglucosidase alfa Avalglucosidase alfa *Alternative terms*: enzyme replacement therapy, ERT
Control	Any kind of control intervention will be included
Outcomes	
Efficacy	▪ Respiratory Function (FEV1, FVC) ▪ Endurance performance (6MWT) ▪ Musculoskeletal outcomes (muscle strength – quantitative and manual muscle testing, motor function, swallowing) ▪ Quality of life
Safety	▪ Adverse events
Study design	▪ Systematic reviews ▪ RCTs with a minimum follow-up of 2 years. ▪ NRCs with a minimum follow-up of 2 years. The minimum sample size should be 5 patients. In case of a sufficient number of studies, only studies with a larger sample size (n>10), will be included. Excluded: in vitro, animal, case studies, conference abstracts, letters to the editors and authors responses.

Abbreviations: 6MWT= Six-minute walk test, ERT= Enzyme replacement therapy, FEV1= Forced expiratory volume at one second, FVC= Forced vital capacity, LOPD= Late-onset Pompe disease, n= Number of patients, NRCs= non-randomized comparative studies, RCTs= randomized controlled trials

Laronidase for Mucopolysaccharidosis Type I (MPS I)

Population	Patients of all ages with Mucopolysaccharidosis Type I, including all three disease stages (Hurler, Hurler-Scheie and Scheie syndrome). Subgroup analyses will be conducted based on disease stage at diagnosis. *Alternative terms*: Mucopolysaccharidosis I OR MPS I OR Alpha-L-iduronidase deficiency
Intervention	Laronidase *Alternative terms*: Enzyme replacement therapy OR ERT
Control	Any kind of control intervention will be included
Outcomes	
Efficacy	▪ Respiratory function (FEV1, FVC, sleep apnoea) ▪ Cardiac outcomes (ECG, echocardiography) ▪ Endurance performance (6MWT) ▪ Cognitive outcomes ▪ Musculoskeletal outcomes (growth, joint mobility) ▪ Hepatosplenomegaly ▪ Urinary GAG ▪ Quality of life
Safety	▪ Mortality ▪ Adverse events
Study design	▪ Systematic reviews ▪ RCTs with a minimum follow-up of 2 years. ▪ NRCs with a minimum follow-up of 2 years. The minimum sample size will be 5 patients. In case of a sufficient number of studies, only studies with a larger sample size (n>10), will be included. Excluded: in vitro, animal, case studies, conference abstracts, letters to the editors and authors responses.

Abbreviations: 6mwt= Six-minute walk test, ERT= Enzyme replacement therapy, FEV1= Forced expiratory volume at one second, FVC= Forced vital capacity, ECG = Electrocardiogram, GAG =Glycosaminoglycan, MPS I= Mucopolysaccharidosis Type I, n= Number of patients, NRCs= non-randomized comparative studies, RCTs= randomized controlled trials

Idursulfase for Hunter syndrome (Mucopolysaccharidosis Type II)

Population	Patients of all ages with Hunter syndrome (Mucopolysaccharidosis Type II). *Alternative terms*: Mucopolysaccharidosis II OR MPS II
Intervention	Idursulfase *Alternative terms*: enzyme replacement therapy OR ERT
Control	Any kind of control intervention will be included
Outcomes	
Efficacy	▪ Respiratory function (FEV1, FVC, sleep apnoea) ▪ Cardiac function (ECG, echocardiography) ▪ Endurance performance (6MWT) ▪ Cognitive outcomes (for neuronopathic form) ▪ Musculoskeletal outcomes (growth, joint mobility) ▪ Hepatosplenomegaly ▪ Urinary GAG ▪ Quality of life
Safety	▪ Mortality ▪ Adverse events
Study design	▪ Systematic reviews ▪ RCTs with a minimum follow-up of 2 years. ▪ NRCs with a minimum follow-up of 2 years. The minimum sample size will be 5 patients. In case of a sufficient number of studies, only studies with a larger sample size (n>10), will be included. Excluded: in vitro, animal, case studies, conference abstracts, letters to the editors and authors responses.

Abbreviations: 6MWT= Six-minute walk test, ERT= Enzyme replacement therapy, FEV1= Forced expiratory volume at one second, FVC= Forced vital capacity, ECG = Electrocardiogram, GAG= Glycosaminoglycan, MPS

II= Mucopolysaccharidosis Type II, n= Number of patients, NRCs= non-randomized comparative studies, RCTs= randomized controlled trials

Elosulfase alfa for Mucopolysaccharidosis Typ IVA (MPS IVA; Morquio A syndrome)

Population	Patients of all ages with Mucopolysaccharidosis Type IVA *Alternative terms*: Mucopolysaccharidosis Type IVA OR MPS IVA OR Morquio A syndrome OR Morquio–Brailsford syndrome
Intervention	Elosulfase alfa *Alternative terms*: enzyme replacement therapy OR ERT
Control	Any kind of control intervention will be included
Outcomes	
Efficacy	▪ Respiratory function (FEV1, FVC) ▪ Endurance performance (6MWT, 3MSCT) ▪ Musculoskeletal outcomes (growth, joint mobility) ▪ Quality of Life
Safety	▪ Adverse events
Study design	▪ Systematic reviews ▪ RCTs with a minimum follow-up of 2 years. ▪ NRCs with a minimum follow-up of 2 years. The minimum sample size will be 5 patients. In case of a sufficient number of studies, only studies with a larger sample size (n>10), will be included. Excluded: in vitro, animal, case studies, conference abstracts, letters to the editors and authors responses.

Abbreviations: ERT= Enzyme replacement therapy, FEV1= Forced expiratory volume at one second, FVC= Forced vital capacity, 3MSCT= Three-minute stair climb, 6MWT= Six-minute walk test, MPS IVA= Mucopolysaccharidosis Type IVA, n= Number of patients, NRCs= non-randomized comparative studies, RCTs= randomized controlled trials

Quality assurance:

As part of the quality assurance process, monitoring by external clinical experts is planned for the entire project process. In addition, the report will undergo an internal review by an AIHTA member and an external review by a clinical expert before project completion.

Time schedule/ milestones (in months)

Time frame	Task
April 2025	Scoping, defining the PICO questions
May 2025	Literature search, abstract screening, study selection, expert meeting
May, June 2025	Data extraction, risk of bias assessment
June 2025	Evidence synthesis, expert meeting
July 2025	Report writing
August and September 2025	Internal and external review, finalizing report, publication

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6. Nudges to Optimise Prescriber Behaviour of Physicians

Project lead: Viktoria Hofer
Project team: Viktoria Hofer, Jule Anna Pleyer
Internal review: Julia Mayer-Ferbas
Duration: Mid-April 2025 until November 2025 (3 PM)
Language: English (with German summary)

Background:

In the healthcare sector, the pressure to comply with clinical and administrative guidelines has intensified considerably in recent years - a development that aims to optimise the quality of care for patients and reduce costs simultaneously [9]. Findings from the behavioural sciences are becoming more popular to improve the quality of medical decision-making processes [10, 11]. In this context, the concept of '"nudging' has attracted particular attention [12]. Nudges are targeted modifications to the decision-making environment that are intended to gently steer people towards certain behaviours. However, these modifications are not dependent on financial/economic incentives, nor are they subject to any commandments or prohibitions. Because nudge interventions are typically straightforward and inexpensive, they are very popular with health managers and policymakers.

Scientific findings from various areas, such as financial markets, education policy, and the health sector, prove the effectiveness of nudges [13]. In the healthcare sector, research on nudging strategies focuses primarily on patient-centred interventions, such as vaccination reminders, improved malaria testing procedures, and self-management of chronic diseases. However, specific nudging approaches for healthcare professionals have also been developed to help increase adherence to guidelines and improve prescribing practices [13, 14].

Prescribing decisions are inherently complex and frequently need to be made under considerable time constraints whilst managing patient expectations. Under such circumstances, extraneous factors —potentially irrelevant from a clinical perspective—may influence medication prescribing patterns. Even highly experienced clinicians might make decisions that deviate from evidence-based practice under these conditions, particularly in therapeutic areas characterised by significant uncertainty regarding benefit-risk profiles, such as opioid prescribing [13]. In this context, strategically designed nudging interventions can

favourably influence prescribing behaviour by reconfiguring the decision architecture whilst preserving the professional autonomy of physicians.

Project aims:

The project aims to systematically categorise nudging strategies in healthcare that can positively influence the prescribing behaviour of physicians. This involves documenting implemented approaches from the literature and evaluating them about their effectiveness and utility. A further focus lies in analysing the transferability of these strategies to the context of the Austrian healthcare system. This leads to the following three research questions:

1. Which nudges for optimising prescribing behaviour have been implemented and evaluated internationally, and how can they be categorised?
2. How effective and safe are the nudges described in international literature for optimising prescribing behaviour?
3. Which nudges have proven to be effective and safe internationally and would be suitable for implementation in the Austrian healthcare system? What criteria should be considered for successful implementation in the Austrian context?

The aim of this study is not to develop implementation strategies or carry out a budget impact analysis.

Methods:

The following methods are used to answer the research questions:

RQ1 + RQ2: To answer the first two research questions, a manual search for current systematic reviews will be conducted first. After selecting a recent systematic review of high methodological quality, a systematic literature search in several databases (update search) will be conducted based on their search strategy to identify relevant primary studies. Following the literature selection, the nudging measures described therein to improve physician prescribing behaviour are categorised, and the evidence on efficacy and safety is extracted in prefabricated tables and then summarised narratively. Depending on the study design, a quality assessment is carried out for the selected literature using a suitable instrument.

RQ3: For the third research question, those nudges that have proven to be effective in the second research question are evaluated for their potential feasibility and usefulness in the Austrian healthcare system. Criteria, supporting and inhibiting factors for successful implementation in the Austrian context are described. This assessment could, if necessary, be empirically collected through a survey of practising doctors (survey and qualitative analysis).

All work steps for answering the three research questions (literature selection, quality assessment, data extraction, and synthesis) are carried out by the two authors (VH and JAP) in a dual control principle.

Inclusion criteria (PICO):

Population	Addressees of the intervention, e.g. general practitioners, medical specialists
Intervention	Nudges (incentives to change behaviour) ... ... which can optimise the prescribing behaviour of medical staff ... ... to optimise the quality of patient care and reduce costs ... ... and have already been implemented internationally.
Comparison	Standard procedures (e.g. economic incentives, prohibitions/bids) or other comparators
Outcomes	**Research question 1**: ▪ Characteristics of nudges used internationally ▪ Categories for categorising identified nudges **Research question 2:** ▪ Effectiveness and safety of the nudges in relation to, e.g.:

	▪ **optimisation of prescriptions of certain medication groups** (e.g. change in the number of prescribed medications/prescription rates, reduction of large prescription quantities, new prescriptions) ▪ **undesirable side effects** ▪ **implementation of the measures** (e.g. effort, feasibility, costs) **Research question 3:** ▪ Feasibility of nudging measures in Austria: criteria for successful implementation, possible obstacles and facilitating factors, respondents' assessment from the survey
Publication type	**Research question 1 + 2**: ▪ Systematic reviews ▪ Primary studies **Research question 3**: ▪ Systematic reviews ▪ Primary studies ▪ Grey literature ▪ Survey
Countries	Europe, North America, Australia, Asia, New Zealand
Languages	English, German

Timetable:

Period	Tasks
April 2025	Scoping and finalising the project protocol
May 2025	▪ Systematic literature search and manual searches ▪ Selection of literature
June 2025	Data extraction and quality assessment, if applicable: survey
July – August 2025	Writing the report
September - October 2025	Internal and external review
November 2025	Layout and publication

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7. Further Development of the Program on Preventive Health Check-Ups

Background:

According to the Federation of Social Insurances in Austria, preventive medical check-ups (PMC; short-term: health check-up) have significantly contributed to the increased life expectancy in Austria since 1974 [15]. In the national context, preventive check-up aims to reduce health risk factors (primary prevention) and enable early disease detection (secondary prevention). A particular focus is placed on cardiovascular diseases and cancer, which are among the most common causes of death in Austria [16]. To sustainably improve the population's overall health, the program is available to all individuals aged 18 and over with a primary residence in Austria [15]. These examinations are primarily conducted by general practitioners and specialists in internal medicine [15]. Depending on age and sex, specific health topics are addressed, including risk assessment for cardiovascular disease (CVD) and lifestyle-related counselling and support [17]. The two-stage preventive process begins with identifying risk factors through blood tests, urine analysis, and physical examinations, followed by a discussion of findings and (lifestyle-related) counselling.

Part 1: Reviews on lifestyle counselling and scores for the prognosis of cardiovascular diseases

Project lead: Jule Anna Pleyer
Project team: Jule A. Pleyer, Lena Grabenhofer, Viktoria Hofer
Internal review: Ingrid Zechmeister- Koss
Duration: Mid-April 2025 until Mid-November 2025 (7 PM)
Language: English (with German summary)

Part 1 focuses on two key areas of the preventive medical check-up: lifestyle counselling (LsC) as a primary prevention measure and risk assessment scores for CVD as part of secondary prevention. Separate reports are provided for each of these aspects.

Report 7.1.1: Brief interventions for lifestyle counselling: Systematic Review

First author: Jule Anna Pleyer

Second author: Lena Grabenhofer

Background:

An unhealthy lifestyle is closely linked to the burden of disease in Austria, where two-thirds of the population is affected by chronic illnesses and health problems [18]. According to the Austrian Health Report 2022, women spend an average of 19.5 years and men 16.4 life years in moderate to poor health. This is mainly due to musculoskeletal disorders, diabetes, asthma, COPD, cancer, cardiovascular diseases, and depression [18]. The development of these chronic conditions is primarily associated with four major risk factors: tobacco use, unhealthy diet, physical inactivity, and excessive alcohol consumption [19].

In 2018, the Austrian Federation of Social Insurances revised the Austrian preventive medical check-up (short-term: health check-up) in collaboration with the Austrian Medical Association [20]. A key outcome of this revision was the significant enhancement of the physician's role as a counsellor. Doctors are now expected to increasingly consider patients' life circumstances and offer tailored counselling on smoking cessation, nutrition, and physical activity. As an integral part of the Austrian preventive medical check-up, lifestyle counselling (LsC) can potentially prevent specific diseases and improve public health more broadly, serving preventive and health-promoting purposes [21].

The guideline for the preventive medical check-up [20] outlines specific interventions when certain thresholds are exceeded (e.g. nutritional counselling in cases of elevated BMI) and recommends a structured approach to addressing alcohol and tobacco use through the "five Es" framework: Enquire, Evaluate, Elicit, Encourage, and Enable. Moreover, the 2016 Austrian health reform introduced a national strategy to improve communication quality in healthcare. This includes communication tools to support healthcare professionals in counselling, as high-quality, patient-centred communication has been shown to positively impact health behaviour [22].

Despite the availability of preventive medical check-up guidelines and communication tools, Austria's dietary and physical activity patterns have worsened in recent years. Tobacco use among men and alcohol consumption in general remain at the EU average, while tobacco use among women is even above average. Furthermore, every second person in Austria demonstrates limited health literacy [18]. These developments highlight the need to examine the extent to which lifestyle counselling contributes to improving population health in Austria and how practitioners can be better supported in delivering effective counselling.

Objectives:

The main objective of Report 1 is to systematically identify lifestyle-related brief interventions on physical activity, healthy diet and alcohol consumption, to comparatively analyse their effectiveness and exploratively investigate their feasibility for implementation in Austrian preventive medical check-ups. This will help to develop evidence-based recommendations for improving the Austrian health check-ups.
The following research questions (RQs) arise from this aim:

1. **RQ1**: What evidence-based brief interventions (e.g. communication models, practical tools) are used in lifestyle counselling for physical activity, healthy diet, and alcohol consumption?
2. **RQ2:** How effective are the identified interventions and their specific characteristics (e.g. trained intervention) in comparison to each other in improving lifestyle change among recipients.
3. **RQ3:** What are the implementation requirements and barriers for lifestyle-related brief interventions within the Austrian preventive medical check-up?

Non-objective:

This report does not aim to create a practice handbook for implementing LsC.

Methods:

Research questions 1 and 2:

To address the first two research questions regarding the identification of lifestyle-related brief interventions for physical activity, healthy diet, and alcohol consumption, as well as a comparison of their effectiveness, we will conduct a systematic literature search in multiple databases for reviews (and primary studies, if reviews are unavailable). Relevant literature will be identified based on pre-defined inclusion and exclusion criteria. Existing brief lifestyle interventions for counselling (tools, communication forms, psychological models, information material) will be extracted from the relevant literature, summarised in pre-structured tables, and narratively synthesised. No quality assessment will be performed for Research Question 1 (RQ1). To answer Research Question 2 (RQ2), the quality of the selected literature will be assessed using appropriate instruments (depending on the study design).

All steps involved in answering the two research questions (literature selection, quality assessment, data extraction, and synthesis) will be carried out using the four-eyes principle by the two authors (JP, LMG, and possibly VH).

Research Question 3:

Qualitative expert interviews will be conducted to answer the third research question. Practitioners who already carry out preventive medical check-ups will be interviewed using semi-structured interview guides. The interviews will focus on the current challenges and needs encountered by the respondents during the implementation of LsC as well as an assessment of facilitators and the feasibility of identified tools and approaches in practice. The interviews will be transcribed and analysed using qualitative content analysis.

PICO LsC:

Population	Recipients of lifestyle-related brief interventions in counselling settings. *Keywords: brief intervention; lifestyle counselling; behaviour change; obesity; nutrition; healthy diet; physical activity; alcohol; check-up; primary care*
Intervention	**Brief Interventions (measures, programs, tools, communication guidelines) for Lifestyle Counselling on:** • Physical activity (PA) • Healthy diet (HD) • Alcohol consumption (AC)
Comparison	Comparison of brief interventions and/or their parameters against each other (or against Standard of care, if reviews comparing interventions are unavailable)
Outcomes	**Research Question 1:** • Lifestyle-related brief interventions on PA, HD, and AC • Characteristics of the brief interventions **Research Question 2:** • Comparative effectiveness of lifestyle-related brief interventions on physical activity, healthy diet and alcohol consumption e.g. in relation to, but not limited to: - Behavioural changes of the recipients (e.g. food intake, physical activities/daily movement, consumption free days etc.) - Improvement of parameters indicating risk reduction (e.g. blood sugar, cholesterol, nutrients, BMI, etc.) - Improvement in (e.g. nutrition-related) quality of life and emotional well-being **Research Question 3:** • Current challenges and needs in the implementation of LsC • Applicability of identified brief interventions
Study design	**Research Questions 1 and 2:** Reviews (primary studies, if reviews are unavailable) **Research Question 3:** Semi-structured expert interviews with physicians (n=~5), who conduct health check-ups in practice and qualitative content analysis (Example questions: What would make the implementation in practice easier? Imagine you have the following tools (identified evidence-based tools from the literature) – how do you envision their practical application?)
Countries	Western countries with comparable healthcare systems
Languages	**Research Questions 1 and 2:** English, German **Research Question 3:** German

Report 7.1.2: Scores for Cardiovascular Diseases (CVD)

First author: Lena Grabenhofer

Second author: Jule Anna Pleyer

Background:

Cardiovascular diseases (CVD) are among the most common non-communicable diseases and causes of death worldwide [23, 24]. The forecast for the coming years is particularly concerning: whilst approximately 17.3 million people currently die annually from the consequences of CVD (as of 2018), despite continuous advances in cardiology, an increase to around 23.6 million deaths is projected by 2030. This development primarily affects Western societies [25]. In Austria, this global issue is reflected in concrete figures: 31,129 persons died from the consequences of CVD in 2023, with 22,510 of these deaths affecting people aged 80 years and older [26].

A complex interplay of various risk factors facilitates the development of CVD. These can be categorised as follows [9]:

- Physical factors (e.g., genetic predisposition, hyperglycaemia, overweight, obesity, diabetes)
- Behavioural factors (e.g., smoking, poor nutrition, lack of exercise)
- Psychological factors (e.g., chronic stress, personality factors)
- Social factors (e.g., education, income, occupational position)

In addition to causing an enormous disease burden, CVD also incurs high costs for the healthcare system. The annual costs due to CVD in the EU are estimated at around €282 billion. Of this, approximately €155 billion (55%) is attributable to direct healthcare costs and long-term care, a further €48 billion (17%) arises from productivity losses. The remaining €79 billion (28%) are attributed to costs incurred through the time and effort of informal caregivers [27].

Through appropriate preventive measures, premature deaths due to CVD and early development of CVD can be delayed, thereby improving healthy life expectancy. The prevention of CVD is a multi-faceted concept that operates on several levels:

Primary prevention: Avoidance and reduction of known risk factors. The promotion of a healthy lifestyle is paramount here before any disease occurs.

Secondary prevention: Early detection of diseases and risks.

Tertiary prevention: Prevention of the progression of existing diseases and possible consequential illnesses [28].

Against this background, the importance of a systematic risk assessment (secondary prevention) for CVD will be examined. In addition to family history, existing diabetes mellitus and smoking status, the most important examination parameters include findings on blood pressure, total and HDL (high-density lipoprotein) cholesterol [20]. Modern scoring models such as SCORE-2, PROCAM, and Arriba (developed from the Framingham Risk Score) enable a prediction of the individualised 10-year overall risk for fatal and non-fatal cardiovascular events [29]. For example, the European Society of Cardiology (ESC) introduced a revised version of the SCORE risk assessment in its 2021 guidelines for preventing cardiovascular diseases, the SCORE2. Additionally, the SCORE2-OP (for "older persons") was developed for the specific risk assessment in people over 70 years of age, which takes into account the particular risk factors of this age group [30].

Objectives:

The second report aims to systematically capture the scientific literature on the possibilities of predicting cardiovascular diseases, compare the most frequently described risk prediction models applicable to the Western European population, and evaluate them regarding their implementation possibilities within the framework of preventive health check-ups. Consideration should be given to which (additional) prerequisites must be fulfilled for the implementation of the respective instruments and how the results of the risk scores affect further health-related examinations. The focus here is on the uniform implementation of the scoring models in Austria.

This gives rise to the following research questions:

1. RQ1: How do cardiovascular risk prediction models (e.g., ARRIBA, SCORE2, SCORE2-OP and SCORE2-Diabetes) compare, and how do they differ in terms of their evidence, predictive validity, benefit-harm balance and their implementability within the framework of Austrian preventive health check-ups?
2. RQ2: To what extent does the application of cardiovascular risk prediction models lead to long-term health benefits, as well as to changes in the health behaviour of patients?
3. RQ3: Which parameters are already standardly collected in preventive health check-ups, which additional examinations are required for an optimal implementation of the risk scores, and which organisational, time and personnel resources are needed for this?

Non-Objectives:

The project does NOT aim to provide a quantitative budget impact analysis for RQ3

Methods:

To answer the research questions RQ1 to RQ3, a systematic literature review will first be conducted. The selection of relevant publications is based on pre-defined inclusion and exclusion criteria. All methodological steps, including literature selection, data extraction and, if necessary, quality assessment, are carried out according to the four-eyes principle: one scientist undertakes the primary processing, whilst a second scientist reviews and validates these results. After completing the literature review, the identified outcomes are systematically extracted and narratively summarised.

Based on this, the most important instruments for cardiovascular risk prediction in the Western European region, including SCORE2, SCORE2-OP, SCORE2-Diabetes as well as PROCAM and ARRIBA, are to be identified and compared. The analysis is structured into several consecutive steps:

First, a comprehensive inventory of existing prognostic instruments and their methodological foundations is conducted.

In the second step, the evidence base of these instruments is critically examined. The central question here is to what extent the prognostic scores can precisely predict the actual cardiovascular risk and whether their application demonstrably leads to measurable health improvements.

The third research focus in the data analysis lies on the practical implementation aspects: which specific parameters are needed for the various scores, which of these are already standardly collected in preventive health check-ups in Austria, and what additional effort is created for patients and medical personnel.

PICO 2 CVD:

Population	Addressees of cardiovascular risk prediction (patients) *Keywords: Arriba, SCORE2, Procam, cardiovascular risk prediction, cardiovascular disease, cardiovascular disease, screening, ARRIBA score, Framingham Risk Score*
Intervention	Risk prediction models for cardiovascular diseases (e.g. SCORE2, PROCAM, Arriba score)
Comparison	▪ Comparison of the various risk models with each other and, if necessary, with standard care without structured risk assessment. ▪ Current prevention programme without extended risk scores.
Outcomes	▪ Predictive validity of the risk models ▪ Long-term effects on cardiovascular event rates and mortality ▪ Quality of life ▪ Practical feasibility ▪ Additional resources required (time, personnel, structures) ▪ Acceptance by physicians and patients
Study Design	High-quality systematic reviews or RCTs/primary studies All other outcomes: no restrictions in study design
Countries	Western Europe, Austria
Languages	English, German

Time table:

Time period	Tasks
April 2025	Scoping and finalisation of the project protocol
May 2025	Systematic Reviews ▪ Systematic literature search and manual searches ▪ Literature selection Primary data collection ▪ Development of interview guideline
June – July 2025	Systematic Reviews ▪ Data extraction and quality assessment Primary data collection ▪ Conduction interviews ▪ Data extraction
August – September 2025	Writing
October 2025	Internal and external Review
November 2025	Layout & Publication

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Part 2: Rapid assessment on screening for chronic kidney disease and short summaries on prostate cancer screening, lung cancer screening and screening for abdominal aortic aneurysm

Project lead: Doris Giess
Project team: Doris Giess, Julia Mayer-Ferbas
Internal review: Ingrid Zechmeister- Koss
Duration: May 2025 to August 2025 (2 PM)
Language: English with German summary

The focus of this part is on screening examinations that are not currently integrated into the Austrian health care system, namely screening for prostate cancer, lung cancer, abdominal aortic aneurysm (AAA) and chronic kidney disease (CKD).

Prostate cancer is the most common malignancy among men in Austria and represents one of the leading causes of cancer-related mortality. According to Statistics Austria, approximately 6,000 new cases of prostate cancer were diagnosed in 2022, corresponding to an age-standardised incidence rate of approximately 110 per 100,000 men [1].

The prostate-specific antigen (PSA) test has been utilised as a screening method since the 1990s. However, the benefits and potential harms associated with its population-wide application remain a subject of ongoing debate.

According to Statistics Austria, around 4,600 new cases of lung cancer were diagnosed in 2021, corresponding to an age-standardised incidence rate of around 50 per 100,000 individuals [3]. Heavy smokers and former smokers are particularly at risk. For early detection, screening using low-dose CT (LDCT) is recommended or already implemented in several countries, as large, randomised studies have demonstrated a significant reduction in lung cancer-related mortality through this method [2-4].

AAA is a potentially life-threatening condition characterised by a pathological dilation of the abdominal aorta. Current data on the prevalence of AAA in Austria are limited. However, a recent global systematic review reports that the prevalence of AAA with a diameter ≥ 3.0 cm, ranges from 3.5% to 6.5% in men over 65 years of age. In women, the prevalence is significantly lower, ranging from 0.8% to 1.4% [5]. The overall mortality rate for patients with a ruptured abdominal aortic aneurysm (AAA) is approximately 75%, even with surgical intervention. If left untreated, rupture typically results in death within hours [6].

Early detection through ultrasound screening has been shown to significantly reduce the risk of rupture and increase survival rates [7].

Chronic kidney disease (CKD) is an escalating health concern worldwide. In Austria, approximately 8-10% of adults are affected by CKD, although the actual prevalence is likely higher due to the asymptomatic progression of the disease. Individuals with risk factors such as diabetes mellitus and hypertension are particularly susceptible.

Early diagnosis and intervention are critical in slowing the progression of CKD and preventing complications, such as kidney failure. According to the Austrian Kidney Report, despite international recommendations advocating for the regular screening of at-risk populations, only around 17% of affected individuals in Austria are screened annually. While CKD screening in the general population is currently being investigated in various research studies, it is not yet implemented in most countries [8].

Project objectives

The objective of this report is to evaluate the evidence base for the respective screening strategies, drawing upon recent health technology assessment (HTA) reports and systematic reviews. The focus is primarily on the benefits for the relevant target populations. Furthermore, the current S3 guideline recommendations are summarised to provide an evidence-based foundation for decision-making within the Austrian screening context.

Research Question 1:
How has the benefit of prostate cancer screening using prostate-specific antigen (PSA) been assessed in recent HTA reports in relation to patient-relevant outcomes, and what recommendations do current guidelines offer in this regard?

Research Question 2:

How has the benefit of lung cancer screening using low-dose computed tomography (LDCT) been evaluated in recent HTA reports with respect to patient-relevant outcomes, and what are the recommendations provided by current guidelines?

Research Question 3:

How has the benefit of abdominal aortic aneurysm (AAA) screening via ultrasound been assessed in recent HTA reports in relation to patient-relevant outcomes, and what are the corresponding recommendations from current guidelines?

Research Question 4:

a) How has the benefit of chronic kidney disease (CKD) screening been assessed in recent systematic reviews, with respect to patient-relevant outcomes?
b) For which target populations was CKD screening found to be beneficial according to these reviews?
c) What are the current guideline recommendations?

Non-Objective:

This report is not intended to conduct a detailed systematic review of primary studies. Instead, the focus is on a structured synthesis of evidence from existing reviews. Diagnostic accuracy studies and cost-effectiveness analyses are not within the scope of this report. The primary focus is on patient-relevant outcomes, such as all-cause mortality and morbidity.

Methods:

Research Questions 1-3:
A manual search will be conducted for recent guidelines. Additionally, a systematic search for HTA reports will be performed in the INAHTA database and on the websites of relevant HTA institutions.
A visual abstract will be created for each topic, illustrating the key elements of the respective HTA reports and guidelines. This visual abstract will include:

- Description of the screening strategy and target population
- Efficacy assessment based on patient-relevant outcomes
- Possible inclusion of results from cost-effectiveness analyses

- Presentation of harms, such as false-positive/negative results and overdiagnosis

Research Question 4a/b/c:
Rapid review of systematic reviews on screening for chronic kidney disease (CKD)

PICO

Population	Adult patients >18 years without diagnosed CKD
Intervention	Screening for CKD, based on eGFR(SCr), eGFR(cystC) and Proteinuria/Albuminuria/ACR testing (POCT dipstick or urinalysis)
Control	No Screening/Standard of care
Outcomes	▪ Clinical endpoints such as all-cause mortality, CKD-specific mortality, morbidity (e.g., improvement of kidney function/ progression to dialysis), ▪ Percentage of positive screening tests ▪ Percentage of confirmed CKD-diagnoses at follow-up ▪ Harms from screening (misdiagnoses, psychological burden, unnecessary further investigations) ▪ Percentage of medication initiation Not: cost-effectiveness, diagnostic accuracy
Study designs	FFa/b: High-quality systematic reviews FFc: Manual search for recent guidelines, search for HTA reports in the INAHTA database and websites of HTA institutions
Geographical Area	Western countries with established healthcare systems (including Europe, USA, UK, Australia)
Language	German, English

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8. Structured Medication Review for Polypharmacy

Project lead: Reinhard Jeindl
Project team: Reinhard Jeindl, Julia Kern
Internal review: Christoph Strohmaier
Duration: April 2025 – November 2025 (4 PM)
Language: English (with German summary)

Background:

The simultaneous, long-term use of several medicines (at least five different active ingredients) is often associated with multimorbidity and is referred to as polypharmacy (synonyms: polymedication, multimedication) [31]. Drug-related problems are very common, especially in older patients who take multiple medications. These problems include adverse drug reactions, interactions, ineffectiveness, taking medications without indication, inappropriate dosages and lack of adherence to therapy [32].

A careful structured medication review is therefore considered for most people with polypharmacy. This involves a structured conversation with patients to identify any problems with use, knowledge of the indications, indications of side effects or lack of adherence to treatment [33]. Propositions and solutions are then developed for relevant drug-related problems, e.g. dose adjustments, medication changes, or the review of the structured discontinuation of medication (deprescribing) for the sake of drug safety [31, 32]. According to a 2023 Cochrane systematic review of interventions to improve polypharmacy, it is unclear whether polypharmacy interventions can actually lead to clinically significant improvements. Nevertheless, the authors emphasise that interventions are increasingly being implemented by multidisciplinary teams and the number of studies on potential prescribing errors has increased [34]. According to a further Cochrane analysis from 2023, the evidence suggests that medication reviews in hospital patients have little to no effect on mortality, but can probably reduce the number of contacts with the emergency department as well as reduce the number of re-admissions [35].

In Austria, about 500,000 people are affected by polypharmacy [36]. In a cooperation project between the Umbrella Organisation of Austrian Social Insurances, the Austrian Chamber of Pharmacists and the Medical University of Vienna, a structured medication review was piloted and evaluated on 198 patients using a randomized controlled trial (RCT) [37]. The study was able to identify interactions and misuse of medications. The results on adherence to treatment and patient-reported outcomes indicated a possible 70 percent reduction of drug-related problems [38]. Based on these results, efforts are being made in Austria to establish structured medication review as a standardized, reimbursed intervention [37]. In Germany, the costs of structured medication reviews for patients with polypharmacy have been covered by health insurances since 2022. The costs are covered once a year, or in the event of a significant change in medication [39].

Project aims and research questions:

The aim of the project is to create a systematic review of the evidence for structured medication reviews and to give an overview of similar projects in selected European countries in order to provide a knowledge base for decision-making.

In addition, the legal situation regarding structured medication reviews in Austria, as well as information on the mechanism of action (mode of action model for weighting the different components of the medication review) will be described in the report's background chapter.

The aim of this study is <u>not</u> to carry out a cost-effectiveness analysis, or to develop a detailed implementation plan for structured medication analysis in Austria. Two research questions (RQ) will be answered:

> **RQ1:** What evidence on the benefits, safety, organisational aspects and costs of structured medication review is described in the literature?

RQ2: How is structured medication review implemented in selected countries, and what recommendations can be derived for Austria?

Methods:

The following methods are used to answer the research questions:

RQ1: Systematic search for systematic reviews and meta-analyses (PubMed/MEDLINE, Embase, Epistemonikos, Cochrane Library), HTA reports (INAHTA database) and guidelines (databases: AWMF, GIN, TRIPS). Quality assessment using ROBIS (systematic reviews) [40] and AGREE II (for guidelines) [41] with regard to the domains effectiveness and safety. Descriptive analysis of the organisational and economic domains. In case of a high number of available literature, restriction to recent, high-quality literature.

Inclusion and exclusion criteria (PICO)

	Inclusion	**Exclusion**
Population	Persons with polypharmacy (long-term, simultaneous use of at least five active ingredients)	Persons without polypharmacy
Intervention	Structured medication review	Indication- and/or drug-specific interventions Clinical decision-support systems, of which the medication analysis is only a part of the intervention
Comparator	No comparative intervention	-
Outcomes	Drug-related problems (adverse effects, interactions) Morbidity Mortality Hospital admissions Adherence to therapy Health literacy Quality of life Organisational aspects (professional groups involved, setting, time required) Influence on the relationship between patients, pharmacists and healthcare providers Costs (direct and indirect)	Clinical parameters, surrogate endpoints
Publication type	Systematic reviews, HTA reports, Guidelines	Narrative reviews, Primary studies, Conference abstracts, Editorials, Opinions
Languages	English, German	All other languages
Publication period	Published since 2020	Published before 2020

RQ2: Structured country selection (focus on countries with established programmes for structured medication analysis, selection of case studies); structured hand search: Websites of health ministries, professional association websites of pharmacies, websites of transnational organisations (WHO, OECD, EU), evaluation reports of pilot projects; data extraction (iterative addition to preliminary categories); qualitative content analysis, narrative summary, description of the transferability of the implementation of other countries to the Austrian setting.

Preliminary data extraction categories:

Category	Data to be extracted
Setting	Pharmacies, hospitals, doctor's office, home environment
Process	Duration of conversation, frequency
Patient selection	Usage of selection criteria
Methods	Questionnaires used (e.g. Medication Appropriateness Index (MAI), Screening Tool of Older Persons Potentially Inappropriate Prescriptions (STOPP), Screening Tool to Alert Doctors to Right Treatment (START) criteria)
Programme components	Clinical components (e.g. analysis of contraindications, interactions, dosages, duration of therapy, identification of drugs without indication) Patient-centred components (e.g. therapy adherence, analysis of administration technique) System-related components (e.g. identification of generic drugs as more cost-effective alternatives)
Workforce requirements	Professional groups involved Qualifications, additional training
Digital tools	Digital documentation Link to electronic health record Automated detection of drug interactions and other drug-related problems
Costs	Costs per intervention Savings potential (potentially fewer medication prescriptions or hospital stays)

Schedule and milestones:

Time period	Tasks
April 2025	Scoping, Project protocol
May– June 2025	Systematic literature search, Abstract screening, Hand search, Full text analysis
July – August 2025	Quality assessment, Data extraction, Evidence synthesis, Drafting/ writing the report
October 2025	Writing the report, Internal review
November 2025	External review, Finalisation, Publication

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Appraisal Board

Project lead: Sabine Geiger-Gritsch
Project team: Sarah Wolf, Michaela Riegelnegg, Naomi Linton-Romir, Alba Colicchia, Diana Szivakova, Eleen Rothschedl, Eva Malikova, Christoph Strohmaier
Duration: ongoing
Publication: continuously
Language: English

Subject: As part of the recent reform of the Austrian healthcare system, establishing an appraisal board for selected high-priced and specialised medicinal products in the hospital sector or at the interface between the hospital and outpatient sectors was laid down by law. The implementation of the appraisal board and the interlinking with the implementation of the EU HTA Regulation require a series of preparatory and ongoing activities. The AIHTA supports the secretariat in the following areas in 2025:

- Ongoing expansion of a database of clinical experts in various medical fields
- Creation of a method and process manual, including preliminary work for method guidelines for health economic evaluations, *see below*
- Support for the prioritisation of medicinal products (longlists, fact sheets, shortlists...)
- Conducting HTAs, taking into account - where available - European joint clinical assessments (JCA), on medicinal products selected by the appraisal board (for 2025: 5 HTAs)
- Coordinating inputs for PICO-questions for JCAs for medicinal products applied in hospitals

Preparatory Work for an Austrian Health Economic Guideline

Project lead: Sarah Wolf
Project team: Christoph Strohmaier, Diana Szivakova, Sarah Wolf
Internal review: Ingrid Zechmeister-Koss
Duration: February 2025 to January 2026
Language: English (with German summary)

Background:

In 2023, the Austrian government established an appraisal board (“Bewertungsboard für ausgewählte Arzneimittel”) under § 62d ff of the Federal Hospitals Act to ensure fair and rapid access to selected high-cost and specialised medicines used in hospitals and at the intersection between hospital and outpatient care, as well as to promote a nationally consistent use [42]. Health Technology Assessments (HTAs) support the board’s reimbursement decisions, contributing to evidence-based decision-making and greater transparency. In addition to evaluating effectiveness, safety, and other factors such as ethical and social impacts, health-economic evidence such as health economic evaluation (HEE) is a core component of these HTAs. In addition, HEEs may be required for healthcare interventions beyond drugs, including new developments such as artificial intelligence (AI) or complex public health interventions. HEE methods may differ from those used for drugs [43].

To improve the harmonisation and comparability as well as the quality of HEEs for healthcare interventions, many countries have developed and adopted health economic evaluation guidelines (HEEGs). These guidelines are widely used in Europe, Australia, North America [44-46] and low- and middle-income countries [47, 48]. Alongside other health systems guidance, such as clinical guidelines (CGs), HEEGs support evidence-based decision-making by ensuring adequate methods [49]. However, Austria has no formal publicly endorsed

guideline with detailed specifications [50, 51]. Although a private industry consulting institute has addressed some methodological issues in a consensus document [52], it lacks precise methodological direction, and its use remains optional, serving as a recommendation rather than a requirement [50, 51].

Developing a HEEG requires a well-defined process. This process must consider potential barriers and facilitators, including the involvement of stakeholders [53, 54]. While Health System Guidance (HSG) documents, including standards and frameworks, are available for the development, dissemination, implementation and sustainment (DDIS) of CGs [55-62] or HTA guidelines [63, 64], no formal and systematic equivalents currently exist for HEEGs. There are only descriptive overviews of HEEG development processes in some countries [48, 65-68] and frameworks for evaluating and using health economic evidence in decision-making [69-72]. The methodological approach used and developed by Daccache, Karam, et al. [73] to accompany the guideline development process in Lebanon, which is based on the WHO approach HSGs [74, 75], comes closest to a DDIS process framework [73]. A clear and traceable DDIS process is crucial not only to ensure the transparency, objectivity, and effective use of such guidelines by research institutions, the pharmaceutical industry, or medical device companies but also to incorporate evidence from HEEs to inform reimbursement decisions, as required in many countries worldwide [47, 76-78].

Additionally, developing a HEEG requires an overview of existing international guidelines, the domains that existing guidelines address and methodological details. Several reviews already exist regarding guideline overviews [44-46, 48]. However, some recently developed and revised guidelines are not part of such reviews (e.g., Dutch and Slovak guideline) [79, 80]. Furthermore, guidelines for non-drug technologies (e.g., complex interventions) are usually not part of such reviews [43, 81].

Against this backdrop, and to strengthen the role of standardised HEEs in decision-making in Austria, scientific support for the DDIS process of a HEEG and its content is essential.

Purpose and Objectives

The primary purpose of this preparatory work is

a) to obtain an overview of international **guideline development processes** and to derive options for such a process in Austria
b) **Identify barriers and facilitators of the HEEG's DDIS process:** Explore potential challenges and enablers in its development, dissemination, implementation, and sustainment to ensure effective adoption and use.
c) to obtain an **overview of international HEEG**, their contents and specific methodological suggestions for different parts of economic evaluations

Research Questions

The reports address the following research questions (RQ):

Report 1: Review of processes (development, dissemination, implementation, sustaining)

RQ1 How can international best practices, guideline development frameworks, and stakeholder engagement inform the whole DDIS process of an Austrian HEEG to ensure its successful adoption? Which barriers and facilitators exist?

RQ2 What are the most effective strategies for disseminating the HEEG to key stakeholders (e.g., policymakers, healthcare providers, patients, industry)?

RQ3 What strategies are needed to ensure the long-term sustainability and continuous use of the HEEG?

RQ4 How can the impact of the HEEG on reimbursement decisions and healthcare outcomes be monitored and evaluated over time?

Report 2: Guideline content review

RQ5 What are the key components and methodological standards in international guidelines, and what additional domains are required for a robust and standardised HEEG to be used across all technologies in Austria?

RQ1 How do existing HEEGs from different countries compare, and what lessons can Austria learn from these frameworks for a nationwide HEEG?

Methods:

Report 1:

- Conduct a ***scoping review*** to explore guideline DDIS processes, good practice frameworks, barriers, facilitators, and stakeholder perspectives related to the DDIS process of the HEEG.
    - Map the existing literature, identify key factors, and clarify gaps in knowledge.
    - Devise a first ***DDIS process draft***
    - Identify ***Austrian stakeholders and training needs***

Report 2:

- Perform a ***comparative analysis*** of HEEGs from selected countries based on existing reviews [44-46, 48] and pharmacoeconomic guidelines [82]
    - Identification of common mandatory standards of HEEGs and variations or conflicting themes, such as evaluation type, primary health economic outcome measure, time horizon, sensitivity analysis, discount rate, etc..
    - Identification of additional domains, such as HEE methods for AI and complex interventions that may be neglected by standard HEEGs or may become necessary.
    - Presentation of choices
- Initiate a ***preliminary draft*** for an Austrian HEEG in the form of a ***living document***.

PICo analysis

Problem	Some decisions in the Austrian healthcare system, such as reimbursement decisions, are based on evidence-based recommendations from HTAs, including health economic evidence. However, no formal publicly endorsed health economic evaluation guidelines (HEEGs) with detailed specifications on the methods to be applied currently exist in Austria. Furthermore, a clear and traceable development, dissemination, and implementation process of such an HEEG is crucial to ensure transparency, objectivity, and effective use by those who produce HEE (research institutions, the pharmaceutical industry, medical device companies) and acceptance by those who use HEE (decision-makers).
Interests	▪ Knowledge of guideline development, dissemination, implementation and monitoring processes, barriers and facilitators. ▪ Key components, methodological standards required, and additional domains (AI, complex interventions) for a robust and standardised HEEG based on internationally used HEEGs.
Context	International healthcare context and countries with similarities in the healthcare system.
Language	▪ Report 1: English/German ▪ Report 2: English/German/Slovakian/Italian
Publication Type for literature used during the process	All types of publications

Abbreviations: HEEG…Health economic evaluation guideline, HTA…Health technology assessment, PICo…Problem, Interests, Context

Internal and external reviewers ensure the quality of the documents produced.

Timeline:

Phase	Activities	Period
Literature search	▪ Hand search for literature on HEEG development processes and frameworks ▪ Literature reviews on HEEG and recently developed/revised HEEG	Feb 2025 – May 2025
Data extraction and data processing	Extract data from the literature and synthesise	June 2025 – Mid Oct 2025
Draft report	Write separate reports	Mid Oct 2025 – Mid Dec 2025
Final reports	Internal and external review, final reports	Mid Dec 2025 – End Jan 2026

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Self-initiated Projects

1. Social Prescribing in Primary Care: A Realist Review

Project lead: Julia Kern
Project team: Julia Kern, Romy Schönegger
Internal review: Ingrid Zechmeister-Koss
Duration: April until November 2025 (5.5 PM)
Language: English (with a detailed German summary)

Background:

Primary care is the first point of contact between patients and the health care system. In addition to initial care, primary care tasks include prevention, patient information and multidisciplinary and integrated care [83]. However, patients often approach primary care with health-related but non-medical problems. Yet, primary care practitioners often do not have the knowledge or time to recommend appropriate interventions [84].

One approach to reducing the burden on primary care and promoting a holistic approach to health is social prescribing (SP). In SP, patients with non-medical health related needs are referred to a link-worker. The link-worker then discusses with the patient what their exact needs are and refers them to services in the area. Depending on the needs, the services may address material and/or social, or self-actualisation needs. In addition to reducing the burden on the health system, SP aims to improve patient access to regional services, promote health equity and achieve economic sustainability [85].

SP is a complex health intervention. The complexity of an intervention increases with (1) the number of components involved, (2) the variation in behaviours and knowledge required, (3) the number of groups of people involved, and (4) the degree of flexibility in its delivery. In addition, the intervention outcomes may vary depending on contextual factors. This includes changes in the outcomes and contexts through increasing participant's familiarity with the intervention [86].

In Austria, following two funding calls, SP has been implemented in 24 primary health care centres between 2021 and 2024 under the supervision and support of Gesundheit Österreich GmbH (GÖG). Initial results show that SP is well suited for multidisciplinary teams, the majority of the patients could be referred, and almost all would recommend SP to others [87]. In addition, an Austrian ideal model was defined to provide a common understanding of SP in Austria. According to this model, the process of SP in Austria is as follows [85, 88]:

1. Patient with non-medical needs is recognised
2. Patient is referred to a link worker
3. Consultation with link-worker takes place
4. Result is reported back to the health care team and documented
5. Patient takes part in the regional service

Additionally, they defined four core mechanisms of SP [85]:

- Increasing awareness among health care professionals
- Link-working consultations
- Network management
- Quality assurance

Project aims:

Based on the theoretical and practical preliminary work of the GÖG on SP in Austria, the theoretical model behind SP will be further developed. Empirical data from SP evaluations will be used to determine which SP approaches work for which target groups, in which contexts and in what ways. The following research questions (RQ) will be answered:

RQ1 What are the theoretical mechanisms of SP based on the Austrian ideal model?
RQ2 What outcomes can be expected in which contexts, and for which target groups?

Non-objectives

- It is not the aim of this review to summarise whether SP is effective overall, i.e. no classical systematic review will be conducted, but rather, the aim is to reveal what results can be expected under which conditions.
- No alternative context for SP apart from primary care will be identified or assessed.
- No new process will be defined for Austria, the already defined process and the proposed ideal model of the GÖG will be further elaborated, refined and the individual aspects expanded with evidence from international literature.
- The implementation of SP in Austria will not be evaluated, but the implementation experiences in Austria will be used to develop the program theory.

Methods:

The Realist Evidence Synthesis or Realist Review (RR) method is used to address the RQs. A RR is an approach to evaluating the evidence for complex social interventions, in which the theoretical and often implicit mechanisms behind an intervention will be made explicit. However, instead of assessing whether an intervention is effective in principle, it is investigated why, for whom, in what context and in what way it works [89]. The results of this work are intended to provide concrete recommendations for different implementation scenarios to support a possible nationwide implementation of SP in Austria in the future.

The RR methodology follows an iterative process: based on the RQ, an initial programme theory (IPT) is developed, which is then tested and continuously refined through an iterative literature search and selection process. It is not limited to specific types of evidence but includes both quantitative and qualitative evidence. The quality of the literature is assessed according to its relevance and precision. Data are extracted, coded and analysed using Context-Mechanism-Outcome-Configurations (CMOCs) to identify patterns (semi-regularities). The result is a refined programme theory that shows under what circumstances and by what mechanisms SP leads to certain outcomes.

Preliminary data extraction:

General information	Authors, publication year, country
Study characteristics	Study design, sample size, results, target population
Intervention	Description of the intervention, intensity and process, setting
Process details	Comments on fidelity to intervention & changes made by implementers
Context	Study background
Theories	Theories about mechanisms of action that affect the success/failure of the intervention

Timetable:

A realist review is an iterative process. The timetable serves as a rough structure, but the steps often take place in parallel, depending on new findings.

Period	Tasks
April 2025	Scoping and finalising of the project protocol
May 2025	▪ First definition of the program theory ▪ Systematic literature search
June 2025	▪ Data extraction and quality appraisal ▪ Re-evaluation of the program theory
July – August 2025	Writing
September - October 2025	Internal and external review
November 2025	Layout & publication

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2. Measures to Improve Cost Data Use for Health Economic Studies and Decision-Making – Overview of Existing Frameworks and Status Quo in Austria

Project lead: Christoph Strohmaier
Project team: Christoph Strohmaier, Judit Erdös
Internal review: Ingrid Zechmeister-Koss
Duration: April to November 2025 (5 PM)
Language: English (with German summary)

Background:

Cost data play a key role in health economic analyses, including health economic evaluations (HEE) and budget impact analyses (BIA). Costs in health economic analyses are usually calculated by multiplying the quantity of resources used in a patient's care or working unit (cost object), such as a hospital department, by a standard unit cost assigned to each resource type. The analysed costs typically include costs for hospital stays (per admission or per day), intensive care (daily rate), emergency department visits, clinic or primary care consultations (per visit), community nursing or therapy (hourly rate), diagnostic tests (per test), and medications (per tablet or vial) [90].

Beyond trial-based cost data collection (such as prospective measurement of resource use in randomised controlled trials), cost data can also be sourced elsewhere. Further data sources include observational or administrative data from routine clinical practice, so-called real-world cost data, as well as cost data from clinical or (hospital) managerial expert opinions (expert-estimated costs). Cost data may also be derived from other scientific sources (literature reviews, meta-analyses, etc.) or from standardised reference cost databases such as National Health Service (NHS) Cost Collections (Reference Costs) [91] or global estimates by WHO-CHOICE [92] and the Global Health Cost Consortium (GHCC) [93].

A few healthcare systems, such as the one in the United Kingdom (UK) [91] and the Netherlands (NL) [94], provide lists of rates, reference prices, or national cost collections for various types of resource use [90, 95, 96]. Furthermore, national health economic evaluation guideline (HEEG) or HTA guidelines define best practice approaches to costing that are appropriate for the specific jurisdiction. However, caution is needed when comparing unit costs internationally or within healthcare systems that use different approaches to calculate unit costs, as definitions of resource items may differ or the unit cost sources used in economic evaluations for comparable services in a specific jurisdiction remain heterogeneous [95].

Standard and validated unit cost reduces data variability – ensuring that any cost differences between interventions reflect actual resource use rather than differing valuations of the same resources[1] [90]. Reducing heterogeneity within the data allows consistent comparison across different studies and sectors [97]. Therefore, standardised unit cost data reflecting the monetary value of resources is the basis for applying the fundamental criterion of economic considerations – the opportunity cost approach. Consequently, a set of standardised unit costs ensures evidence-based and informed decision-making regarding optimal allocation of resources in the healthcare system or, in simple terms, whether an intervention is worth its costs [78, 98].

In 2016, the Department of Health Economics (DHE) at the Medical University of Vienna developed a Microsoft Excel-based, publicly accessible catalogue of unit costs as reported in published Austrian economic evaluations and costing studies called the DHE Unit Cost Online Database [99, 100]. Furthermore, the ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA), funded by the European Union (EU), provides a tool to calculate unit

[1] The adequacy of the valuation in reflecting the resource's true value constitutes a distinct issue. The application of standardised unit costs, nevertheless, guarantees at least baseline comparability when evaluating different interventions.

costs comparable across countries and sectors. It highlights some practical problems when calculating unit costs. Although the DHE Unit Cost Online Database and the PECUNIA were well-received by Austrian and international scientific communities, there are still some shortcomings regarding the availability and use of unit costs, partly due to the relatively minor role of efficiency considerations in health care decision-making in Austria [78]. Austria currently does not have a nationwide unit cost programme, a firmly established standardised method to calculate unit cost, or a universal unit cost database. In addition, current practices in Austria related to unit cost lack standardisation in data sources (LKF points/Austrian DRG system and hospital controlling data) and have regional variations (differences in unit costs across federal states).

Against this backdrop, the project aims to establish the foundations for a standardised calculation method and a permanently expandable unit cost database. The primary focus lies on applications in health economic analyses for Austrian decision-making processes, such as HTAs conducted in the Austrian Appraisal Board for selected, high-priced, and specialised medicinal products in the inpatient sector [101, 102]. Methodologically, it builds upon both literature identified within the project and insights from two key predecessor projects: the Austrian DHE Unit Cost Online Database [99, 100], which already provides a collection of national cost data, the EU-funded PECUNIA project [97] with its internationally comparative costing methods. These established approaches will be specifically adapted and further developed to meet the requirements of policy-relevant decision-making processes in Austria.

Objectives:

The project's main aims are to…

- Compare international best practices regarding unit cost calculation, use, and reporting (e.g., UK NHS Reference Costs, WHO-CHOICE, GHCC Unit Costing, remuneration system by the German Institute for the Hospital Remuneration System/InEK, PECUNIA) and outline basic concepts and methods in the unit cost context.
- Map existing cost data sources in Austria (e.g., LKF points/Austrian DRG system, hospital controlling data) and identify data fragmentation issues.
- Pilot selected unit cost calculation methods in selected reference hospitals and identify potential variability in unit costs across regions/hospitals.
- Propose best practice strategies for a sustainable national unit cost database and unit cost application in the Austrian context.

Non-objectives:

The report does not provide a universal unit cost framework nor a complete unit cost database for Austria.

Research questions:

The report addresses the following research questions (RQ):

RQ6 What are the international best practices for calculating and reporting unit costs in health economic evaluations, and how can they be adapted for national standardisation?

RQ7 How do existing national cost data sources (e.g., LKF points/Austrian DRG system and hospital controlling data) differ in scope, accuracy, and applicability for unit cost estimation?

RQ8 To what extent do unit costs vary across settings when different calculation methods are applied, and what factors may contribute to these variations?

RQ9 What structural and conceptual requirements are needed to enhance existing national unit cost data sources, including databases, and sustain unit cost use for health economic evaluations and decision-making?

Methods:

RQ1 International best practices: targeted literature review of (unit) costing methods in national HEEG and HTA guidelines, costing projects, programmes, and databases:

- National HEEG and HTA guidelines sources such as ISPOR Overview of pharmacoeconomic guidelines [103], Guide to Economic Analysis and Research (GEAR) Online Resource [104], etc..
- Costing projects, programmes, and databases such as the PECUNIA [97], NHS National Cost Collections (formerly Reference Costs) [91], the costing approach by the Personal Social Services Research Unit (PSSRU) [105, 106], GHCC Unit Costing [93], or the DHE Unit Cost Online [99] etc.
- Consultation of experts of the respective identified country in case of insufficient or missing information.
- Tabulation of identified countries, costing approaches, and further relevant characteristics.
- Narrative synthesis and analysis of gathered information to identify common practices, differences, and implications for national standardisation in Austria).

RQ2 Cost data sources: Mapping Austrian data sources and describing strengths and limitations.

- Identifying existing and potential data sources, including existing databases for unit costs.
- Outlining the data source's specific and general strengths/limitations.

RQ3 Pilot: Applying selected calculation methods in selected hospitals and describe possible factors associated with variations in unit costs.

RQ4 Structural and conceptual requirements: Defining a best-practice framework.

PICo analysis:

Problem	There are still some shortcomings regarding unit costs due to the relatively minor role of efficiency considerations and the use of health economic evaluations (HEE) in health care decision-making in Austria. Austria does not have a nationwide unit cost programme, a firmly established standardised method to calculate the unit cost or a universal unit cost database. In addition, current practices in Austria regarding unit cost lack standardisation in data sources (LKF points/Austrian DRG system and hospital controlling data) and have regional variations (differences in unit costs across federal states).
Interests	**RQ1:** Best practices regarding unit cost use and basic concepts and methods in the unit cost context. **RQ2:** Existing cost data sources in Austria (e.g., LKF points/Austrian DRG system, hospital controlling data) and data fragmentation issues. **RQ3:** Impact of different calculation methods on unit cost across a selection of different hospitals **RQ4:** Structural and conceptual requirements to enhance existing national unit cost data sources, including databases, and sustain unit cost use for health economic evaluations and decision-making. *Not of interest/Not an objective: A universal unit cost framework or a complete unit cost database for Austria.*
Context	International healthcare context with a focus on European countries and countries with similarities in the healthcare system.
Language of the literature / publications	English/German
Publication Type	▪ Health economic evaluation guidelines (Pharmacoeconomic guidelines, pharmacoeconomic recommendations, submission guidelines) ▪ Health technology assessment guidelines ▪ Peer reviewed and grey literature on unit cost and costing projects, programmes, and databases ▪ Strategy and policy documents addressing unit costs and costing

Abbreviations: HEE…Health economic evaluation, PICo…Problem, Interests, Context

Internal and external reviewers ensure the quality of the report.

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3. Implementation of the HTA Regulation (HTA-R)

Project lead: Ingrid Zechmeister-Koss
Project team: Ingrid Zechmeister-Koss, Sabine Geiger-Gritsch, Gregor Götz, Judit Erdös
Duration: ongoing (4 PM)
Language: English

Subject: The HTA Regulation became legally binding in January 2025. Although the HTA-R does not intervene in national reimbursement decisions, it requires that the member states contribute their priorities for the evaluation of products to the central steering committee (Coordination Group). In highly decentralised countries (such as Austria), where many decisions are made regionally, but where the needs for health policy decisions also arise regionally, coordination is a prerequisite for the successful implementation of HTA-R. The work carried out in this context involves participating actively in the HTA Coordination Group and the subgroups and contributing to the ongoing development of documents (e.g., guidelines).

Method: Involvement (preparation and follow-up work) in the working groups, acting as assessor/co-assessor in JCAs (plan: 1 JCA in 2025)

4. Preparation for Evaluation

Project lead and team: Ingrid Zechmeister-Koss, Sabine Geiger-Gritsch
Duration: June to December 2025 (1 PM)
Language: English

Subject: An evaluation of the AIHTA is to take place in 2025. In addition to the actual inspection, extensive materials must be compiled for the evaluators beforehand.

Method: Preparation of evaluation report

5. Master's Theses Supervised by the AIHTA in 2025

Project lead: Ingrid Zechmeister-Koss
Project team: Ingrid Zechmeister-Koss, Sabine Geiger-Gritsch, Claudia Wild
Duration: ongoing (1.5 PM)

Currently ongoing:

- Robots in neurorehabilitation
- Waste avoidance in the hospital
- Comparative analysis of climate protection strategies
- Hämostyptika in heart surgery

Third-party funded projects

1. FWF project #Connecting Minds: Co-design of Perinatal Mental Health Care in Tyrol,https://aihta.at/page/mitgestaltung-der-peripartalen-psychiatrischen-versorgung-in-tirol/de

Overall lead: Jean Paul (Medical University of Innsbruck)
Project partners: AIHTA, University of Innsbruck, LBI for Rehabilitation Research
Project lead at AIHTA: Ingrid Zechmeister-Koss
Project team: Ingrid Zechmeister-Koss, Inanna Reinsperger, Julia Kern, Yui Hidaka
Duration: April 2022 until March 2027
Languages: English and German

Subject: Mental illness is one of the most common complications associated with pregnancy and childbirth. They affect around one in five mothers and more than one in ten fathers during the perinatal period (including 1 year after birth). Mental illness in parents around the time of birth can have a significant impact on child development. In addition to the impact on the health and quality of life of those affected, peripartum mental illnesses also result in considerable economic costs. In Austria, the existing prevention and support structures vary greatly from region to region.

Methods: The project analyses the international evidence and the Austrian situation regarding peripartum psychiatric care models, develops concrete improvement approaches in Tyrol in a participatory manner with regional stakeholders and implements and evaluates these.

AIHTA Work 2025: main tasks completed; Consultancy activities on a small scale.

2. High PRIX: Innovative payment and pricing models
https://hiprixhorizon.eu/

Project lead: Claudia Wild
Project team: Claudia Wild, Daniel Fabian
Duration: January 2023 to December 2025

Subject: Drug prices have risen rapidly in recent decades and the many high-priced therapies are exerting enormous financial pressure on healthcare payers worldwide. In view of the high prices per patient (often over one million euros), it is questionable whether access to these therapies can be guaranteed in the future. Against this background, the AIHTA collects public contributions (R&D) in drug development in order to create transparency regarding the costs and expenditure of various stakeholders.

Methods:

- Systematic collection of data on R&D funding and expenditure
- Development of a handbook on funding categories and sources for data research

3. ASSESS-DHT: Development and Harmonisation of Methodologies for assessing Digital Health Technologies in Europe

Project lead: Yui Hidaka
Project team: Yui Hidaka, Gregor Götz, Reinhard Jeindl, Claudia Wild
Duration: January 2024 to December 2026

Subject: The importance of trustworthy and effective digital health technologies is considered to be significant for the digital transformation of European healthcare systems. The aim of the project is to develop a harmonised evaluation methodology that also covers innovative areas such as intelligent AI-based systems (digital therapeutics (DTx) or digiceuticals) and to test it using pilot examples. In 2025, the AIHTA has the task of piloting the methodology on telemedical care for diabetics.

Methods: Piloting the evaluation methodology on telemedical intervention for diabetics

4. FALCO: Fighting Addictions, improving Lives: COmprehensive drug rehabilitation with music

Project lead: Norwegian Research Centre (NORCE)
Project lead AIHTA: Lucia Gassner
Project team: Lucia Gassner + int. partners
Duration: January 2025 to December 2029

Subject: Drug abuse and addiction are associated with a high burden of disease worldwide. Music therapy has shown short-term effects in patients who do not respond to conventional treatments, but its long-term effects are unknown. The FALCO project is investigating the long-term effects of different music therapy approaches compared to conventional treatment as part of a randomised multicentre clinical trial (lead: NORCE Norwegian Research Centre). The AIHTA is responsible for conducting a literature review on ways of measuring outcomes and assisting with stakeholder involvement and dissemination of results to different target groups throughout the project process.

Methods: systematic literature review, stakeholder mapping, drafting of policy briefs

Deliverable: Music therapy: Clinical and socioeconomic outcome parameters and long-term measuring instruments in individuals with substance use disorders. A systematic review

Background:

Substance use disorder (SUD) is associated with a high global burden of disease, with 1.3% of all disability-adjusted life years lost due to illicit drugs and 4.2% due to alcohol [107]. There are 1 million high-risk opioid users in the European Union [108]. Multimorbidity is highly prevalent and includes polysubstance use, co-occurring mental health conditions, and various sequelae which could be prevented by more effective SUD treatment, including infectious and non-communicable diseases [107]. SUD is also related to crime and poverty through multiple bidirectional links, which increases the societal importance of improving rehabilitation in SUD [107]. Many patients drop out or do not benefit from existing non-pharmacological and pharmacological interventions [109].

Music can engage the brain's reward system similarly to addictive substances [110-112]. It is also rated as one of the most intrinsically rewarding activities [113]. Therefore, music can provide an effective and affordable addition to reduce SUD [114]. Due to the high level of

relapses in the first year after the treatment, an evaluation of substance use patterns in the second year following treatment is needed [114]. Longer lengths of substance use treatment are associated with lower levels of substance use at long-term follow-ups and better engagement in aftercare programmes [115, 116]. More extended periods of music interventions would likely be required to impact substance use behaviours at long-term follow-ups. Thus, it is crucial to investigate the impact of MT on retention in treatment over more extended periods and evaluate the long-term impacts of MT for people with SUDs [114]. For that purpose, a systematic review will be carried out to identify appropriate long-term (>1 year) outcome measures and tools. In order to better understand which outcomes might be most relevant for patients, we will conduct interviews with SUD patients. This shared understanding of perspectives will ultimately aid in understanding patient-relevant measuring instruments.

Aims of the report:

The report aims to give an overview of **clinical** (e.g. addiction severity, recovery, substance use, craving) and **socioeconomic** (i.e. payer-relevant criteria such as integration to work life, unemployment days, health service use, retention in treatment) **outcome parameters** and **types of (serious) adverse events** identified in the existing evidence (of music therapy) in people with SUD (RQ1), how these outcomes are **measured,** and which **characteristics** do those **instruments** have (RQ2).

As research on the long-term outcomes of (long-term) MT treatment is lacking, next to our results of the systematic review (i.e. RQ1+2), fact sheets will give an overview of which measuring instruments are appropriate, feasible and user-relevant, especially for **long-term measures** (RQ3). Additional interviews with SUD service users in two partnering countries, Norway and Poland, will give insights into SUD service user's perspectives. The main question of the interviews is whether these service user inputs correspond to the outcomes/instruments from the review's prior research questions. In Austria, we aim to collect the perspectives of three service users. These perspectives will help us understand service-user-relevant measuring instruments for further work packages for the FALCO project.

Research questions (RQs)

RQ1: Which **clinical and socioeconomic outcome parameters** and **types of (serious) adverse events** can be identified in the existing evidence (of music therapy) in people with SUD? (→ *review of relevant clinical and socioeconomic **outcome parameters** and types of (serious) adverse events)*

RQ2: How are these clinical and socioeconomic outcome parameters and types of (serious) adverse events **measured,** and what are the **characteristics** of those instruments? (→ *review of measuring **instruments** and their **characteristics**)*

RQ3: Which measuring **instruments** are appropriate, feasible and user-relevant, especially for **long-term** measures in patients with SUDs? (→ *fact sheets of **long-term** measuring instruments*)

<u>Methods RQ1 & RQ2</u>

- Systematic literature search of clinical music therapy studies (only reviews)
- Databases: The Cochrane Library, Centre for Reviews and Dissemination (CRD) database, Embase, MEDLINE, PsycINFO, Web of Science
- Manual search and brief survey in selected countries (AUT, NOR, POL) regarding additional instruments measuring socioeconomic criteria; possible sources: websites

of SUD rehabilitation centres, institutions evaluating SUD rehabilitation centres, healthcare system payers (insurances), general search in Google and Google Scholar (e.g. evaluation reports, project reports, validation reports)

- If applicable: manual search in non-MT areas (patients with SUDs) → which additional socioeconomic instruments can be found?
- Creating a table of relevant clinical and socioeconomic outcome parameters and types of (serious) adverse events
- Creating a table of measuring instruments and their characteristics (deliverable 1)
- No risk of bias assessment (e.g. AMSTAR - Assessing the Methodological Quality of Systematic Reviews) since the focus is on the outcome parameters and measuring instruments and not on the effectiveness/efficacy of music therapy

PICO for RQ1 & RQ2

Population	Inclusion criteria: ▪ patients seeking or receiving treatment at the recruitment site for an existing substance use disorder (SUD) based on ICD-10 criteria ▪ ≥18 years old ▪ not currently undergoing detoxification (detoxification has been completed or is not currently planned at the time of recruitment) ▪ any type of substance use including polysubstance and alcohol use Exclusion criteria: ▪ exclusively nicotine dependence ▪ psychotic episode in the last 3 months ▪ insufficient language skills to participate in treatment without the use of a translator ▪ hearing impairment that considerably impairs hearing of music played at a moderate volume (not relevant if hearing is sufficiently compensated by a hearing aid) ▪ existing diagnosis of dementia ▪ is currently receiving music therapy or has received regular music therapy (i.e. at planned and reoccurring intervals, not counting single random occurrences) during the past year
Intervention	Active music groups (AMG) and music listening groups (MLG)
Control	-
Outcomes	RQ1: Clinical and socioeconomic outcomes parameters[2] and types of (serious) adverse events (e.g. relapse requiring hospitalisation, suicide (attempts)) RQ2: Measuring instruments and their characteristics *General characteristics:* ▪ Short description, method ▪ Validity/reliability ▪ Target group, (primary) diagnosis of patients ▪ Test points ▪ Languages, validated/quality-checked translation

[2] **Predefined questionnaires from proposal:**
- Addiction severity: Anxiety Sensitivity Index (ASI)
- Recovery: Substance Use Recovery Evaluator (SURE)
- Alcohol/substance use: Drug Use Identification Test (DUDIT), Alcohol Use Disorders Identification Test (AUDIT)
- Quality of life: EuroQoL-5D (EQ-5D)
- Psychological symptoms: Montgomery-Åsberg Depression Rating Scale (MADRS), Beck's Depression Inventory (BDI)

Additional tools, e.g. from [114]
- Addiction severity: Drinking Inventory Consequences (DrinkC), Severity of Dependence Scale (SDS)
- Alcohol/substance use: amount, frequency, peak use (as measured by self-report, reported by independent evaluators, urine analysis, blood samples)
- Psychological symptoms: Hamilton Rating Scale for Depression (HRSD), State-Trait Anxiety Inventory (STAI), visual or analogue scales
- Substance craving: Brief Substance Craving Scale (BSCS)
- Motivation for treatment/change: Readiness to Change Questionnaire (RTCQ), Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES), University of Thode Island Change Assessment Scale (URICA), visual or analogue scales
- Motivation to stay sober/clean: Commitment to Sobriety Scale (CSS), visual or analogue scales
- Retention in treatment (as measured by the number of participants remaining in treatment at the end of the study)
- Capacity for emotion regulation: Stroop test
- Service use: Client Service Receipt Inventory (CSRI)

	▪ Intervention evaluated (active music groups or music listening groups) ▪ Setting of assessment (e.g. outpatient/inpatient treatment) *Application characteristics:* ▪ How many items ▪ Testing time (min) ▪ Administrative effort ▪ Documentation (e.g. pen-paper, iPad) ▪ Who assesses (e.g. self-, clinician-, performance reported) ▪ Free or licenced instrument
Study design	Reviews
Publication period	From inception to 2024
Databases	The Cochrane Library, Centre for Reviews and Dissemination (CRD) database, Embase, MEDLINE, PsycINFO, Web of Science
Languages	All

Methods RQ3

- Presentation of a long and short list of measuring instruments (from prior RQs) to the FALCO partners
- Prioritisation of a short list of measuring instruments among FALCO partners → Are the selected instruments appropriate for long-term (>1 year) measurements?
- Manual search for specific measuring instruments from the shortlist: appropriate for long-term measures, languages, validation (validity/accuracy/reliability literature), minimum important difference, pros & cons etc.
- If applicable: search for measuring instruments for non-SUD → transferability to SUD?
- Creating fact sheets of the most appropriate, feasible and user-relevant long-term measuring instruments

Service user involvement:

In the frame of the systematic review, interviews with people with lived experience are planned in three countries (Austria, Norway, Poland). Professional knowledge cannot replace the lived experiences of people with SUDs, as the service users are the key actors contributing to the project. In this report, service user involvement should achieve knowledge that would otherwise not be produced and should help uncover, e.g., restrictions or suffering due to SUD or aspects that should improve due to MT. We aim to explore with people with lived experience their understanding of patient-relevant outcomes and consequently measuring instruments.

The service users might have additional physical illnesses, disabilities or mental illnesses and are a vulnerable group. Therefore, the interviews take place at the Anton Proksch Institute, where psychotherapists, clinical/health psychologists, or social workers can protect and inform the participants.

Methods

- Creating a semi-structured interview guide for the service user involvement among input from FALCO partners
- Creating participant information sheet and consent form
- Ethical approval
- Service user acquisition in Austria, Norway, and Poland
- Interviews will be conducted in a clinical setting (outpatient clinic, daycare centre or other hospital setting)
- The interviewees should be in therapy with at least one year of sobriety but not in music therapy

- Recruitment in Austria within the outpatient clinic by their practitioners (doctors, psychotherapists, clinical and health psychologists, social workers) at the Anton Proksch Institute, Vienna
- Doing face-to-face interviews with three service users at each site, which are audio-recorded using a smartphone voice recorder
- Transcribing using e.g. Good Tape, Trint or Word 365 and translating interviews
- Analysing and interpreting interviews with the qualitative content analysis using e.g. MAXQDA
- Summarising nine service user interviews

➔ Do these service user inputs correspond to the outcomes/instruments from RQ1 & RQ2? (→ service user relevant instruments)

Workflows are organised according to the principle of dual control; the results are subject to internal and external reviewers.

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5. HTA Capacity Building (HAG insight)

Project lead: Agenas, Italy
Project team: Consortium of 15 HTA institutes
Project lead AIHTA: Judit Erdös
Duration: November 2024 to February 2027

Background: The HAG Insight project aims to strengthen the long-term capacity and expertise of HTA institutes in the EU. This initiative will not only establish a comprehensive training platform for HTA regulatory processes and methods, but will also develop a competence framework detailing the expertise required to conduct joint clinical assessments and scientific advice. This framework will serve as a guide for national and regional HTA institutes to help them recruit or identify suitable staff with the required skills and competencies. A consortium of 15 HTA institutes will implement the project, led by Agenas in Italy.

Methods: The training courses include online courses, recorded modules and tutorials. The competency framework is developed through systematic research in academic sources as well as job adverts and CVs of reviewers, interviews and focus groups.

Role of AIHTA: The AIHTA is part of the advisory body. During regular meetings with the committee, the members discuss and review results and milestones.

6. Teaching PMU

Project lead: Ingrid Zechmeister-Koss
Project team: Ingrid Zechmeister-Koss, Sarah Wolf, Gregor Götz, Nicole Grössmann-Waniek, Lucia Gassner
Duration: ongoing

Background: The AIHTA has had a cooperation agreement with the Paracelsus Medical University Private Foundation (PMU) since 2021. This cooperation agreement aims to build the capacity of junior staff in the Master's degree programme in Public Health in Health Technology Assessment (HTA) to implement evidence-based decision support in healthcare. Teaching takes place several times a year in the form of virtual lecture theatres.

Methods: Exercise and creation of scoping documents

HTA Austria
Austrian Institute for
Health Technology Assessment
GesmbH