

Project Protocol

Integrated Digital Wound Management Systems (IDWMS) in the Care of Chronic Wounds: Evidence Assessment and Evaluation Framework for Implementation in the Austrian Healthcare System

Project Lead: Yui Hidaka

Authors: Oliver Bernecker (PMU-Student), Yui Hidaka

Quality Assurance: Gregor Goetz

Duration: Q1 to Q3 2026

Resources: 1.5 PM (Master thesis with in-house support)

Language: English (with German summary)

Background

Chronic wounds (e.g. venous leg ulcers, diabetic foot ulcers, and pressure ulcers) are associated with a high disease burden, prolonged care trajectories, and repeated contacts across different care settings [1,2]. In practice, documentation, longitudinal monitoring, and information exchange are often fragmented, which complicates clinical decision-making and ties up staff resources. At the same time, requirements for quality assurance, traceability, and cross-sectoral collaboration are increasing. The main challenges in chronic wound care can be summarized as follows:

- Multiple interfaces between care sectors
- Missing or heterogeneous longitudinal documentation
- Inconsistent wound measurement with low reliability
- High process burden with substantial staff involvement

Robust prevalence and incidence data are lacking at both the international and national levels, as definitions, data collection methods, and data sources vary [1,3,4]. International estimates from the Organisation for Economic Co-operation and Development (OECD) place the proportion of affected individuals in high-income countries at approximately 1% to 2.5% [6]. For Europe, costs are estimated to account for 2% to 5% of total health expenditure, with inpatient stays and personnel costs representing the main cost drivers [7,8].

Integrated digital wound management systems (Digital Wound Management Systems, DWMS) aim to standardize the measurement and documentation of chronic wounds across different interfaces and to make this information digitally available on a shared platform. They are also intended to support the efficient telemedical care of affected individuals [3]. DWMS typically combine wound imaging (two-dimensional/three-dimensional [2D/3D]), (semi-)automated measurement and analysis, structured documentation, and platform functions (dashboard, export functions, and interfaces). In doing so, they incorporate various digital health technologies.

Many DWMS are designed for telemedical use. Wound data are captured and transmitted independent of location and can be assessed by treating healthcare professionals. These systems require the digital transmission and central storage of information between users and healthcare providers. Another digital health technology used in DWMS is artificial intelligence (Artificial Intelligence, AI). AI is expected to be used primarily for image analysis (e.g., segmentation and area/volume measurement) and for decision support (e.g., risk prediction or prognostic assessment of wound progression). Depending on the system, this may involve either static (fixed) or adaptive (self-learning, on-market evolving) AI.

DWMS is an intervention consisting of a software-based medical device, but also other components. In this report, the ASSESS-DHT framework [5] is used as a structuring reference framework to address, alongside the classical health technology assessment (Health Technology Assessment, HTA) domains, DHT-specific cross-cutting issues (e.g., interoperability, data protection, and cybersecurity) in a consistent manner.

Project Objectives:

- To map DWMS solutions and structure use cases (indication × setting/workflow) as well as the evidence landscape (clinical, organizational, and economic).
- To assess the evidence on clinical effectiveness and safety.

- To systematically identify requirements, barriers, and implementation options for Austria and to outline a concept for evaluation.

Non-objectives:

- Assess technologies that do not meet the inclusion criteria (e.g., simple photo storage, stand-alone tools without an integrated workflow, or telemedicine-only solutions without integrated measurement/analysis).
- Conduct a health economic evaluation (cost-effectiveness analysis).

Research questions:

RQ 1: Which DWMS solutions/models are internationally available or currently in use/being piloted in Austria, and how is the related evidence landscape (clinical and organizational) structured?

RQ 2: How do integrated digital wound management systems (IDWMS) perform in clinical practice with regard to clinical effectiveness and safety, technical performance/validity, organizational and process-related effects, and usability/trust, and which evidence gaps remain for a later comparative assessment against standard care?

RQ 3: Which recommendations can be derived for implementation in Austria, and how should pilot implementation be evaluated (key performance indicators [KPIs], minimum dataset, and design options)?

Methods:

FF1: Mapping of technologies and the evidence landscape

Data sources:

- Results of the systematic literature search from RQ 2 (publications on IDWMS).
- Supplementary sources: gray literature (websites/project reports), manufacturer information, national programs/strategies, and relevant government and social insurance contexts.

Procedure and Output:

- Identify IDWMS candidates and describe them based on minimum characteristics (area of application, setting, workflow integration).
- Define use cases (indication x setting/workflow) and assign evidence types (validation/performance, implementation, comparative evidence).
- Create an evidence map and identify evidence gaps.

RQ 2: Systematic review update using a layered approach

1. Structured search of the last five years for systematic reviews (SRs) on IDWMS.
2. Selection of one systematic review as the base review: two reviewers assess independently; selection criteria, in order, are risk of systematic bias in the SR (Risk of Bias in Systematic Reviews, ROBIS), fit with the scope and the Population, Intervention, Comparator, Outcomes (PICO) structure, recency, and coverage (search cut-off date and time period).
3. SR update: Inclusion of the primary studies from the base review plus a systematic update search from the search cut-off date of the base review to the project search cut-off date.
4. Extraction and synthesis: structured according to the European Network for Health Technology Assessment (EUnetHTA) Core Model 3.0 [9] and the ASSESS-DHT manual; risk-of-bias assessment by two independent reviewers; for comparative clinical outcomes, the certainty of the evidence is assessed using Grading of Recommendations Assessment, Evaluation and Evaluation (GRADE) where appropriate.

RQ 3: Austrian context, implementation options, and pilot evaluation

Data sources:

- Results from RQ 1 and RQ 2.
- Targeted sources on the Austrian context (guidelines, care models, programmes, eHealth/interoperability, data protection/governance, reimbursement/financing).
- Expert input: collected through semi-structured expert interviews across different care sectors.

Procedure and Output:

- Derive requirements and barriers for implementation (information technology (IT)/interoperability, roles and workflows, responsibilities, training needs).
- Define a pilot evaluation concept (key performance indicators (KPIs), minimum dataset, data collection pathways, design options such as before-and-after studies, controlled observational studies, or phased implementation).

Inclusion and exclusion criteria (PICO)

Element	Inclusion criteria	Exclusion criteria
Population	Patients with chronic wounds (e.g., leg ulcers, diabetic foot ulcers, pressure ulcers).	Acute/postoperative wounds, burns, oncological wounds (if outside the scope)
Intervention	IDWMS with the following minimum features: digital imaging + (semi-)automated analysis/measurement + structured documentation/tracking + platform/workflow functions.	Stand-alone tools without an integrated workflow, or simple photo storage without a system-based approach
Comparator intervention	No inclusion criterion. Comparative studies, if available, will be analysed separately, if available.	No explicit exclusion criterion.
Outcome	■ Clinical effectiveness (wound healing time, wound healing rate, reduction in wound area, hospital readmission rates, therapeutic escalation) ■ Safety (wound complications, safety-relevant misclassifications, delay in therapeutic escalation, false-negative or false-positive classifications, where relevant) ■ Patient-reported outcomes (pain, symptom burden, wound-related quality of life, functional status, self-management burden, treatment burden, adherence, if reported by patients) ■ Patient-reported experiences (communication, coordination or continuity of care, usability, acceptance, perceived benefit, satisfaction with care or technology) ■ Technical performance and validity (reliability, accuracy, measurement quality, error rates) ■ Organization / workflow / human Factors (resource use, care time, documentation time, number of contacts/visits, protocol adherence, feasibility of implementation, usability from the perspective of healthcare professionals, trust of healthcare professionals, integration into the care pathway)	No explicit exclusion criteria.
Setting	Outpatient, inpatient, community care/long-term care	–
Time period	Base-layer systematic reviews/health technology assessments: last five years; primary study update: from the search cut-off date of the base review to the project search cut-off date.	–
Language	English and German.	–

Kommentiert [IZ1]: Table can have another column (inclusion/exclusion criteria)

Timetable:

Timeframe	Tasks
Q1 2026	Scoping/finalization of the protocol
Q1 2026	Literature selection for areas of application: systematic literature search and handsearching, data extraction
Q1 2026 to Q2 2026	Extraction/synthesis & development of the pilot concept
Q2 2026	Internal and external review
Q2 2026	Layout and publication

References

- [1] Schneider, C., Drgac, D., Niederleithinger, M., Hruschka, V., & Himmelsbach, R. (2022). The management of chronic wounds in the Austrian healthcare system – an overview. Ludwig Boltzmann Research Group on Aging and Wound Healing. <https://doi.org/10.5281/zenodo.6406108>.
- [2] Martinengo, L., Olsson, M., Bajpai, R., Soljak, M., Upton, Z., Schmidtchen, A., Car, J., & Järbrink, K. (2019). Prevalence of chronic wounds in the general population: Systematic review and meta-analysis of observational studies. *Annals of Epidemiology*, 29, 8–15. <https://doi.org/10.1016/j.annepidem.2018.10.005>.
- [3] England, C., Boyce, R., Hasler, E., Hughes, S., & Jarrom, D. (2025). The clinical effectiveness of integrated digital wound management systems. *Journal of Wound Care*, 34(10), 852–860. <https://doi.org/10.12968/jowc.2024.0086>.
- [4] Health Technology Wales. (2023). Integrated Digital Wound Care Management Systems to assess and manage people receiving wound care (Evidence Appraisal Report No. EAR051). Health Technology Wales.
- [5] Bowie, D., Needham-Taylor, A., et al. (2025). Working paper on the interim Manual for piloting assessment methods for digital health technologies (ASSESS-DHT Interim Manual 2). (Accessed February 20, 2026).
- [6] de Bienassis, K., Llana-Nozal, A., & Klazinga, N. (2020). The economics of patient safety Part III: Long-term care: Valuing safety for the long haul. OECD Health Working Papers, No. 121. OECD Publishing. <https://doi.org/10.1787/be07475c-en>.
- [7] World Health Organization. (November 28, 2022). Diabetes interventions: Technical briefing for Appendix 3 of the Global Action Plan for Non-Communicable Diseases (Version November 28, 2022).
- [8] Guest, J. F., Fuller, G. W., Vowden, P., & Vowden, K. R. (2020). Cohort study evaluating the burden of wounds on the UK's National Health Service in 2017/2018: Update from 2012/2013. *BMJ Open*. <https://doi.org/10.1136/bmjopen-2020-045253>.
- [9] EUnetHTA Joint Action 2, Work Package 8. HTA Core Model® version 3.0. 2016.