Improving the effectiveness and cost-effectiveness of healthcare through enhanced data production, analytics, and research

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Abstract:

This collaborative project, **led by HUS, in partnership with Vantaa-Kerava Wellbeing Services County and the University of Eastern Finland (UEF)**, aims to advance healthcare effectiveness and cost-effectiveness by developing systematic data production workflows and real-world data (RWD) analytics. The project constitutes systematic public R&D activity aiming to generate new, scalable methods for clinical outcome and economic data, and real-world evidence (RWE) production across the social and healthcare service chains. It builds upon a framework originally developed by HUS during the 2022–2025 Sustainable Growth Programme for Finland (RRP2 and RRP3), designed to support end-to-end data workflows from database management to disease-specific monitoring of clinical and economic outcomes in specialized care.

This project now focuses on ensuring the **scalability, institutionalization, and continuity** of this data-driven approach by embedding outcome and cost-effectiveness assessments into routine healthcare management and clinical decision-making. **The goal is to establish permanent capabilities that improve care quality, effectiveness, and cost-effectiveness, as well as the wider societal impact (e.g., in terms of improved work ability) of provided services.**

As a core part of its research component, the project will develop and validate **predictive analytics models** that estimate clinical complication risks and economic outcomes. Use cases include 1) estimating cost-effectiveness across the care and rehabilitation pathway of **older patients with hip fractures**, with scalability to elective surgical care (e.g., hip and knee arthroplasty) (i.e., **Use Case 1**), and 2) predicting complication risks and economic outcomes in the treatment of **Type 1 Diabetes (T1D)** across both primary and specialized care (i.e., **Use Case 2**). All developed RWD production methods and models will be evaluated in a scientific research context to ensure generalizability and support broader regional and national adoption. **The project will contribute significantly to public health by increasing the health benefits patients receive through cost-effective care while aiming to reduce the use of low-value, ineffective, or potentially harmful interventions.** The project also seeks **to promote research and development (R&D) activities across the wellbeing services counties** and to strengthen inter-organizational collaboration within the newly restructured social and healthcare system.

1 Background and significance

1.1 Alignment with call objectives and strategic goals

The project is led by a HUS Helsinki University Hospital - Finland's largest provider of health care services, which produces services for more than 1.6 million residents of its 26 member municipalities - and implemented as a **consortium** including a wellbeing services county (Vantaa-Kerava) and a university (UEF) and its directly supports the call's objectives to promote **publicly beneficial research and development (R&D) activity** that enhances productivity, care quality, and societal

impact in the social and healthcare sector, as well as **strengthen collaboration between wellbeing services counties and higher education institutions**. The project is also aligned with the strategic goal of **institutionalizing outcome-driven management**, by embedding systematically produced RWE into routine healthcare decision-making and service development. Furthermore, the project builds on **prior public investments** (i.e., Sustainable Growth Programme for Finland) and ensures **scalability and continuity** of previously piloted solutions. By integrating structured outcome and economic data production into both primary and specialized care workflows, and by developing AI-driven predictive tools, the project contributes to the call's aim to **create something fundamentally new** and actionable. Finally, the project promotes **regional R&D capacity building** and lays the groundwork for scalable collaboration models that can be expanded to other wellbeing services counties in the South Finland collaborative area, aligning with national objectives for data-driven, value-based healthcare transformation.

1.2 Strengthening regional R&D capacity and collaboration

This project focuses on the **institutionalization and permanent integration** of previously developed practices into routine RWD generation workflows, research activities, and healthcare decision-making. By embedding effectiveness- and cost-effectiveness-oriented data production into everyday care processes, the project strengthens the continuity and scalability of earlier R&D efforts. These developments enable the implementation of **outcome-based management** across the full continuum of care, from specialized healthcare to primary care services.

Beyond internal development, the project also **reinforces collaboration between HUS and the Vantaa-Kerava Wellbeing Services County by inter-organizational cooperation**, which enhances the regional R&D infrastructure and **supports the joint development, piloting, and implementation of RWE-based practices across healthcare system** boundaries. Moreover, the collaborative model established between HUS and Vantaa-Kerava is **designed to be scalable and replicable in cooperation with other wellbeing services counties**, thereby supporting broader regional dissemination and impact. In addition, the project strengthens collaboration with the UEF, the national leader in the effectiveness and economic evaluation research, creating RWD-driven research models for collaboration between healthcare providers and research organisations. These models ensure the **continuous translation of research into practice and are designed for national scalability** across Finland's wellbeing services system.

1.3 Scientific and methodological foundations of the project

The project builds on the growing body of evidence and best practice guidelines related to the use of EHR data in research and healthcare system development. Advances in **data integration, semantic harmonization, and RWD analytics** have made it increasingly feasible to utilise routine care data for systematic outcome and economic evaluation. The project applies **state-of-the-art statistical methods**, such as longitudinal trajectory modeling and prediction techniques (xx), to estimate the health and economic outcomes of health services in real-world settings. These methods allow for valid comparisons across patient groups and care pathways, while accounting for heterogeneity in patient characteristics and care processes. In addition, the project leverages **AI/ML techniques** to build predictive models that estimate individual risk for complications and long-term economic outcomes (XX). These models could potentially support proactive care planning and targeted interventions, particularly in chronic diseases such as T1D and in complex care episodes such as hip fracture rehabilitation. Methodologically, the models will be developed and validated using rigorous cross-validation and external validation processes to ensure generalizability and clinical utility. The project

also emphasizes **methodological transparency and reproducibility**, aligning with guidelines for trustworthy AI (xx) and RWE generation (xx). The analytical framework is designed to support both service development and peer-reviewed scientific research, ensuring dual value creation.

1.4 Use case background and significance: Older patients with hip fractures

Finland's ageing population and increasing burden of chronic diseases present substantial challenges to the **sustainability and effectiveness of healthcare and social welfare services**. This is especially underscored as an increasing number of various procedural treatments are available – and potentially beneficial as well – also for older adults.

Hip fracture patients, typically older adults living with frailty and several comorbidities, serve as an example of a high-risk, high-cost population whose care involves **multiple sectors of the health and social care** system (Panula et al. 2011, Dyer et al. 2016). Variations in outcomes and resource use between regions indicate gaps in data availability, coordination, and evidence-based planning. Although many data registers and outcome indicators exist nationally, their integration and operational use remain fragmented across wellbeing services counties, and furthermore, across various register boundaries. For the present, lack of up-to-date data and established real-time reporting systems creates barriers in the real-time follow-up of treatment outcomes and costs among various care pathways. Therefore, there is a pressing need to strengthen analytic and collaborative capacity across organisational boundaries (Sund et al. 2011). Our current project will use the care pathway of older hip fracture patients as a model to develop and scale the improved data-driven approaches to **care coordination, outcome tracking, and resource optimisation across the continuum of care**. This will require intensive collaboration between secondary (Helsinki University Hospital) and primary care and social services provided by wellbeing services county (Vantaa-Kerava).

By enhancing data production and analytical capacity across institutional boundaries - including hospitals, primary care, rehabilitation, and long-term care - the project will enable better **integration of care processes** and improve decision-making both at the clinical and system level. From this foundation, the analytic and operational framework could be further expanded to other procedure-based geriatric care pathways, such as elective hip or knee arthroplasty and transcatheter aortic valve implantation (TAVI), which also require tightly coordinated multidisciplinary care and are increasingly common in ageing populations (Kjelsnes et al. 2021, Cook et al. 2022, Van Heghe et al. 2022).

This project will strengthen R&D capacity in the collaborative healthcare and social welfare sector by developing **unified data infrastructures, harmonized outcome indicators, and regionally scalable analytics tools**. It brings together wellbeing services counties, universities, and national research institutes (e.g. *Finnish Institute for Health and Welfare (THL)*, *Statistics Finland*) in a co-creative framework, directly linking academic research with operational needs. The involvement of frontline clinicians, administrators, and data specialists ensures relevance, usability, and uptake of research outputs.

The added value of this collaboration for wellbeing services counties lies in **shared access to advanced analytics, benchmarking tools, and predictive models** that inform service development, resource allocation, and quality improvement. Furthermore, joint development of digital tools and processes (e.g. using harmonized and anonymized data as a tool in regular reporting systems) facilitates knowledge transfer and supports sustainable, evidence-based knowledge-management.

This kind of model aims at improving processes of integrated geriatric care. This enhances the societal impact of R&D activities and supports regional innovation and workforce development.

Internationally, **integrated care models** have shown promise in improving outcomes in frail older populations (Van Heghe et al. 2022), yet translation into routine practice is uneven and context sensitive. Our current project aims at integrating evidence from international studies (Johansen et al. 2022) while addressing specific Finnish challenges, including regional disparities, siloed data systems, and somewhat underutilised outcome analytics. It aligns with EU-level calls for data-driven and value-based healthcare. The project is also closely aligned with the goals of Finland's health and social services reform, strengthening the capacity of new structures to deliver **high-quality, cost-effective, and equitable care** through data-driven collaboration. The project builds on recent structural reforms in Finland's health and social services, providing a timely opportunity to enhance R&D practices.

1.5 Use case background and significance: Type 1 diabetes

Type 1 diabetes (T1D) is a chronic autoimmune condition requiring lifelong insulin therapy and intensive self-management to prevent both acute complications (such as severe hypoglycemia or diabetic ketoacidosis) and long-term complications (e.g. nephropathy, retinopathy, cardiovascular disease) (REF). The management of T1D is rapidly evolving due to advances in diabetes technology, which has the potential to improve glycemic control, reduce patient burden, and decrease healthcare costs. A major transformation in T1D care has been the integration of **advanced insulin pump therapy combined with continuous glucose monitoring (CGM)**. These so-called "hybrid closed-loop systems" or "automated insulin delivery (AID) systems" dynamically adjust insulin delivery based on real-time glucose measurements, supporting tighter and safer glucose control compared to manual insulin dosing. In contrast, **traditional insulin injection therapy** (multiple daily injections, MDI) and **older-generation insulin pumps** rely more heavily on patient input, do not automate insulin dosing based on real-time glucose levels, and are associated with greater glycemic variability and treatment burden. Despite their widespread use, these older modalities may not adequately support optimal long-term outcomes for many individuals with T1D. Emerging evidence suggests that newer technologies improve not only **time-in-range (TIR)** and **HbA1c levels** but also reduce the incidence of severe hypoglycemia and hospitalizations (XX). They also offer **potential economic benefits** through reduced complication rates and lower healthcare utilization over time. However, their cost-effectiveness in real-world settings and across patient subgroups remains under-explored. This project will use the T1D population as a second real-world use case to evaluate the **clinical and economic impact of advanced versus traditional insulin therapies**, leveraging RWD from primary and specialized care.

2 Impact

2.1 Impact and cost-effectiveness evidence produced by the project

The project will generate significant measurable impact across healthcare practices and data-driven management. The effectiveness data, metrics and reporting models developed will enable the evaluation and optimization of care pathways from both effectiveness and cost-efficiency perspectives within HUS and across the South Finland collaborative area.

The project aims to increase health benefits and patient-centred decision-making by identifying ineffective or even harmful treatments.

The project serves as a pilot for EHDS-compliant analysis methods, enabling future federated data use in both research and operational contexts.

The cost-effectiveness of interventional procedures, such as surgical treatments, across the entire continuum of care - including specialized medical care, primary healthcare, and social services - has not been sufficiently studied in Finland. This gap is particularly significant in the context of older adults, for whom conventional cost-effectiveness indicators, such as direct treatment costs (encompassing the procedure itself and the immediate need for hospitalization and rehabilitation), repeat interventions, and mortality rates, fail to adequately capture the long-term impacts of care. These include changes in functional ability, quality of life, and evolving needs for health and social services.

Older adults undergoing interventional procedures are at higher risk of complications, longer recovery times, and increased resource use. There is a critical need for **continuous and integrated reporting systems to monitor clinical outcomes and cost-effectiveness throughout the entire care pathway** from preoperative assessment to post-discharge recovery (Joeris et al. 2023).

Understanding the cost-effectiveness of interventional procedures in older adults is essential for building a sustainable, equitable, and patient-centered healthcare system. This research will provide critical evidence to support value-based care, where **improved clinical outcomes are achieved alongside more efficient resource use**. By enabling systematic evaluation of the entire care pathway - including acute, rehabilitative, and long-term support phases - the study will help identify inefficiencies and potentially harmful practices early, ensuring safer and more appropriate care. Furthermore, the insights gained will support **shared decision-making** by equipping patients, families, and clinicians with transparent data on likely outcomes, quality of life impacts, and care needs. Finally, the project will facilitate **benchmarking and continuous quality improvement** across institutions, contributing to the development of national standards and best practices in aging populations.

2.2 A framework for assessing value in interventional procedures for aging populations

To comprehensively evaluate the cost-effectiveness of interventional procedures in older adults, it will be necessary to employ a robust set of outcome and economic metrics that capture both **short-term and long-term impacts** across the care continuum (Johansen et al. 2022, Johansen et al. 2023). In this study effectiveness will be assessed using clinically meaningful indicators, including mortality and morbidity rates, readmissions, complication rates, and time to recovery or return to baseline function. Special emphasis will be placed on functional status and quality of life, using validated instruments such as the 15D quality of life and activities of daily living (ADLs) to ensure that the **patient's perspective** is central to the evaluation. In parallel, **cost metrics** will encompass both direct and indirect costs, including expenditures related to the interventional procedure, hospital stay, medications, and rehabilitation. Additionally, long-term healthcare utilisation will be analysed to account for downstream costs associated with complications, institutionalization, or ongoing service needs. This multidimensional approach will enable a comprehensive assessment of value, tailored to the complexities of care in the aging population.

While the proposed study has strong potential to inform more effective and equitable care for older patients undergoing interventional procedures, several challenges must be proactively addressed to ensure its success. First, data interoperability across healthcare and social care systems remains a significant barrier; integrating diverse datasets from hospitals, primary care, rehabilitation services, and long-term care requires harmonized data standards and robust technical solutions. Second, safeguarding patient privacy will be essential, particularly given the sensitive nature of health and social service utilisation data over time. Third, the project will necessitate careful resource allocation for IT infrastructure and advanced analytics, including secure data platforms and

capacity for real-time or near-real-time data processing. Lastly, the study must account for the substantial variability in patient complexity and care environments, which can affect both clinical outcomes and cost patterns.

2.3 A framework for assessing value in advanced treatment technologies in type 1 diabetes

By focusing on insulin pumps with CGM systems, the project bridges a critical gap between innovation, evidence generation, and real-world implementation. The impact of this framework will be visible across five key dimensions: 1) timely and context-specific evidence for decision-making. The framework enables systematic production of real-world evidence on the effectiveness and cost-effectiveness of T1D treatments, tailored to specific patient groups and care settings. 2) optimized use of public resources. By identifying which patient subgroups benefit most from CGM-enabled insulin pumps, the framework enables more targeted adoption of costly technologies and thereby improving outcomes while avoiding unnecessary expenditure. 3) support for value-based care and reimbursement models. The increased ability to quantify outcomes and economic value in real time supports the development of outcomes-based contracting and reimbursement schemes, aligning incentives between providers, payers, and patients. Finally, 4) the framework will accelerate research translation and learning healthcare system development. By combining RWD with advanced analytics, the framework strengthens research-practice integration. It enables the early identification of new research hypotheses and rapid learning loops between clinical innovation, evaluation, and practice refinement.

2.4 Implications for clinical practise, policy, and digital infrastructure

The impact on clinical practice includes revised eligibility criteria for interventional procedures that incorporate frailty and functional status to better identify older patients who are likely to benefit from these interventions. The findings may also facilitate the implementation of standardized post-operative care protocols aimed at reducing complications and readmissions among high-risk older adults. Personalized recovery pathways can be developed based on predictive models built from study data.

Health system and policy impact involves the development of national benchmarks for cost and outcome performance in care of older adults, enabling cross-hospital comparisons. Resource allocation decisions are informed, allowing policymakers to shift investments toward interventions and services, such as rehabilitation and home care, that demonstrate favorable cost-effectiveness profiles.

Data and digital infrastructure impact is addressed through improved interoperability between hospitals, primary care, and social care systems, enabling continuous tracking of outcomes and costs. Digital dashboards are developed to provide clinicians and managers with real-time effectiveness and cost metrics for older patients going through interventional procedures.

2.5 Collaboration to strengthen impact and R&D in wellbeing services counties

The project involves close collaboration with key actors across the South Finland collaborative area, including wellbeing services counties, academic institutions, and healthcare providers. This cooperation ensures that the developed data, tools, and models are not only scientifically valid but also aligned with real-world needs and operational priorities. By co-developing solutions with

regional partners, the project strengthens the regional R&D ecosystem and fosters knowledge transfer between organisations, enhancing the scalability and sustainability of impact.

2.6 Promoting impact-driven R&D in wellbeing services counties

The project contributes to building an impact-driven research and development culture within the reformed health and social care structures in Finland. It supports wellbeing services counties in adopting data-informed decision-making by providing validated tools for evaluating cost-effectiveness and clinical value. The project also promotes systematic use of outcome data in service development, aligning with national goals for value-based care and the long-term strategic transformation of the healthcare system.

2.7 Outcomes and impacts of research within academia

The project will generate added academic value through the systematic utilisation of RWD and the development of methodologically robust, reproducible frameworks for evaluating health and economic outcomes in routine care settings. By integrating RWD from both primary and specialized care, **the project creates new possibilities for RWD-based research** on care effectiveness, predictive modeling, patient-reported outcomes (PROMs), and long-term service impact across care pathways. Collaboration with UEF ensures that the methods and findings developed in the project are aligned with academic research agendas in public health, health economics, health informatics, and implementation science. The project also serves as **a platform for interdisciplinary RWD-based research** that bridges different research disciplines. The projected academic outcomes and impacts of the project include: 1) **production of peer-reviewed scientific publications** that utilise RWD generated in collaboration with healthcare providers, contributing to international research on effectiveness and health system performance, 2) **creation of novel research infrastructures and curated longitudinal datasets**, which support robust observational and comparative studies across care levels, 3) **strengthening of research capacity and training** by offering concrete research environments and data for doctoral dissertations, master's theses, and early-career researcher projects, 4) **advancement of AI/ML methods in clinical prediction and economic evaluation**, including model development, validation, and implementation in real-world settings, 5) **establishment of RWD-driven academia-healthcare collaboration models**, which enable continuous knowledge exchange and can be scaled nationally to support RWE-informed service development, 6) **facilitation of hypothesis generation through exploratory RWD analysis**, enabling researchers to identify new and relevant research questions and hypotheses based on observed patterns and associations in real-world healthcare delivery, and finally 7) **strengthening of Finland's competitiveness in health research and innovation**, particularly in the context of the forthcoming implementation of the **European Health Data Space (EHDS)**. The methods and governance models developed in the project will support secondary use of health data in line with EHDS objectives and position Finland as a frontrunner in **secure, impactful, and ethically sound data use** in academic research.

3 Implementation

3.1 Project Plan and Schedule

3.1.1 Objectives, scientific references and preliminary data

Overall, as a core part of the project's research component, the project will develop and validate **predictive analytics models** that estimate health and economic outcomes, as well as to develop **methods needed to evaluate the real-world cost-effectiveness of provided services.** In Use Case 1, the primary aim is to improve the overall effectiveness and cost-effectiveness of care for older adults through enhanced data production, linkage, and real-time analytics. Specific research objectives of the **Use Case 1** are as follows:

1. **Developing standardized**, comparable outcome indicators across care sectors.
2. Building **data infrastructures and analytics** that support clinical and operational decision-making continuously.
3. **Strengthening inter-organisational collaboration** across wellbeing services counties, University Hospital, and research institutions.
4. **Scaling** successful models from hip fracture care to other procedure-based pathways.

In addition, the Use Case 1 -specific R&D questions are:

1. How do variations in **patient-related factors, care pathways, and inter-organisational coordination affect outcomes and costs** in hip fracture and elective procedure-based care for older adults?
2. What is the added value of **integrated data and analytics** in supporting better resource allocation and patient outcomes?
3. How can **shared digital tools and outcome frameworks** be scaled across different types of geriatric interventions?

The Use Case 1 -specific R&D hypotheses are:

1. Integrated, data-informed care pathways **reduce variation in patient outcomes and resource use** across regions. They also enable the **comparison of outcomes** between various wellbeing services counties.
2. Collaborative R&D, and **availability of up-to-date data** between wellbeing services counties (Vantaa-Kerava) and secondary hospital services (HUS) **accelerates implementation of effective practices.**
3. Scalable analytics and outcome frameworks enhance decision-making beyond hip fractures to other high-impact procedures in older adults.

The T1D use case (**Use Case 2**) focuses on leveraging RWD and advanced statistical and machine learning methods to evaluate the clinical and economic impact of modern diabetes technologies. The goal is to enable **real-time and predictive assessment of cost-effectiveness** to support value-based care decisions. The specific research objectives are:

1. **To model and compare the long-term health and economic outcome trajectories** of patients using advanced insulin pump therapy with continuous glucose monitoring (CGM) versus those using traditional multiple daily injection (MDI) therapy and older-generation insulin pumps. The analysis will explore clinically relevant subgroups of T1D patients, including age, glycemic control history, comorbidities, and socioeconomic status.
2. **To evaluate the cost-effectiveness** of advanced insulin pumps with CGM compared to traditional insulin therapies, using a combination of real-world outcomes data and health

economic modeling techniques. Subgroup analyses will be conducted to identify patient populations where technology adoption provides the highest value-for-money.

Study hypotheses for Use Case 2 are:

1. **Clinical Outcome Hypothesis**. T1D patients using advanced insulin pump therapy with CGM achieve significantly better glycemic control (e.g., higher Time in Range, lower HbA1c) and fewer acute complications (e.g., hypoglycemia, ketoacidosis) than those using MDI or older-generation pumps.
2. **Economic Outcome Hypothesis.** Advanced insulin pumps with CGM are associated with lower long-term healthcare costs compared to MDI or older-generation pumps, primarily through reduced hospitalizations, emergency visits, and diabetes-related complications.
3. **Cost-Effectiveness Hypothesis**. The use of advanced insulin pumps with CGM is cost-effective compared to MDI and older-generation pumps when assessed over a 5- to 10-year time horizon, from both payer and societal perspectives.
4. **Subgroup Heterogeneity Hypothesis.** The magnitude of clinical and economic benefits of advanced insulin pumps with CGM varies by patient subgroup (e.g., patients with poor baseline glycemic control vs. stable control).
5. **Predictive Modeling Hypothesis.** Machine learning models trained on RWD can accurately predict individual risk of complications and healthcare costs, enabling real-time estimation of treatment-specific cost-effectiveness.

Recently, we have applied RWD and advanced analytics to investigate longitudinal glycemic trajectories and their associations with clinical and economic outcomes in patients with T2D (Lavikainen et al., 2019). Our prior work has explored **data-driven clustering** of long-term glycemic control patterns, identification of individualized predictors for these trajectories (Lavikainen et al. 2023), and **explainable machine learning models** to predict changes in long-term HbA1c response (Chandra et al. 2025). In addition, we have **utilized RWD to estimate the long-term outcomes of CGM technologies** (Mustonen et al. 2022 and 2023) and integrated these findings into a health economic model to assess **the lifetime cost-effectiveness of CGM use in T1D care** (Mustonen et al. 2024). Building on these foundations, this project will apply similar methodologies to patients with T1D, while also **introducing advanced techniques such as Bayesian network analysis** to better understand the complex, multivariate relationships between treatment types, patient characteristics, complications, and costs (Petäjä et al. 2025, Karki et al. 2023, Saari et al. 2023, Haapaniemi et al. 2019).

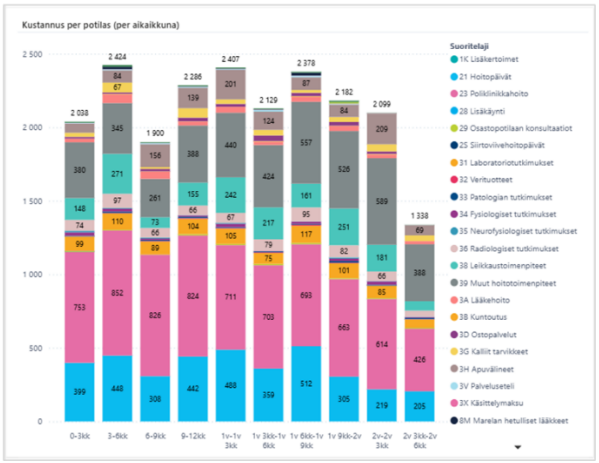
3.1.2 Data-driven knowledge management at HUS

At HUS data-driven leadership and knowledge management combines information/data, technology, healthcare professionals, and strategic management to serve the goals of the organization. With information, it is possible to foster dialogue, make better decisions, and take actions that enable optimization and renewal of current care methods

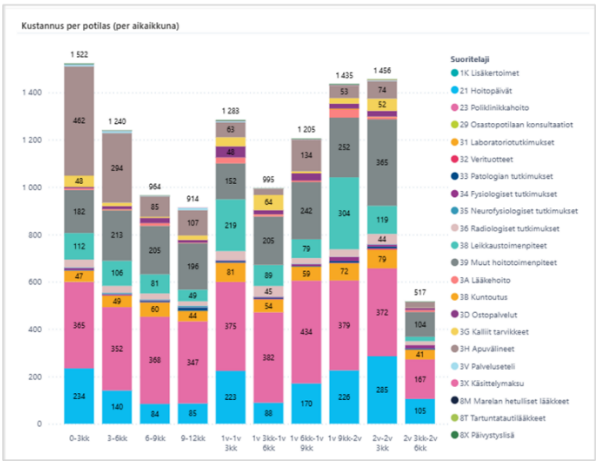
By already modelled care pathway in special care HUS has created a scalable cost-effectiveness model which can be used in different patient groups and care. It aims to report continuous effectiveness and cost-effectiveness data obtained from health benefits and costs of care at HUS. This value-based health care (VBHC) model is a management system of secondary care, in which cost-effectiveness is measured with real costs and gained QALYs.

To support data-driven decision-making at HUS, disease-specific cost analyses have been conducted. The image below shows the average per-patient costs of two different treatment methods from the start of therapy.

Insulin injection therapy – average costs per patient over time



Smart insulin pump therapy – average costs per patient over time



3.1.3 R&D work packages and tasks, and their implementation and interconnections

The project will be implemented as a broad multi-actor consortium including HUS (coordinating partner), Vantaa-Kerava Wellbeing Services County, and the University of Eastern Finland, with the potential for additional R&D partners. Each party will take responsibility for specific areas such as modelling of data production, clinical effectiveness evaluation, and analytics development.

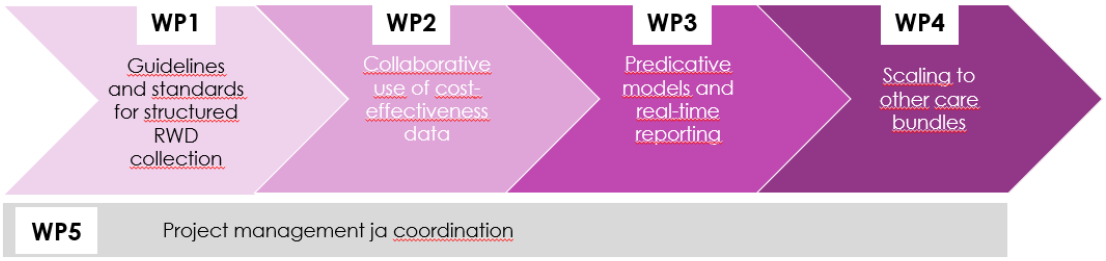
The implementation will leverage HUS's existing data infrastructure and earlier modelling efforts in effectiveness analysis. The work builds on clinical systems and research environments already in place. Key work packages include:

- Development of data models and analytics platforms
- Piloting structured documentation and reporting
- Deployment of effectiveness indicators
- Development of EHDS-readiness and interoperability

The project will be implemented in phases, with a detailed risk management plan in place. Key risks include data system integration and data accessibility. If necessary, alternative strategies such as synthetic data modelling will be applied. Human resources and responsibilities are allocated per work package.

The project workplan consists out of five distinct but highly interconnected work packages (WPs):

- WP1: Guidelines, standards, and SOPs for RWD collection based on fully structured data
- WP2: Reporting and utilisation of cost-effectiveness data within HUS and the Southern Finland regional health and social care system (specialist care + primary care + social care). Care pathway for older hip fracture patients as a model of care and elective total hip and/or knee endoprostheses surgery and trans-aortic valvular implantation as use cases.
- WP3: The creation of health and economic outcome prediction models and real-time reporting for cost-effectiveness. T1D as use case.
- WP4: Scaling the existing specialised healthcare cost-effectiveness reporting model to other relevant care bundles.
- WP5: Project management and coordination.



3.1.4 Responsibilities, management and implementation related to R&D WP's and tasks

The figure below presents the five project work packages (WPs), their associated tasks, and their timeline over a three-year period. Work Packages 1 and 2 are jointly led by HUS and the Vantaa-Kerava Wellbeing Services County. WP3 is led by the University of Eastern Finland (UEF), and WP5 is coordinated by HUS.

Project Implementation Plan by Year and Quarter: Breakdown into Work Packages and Tasks

Work Package (WP)	WP leader	TASKS	Y1/Q1	Y1/Q2	Y1/Q3	Y1/Q4	Y2/Q1	Y2/Q2	Y2/Q3	Y2/Q4	Y3/Q1	Y3/Q2	Y3/Q3	Y3/Q4
WP1 Guidelines and standards for structured RWD collection	HUS & VAKE	T1.1 Identify RWD sources												
		T1.2 Define data quality												
		T1.3 Document architecture solution												
WP2 Collaborative use of cost-effectiveness data	HUS & VAKE	T2.1 Design scalable data pipelines												
		T2.2 Integrate data across sources												
		T2.3 Build shared data repository												
		T2.4 Handle missing and biased data												
		T2.5 Automate data ingestion												
WP3 Predicative models and real-time reporting	UEF	T3.1 Evaluate suitable predictive models												
		T3.2 Create features from unified data												
		T3.3 Train and validate models												
		T3.4 Monitor prediction accuracy												
		T3.5 Deploy with CI/CD practices												
WP4 Scaling to other care bundles	HUS	T4.1 Identify new care bundles												
		T4.2 Define relevant clinical data												
		T4.3 Build on existing data pipelines												
		T4.4 Add new features from data												
		T4.5 Train and validate models												
		T4.6 Deploy with CI/CD practices												
WP5 Project management and coordination	HUS	T5.1 Project management												
		T5.2 Project coordination												

3.2 Collaborators

We engage with multiple stakeholders across clinical, ICT, and methodological domains through expertise sharing and by assessing the applicability of developed workflows to data from other well-being service counties. For example, UEF has long-standing collaborations with the North Karelia Wellbeing Services County and the Biomimetics and Intelligent Systems Group (University of Oulu, Oulu, Finland) in the development of RWD workflows and explainable AI/ML applications (i.e., XAIs) by applying electronic health record data. During the project, the applicability of these workflows to data from other counties will be evaluated to support their effective use in future implementations, with the aim of enabling national scalability.

In addition to the information obtained from the data lakes of HUS and the wellbeing services counties, the data will be supplemented as needed with information from other data controllers, such as the Social Insurance Institution (KELA), Finnish Institute for Health and Welfare (THL), and Statistics Finland.

3.3 R&D data, methods and research environment

3.3.1 R&D data and methods

As described above, T1D will serve as **Use Case 2**, leveraging longitudinal data extracted from EHRs applied in the planned study. Model development will consider a range of methodological approaches, including 1) **longitudinal time-to-event and trajectory modeling combined with the AI/ML-based feature selection of predictive factors**, and 2) **Bayesian network models** capable of handling uncertainty and causal inference. We have previously applied trajectory modeling with AI/ML-based prediction in the case of T2D (Lavikainen et al. 2023). In this project, we will apply similar types of modelling in the case of T1D to assess the long-term health and economic outcomes of advanced insulin pumps with CGM versus traditional insulin injection therapy and older-generation pumps. In addition, Bayesian causal models will be used to simulate interventions by estimating counterfactual outcomes, supporting robust inference even when randomized trials are infeasible. Importantly, economic and quality-of-life data can be incorporated directly into these models, allowing for estimation of cost per quality-adjusted life year (cost/QALY) and supporting decisions about the economic value of treatments. To test this approach, we will apply **Bayesian analysis to assess the cost-effectiveness of advanced insulin pumps with CGM versus traditional insulin injection therapy and older-generation pumps.** Using a combination of predictive modeling (e.g., tree-augmented naïve Bayes) and causal network models grounded in directed acyclic graphs, we aim to estimate both clinical effectiveness and cost per QALY gained. This will allow us to separate causal effects from confounding influences and to integrate financial data into a unified probabilistic framework, providing robust evidence for healthcare decision-making. We will also **explore model transparency, interpretability, and usability of the developed models in clinical settings to improve the future integration** of these developments into digital health tools or dashboards designed for clinicians, researchers, and decision-makers. **We have recently combined published RCT-based evidence with RWD** to improve predictions when applying **explainable AI models** in the case of T2D (Chandra et al. 2025). In this project, we will apply a similar kind of approach by conducting a systematic literature review and apply AI-assisted quality appraisal (using large language models) to identify and synthesize high-quality evidence. From this, we will construct a Bayesian network capturing factors associated with clinical and economic outcomes. This data-driven network will be compared with an expert-validated network derived from domain knowledge and published literature. A panel of medical and methodological specialists will evaluate and refine both models.

Regarding **Use Case 1**, the older hip fracture population, the study will utilize register-based clinical data from data lakes (HUS and wellbeing services counties), supplemented by information from other, abovementioned health and social care data sources when applicable. Factors associated with care outcomes will be examined using statistical methods such as logistic regression, Cox proportional hazard models, or generalized estimating equations. With the collaboration and support from data analysts, datashare solutions will be developed to create a real-time clinical reporting and operational decision-making system to follow-up the possible variation, costs and care outcomes across the whole care pathway. Further, these solutions are intended to be used as a scalable model to monitor care-pathways related to other procedure-based treatments and care pathways as well.

3.3.2 Research environment

The project's R&D-activities utilises **a secure research infrastructure** based on the HUS Acamedic environment, which enables the privacy-preserving use of sensitive health data for research purposes. The infrastructure provides a controlled computing environment with access to curated healthcare data, analytical tools, and secure user authentication. It supports GDPR-compliant data processing and allows for the implementation of advanced analytics, including AI/ML models

developed in the project. The environment is designed to facilitate **collaboration between researchers**, ensuring both data security and scientific reproducibility.

3.4 Risk assessment

We have recognised several operational, technical, organisational, and scientific risks that have been carefully identified and assessed. A proactive risk management strategy will be applied throughout the project lifecycle to ensure that risks are mitigated and do not compromise project objectives or timelines. Most important risk are: **1) Data access and privacy risks.** The project utilises sensitive health data, and any delays in data access or challenges in ensuring GDPR compliance could affect progress. To mitigate this, the project builds existing data governance models and data infrastructure established in earlier initiatives (e.g., RRP2/RRP3). All data processing will be conducted in secure environments with appropriate approvals. Research with healthcare data is guided and regulated by the Finnish Act on the Secondary Use of Health Data. In this project, patient data is extracted, maintained and utilized according to this act aiming to enable efficient and secure health-related data processing for research purposes. **2) Inter-organisational coordination risks.** As a multi-partner project involving HUS, Vantaa-Kerava Wellbeing Services County, and UEF, effective coordination is critical. Risk is mitigated by clearly defined roles, a steering group with representation from all partners, and regular project meetings to ensure alignment and transparency. **3) Methodological and scientific risks.** Predictive modeling using RWD may be affected by data quality issues, missing data, or heterogeneity across care settings. The project mitigates this through expert input from academic partners, use of validated modeling techniques, and multiple imputation or sensitivity analyses as required. **4) Organisational change and adoption risks.** Embedding new data-driven practices into routine care and management requires change in workflows and decision-making culture. The project addresses this by engaging clinical and managerial stakeholders early, and by co-developing tools and indicators to ensure relevance and usability. **5) Scalability and sustainability risks.** The risk of limited adoption beyond the pilot sites is mitigated by involving multiple levels of care (primary, specialized, social care), producing transferable documentation, and by building on tested tools and workflows already piloted. Overall, the project's strong foundation, experienced consortium, and established practices in secure data use and cross-sector collaboration support a low overall risk level, with clear mitigation strategies in place. Where applicable, ethical approvals will be secured to ensure compliance with relevant regulations.

3.5 Project Personnel

Dr. Sami Pakarinen (male), PhD, MD is a specialist in cardiology and internal medicine, currently serving as the Chief Physician for clinical auditing at the Helsinki University Hospital (HUS) Corporate Administration. In addition to his primary role, he is actively involved in secondary positions, including HTAs with the Pharmaceutical Division of Cohere (Council for Choices in Health Care in Finland), hospital-level mini-HTA evaluations with FinCCHTA (Finnish Coordinating Center for Health Technology Assessment), and EU-level initiatives regarding to cancer medication therapies such as Oncovalue and Valo. His expertise and contributions span across clinical medicine, RWE-data production, healthcare evaluation, and policy development.

Dr. Hanna Öhman (female), PhD, MD is a specialist in Geriatrics and General Practice. She serves as the Chief Physician of Department of Geriatrics at Helsinki University Hospital (HUS). Her expertise in research lies in Hospital Geriatrics. She currently leads the RRP3 Hip fracture project being the PI.

Dr. Ulla Aalto (female), PhD, MD is a specialist in Geriatrics and General Practice. She works currently as Consultant Geriatrician at Helsinki University Hospital (HUS), where her clinical work is mainly allocated to Orthogeriatrics. Additionally, she works as a postdoc researcher in RRP3 Hip fracture project, and she belongs to the EU Horizon 2020 RECETAS (Re-imagining Environments for Connection and Engagement: Testing Actions for Social Prescribing in Natural Spaces) - research consortium.

Dr. Janne Martikainen (male), PhD (Health econ) is a health economist and a full professor of pharmacoeconomics at UEF and a head (Health Sciences) of UEF House of Effectiveness. He leads a research group at UEF focusing on data-driven health economics and outcomes research. The group use a multidisciplinary approach that applies different computational methods and multiple data sources, including electronic health records, genomic, survey, and other real-world data with a focus on the health economic aspects of precision and digital population health management approaches in the prevention and treatment of cardio-renal-metabolic diseases, such as type 1 and 2 diabetes, chronic kidney disease, and cardiovascular diseases. Currently, another focus area is the development of a novel Productivity-Adjusted Life Year (PALY) as a societal-relevant productivity outcome measure (a collaboration with Monash University, Australia).

Dr. Piia Lavikainen (female), docent in statistical methods in evaluation of drug therapies, is a senior researcher at the School of Pharmacy, UEF. She is a highly experienced researcher in pharmacoepidemiology and pharmacoeconomics. Her expertise is in statistical analysis and management of RWD data and recently, her research has concentrated on the prevention and care of cardiometabolic diseases. She has 80 publications in peer-reviewed international journals.

Dr. Kaisa Rajala (female), PhD, MD is a specialist in Geriatrics and General Medicine and she has special competence of Palliative Medicine. Currently serving as Medical Director of the hospital services at wellbeing services county of Vantaa and Kerava.

MSc Pia Rantamäki (female), MSc (Health Sciences) is director of the hospital services at wellbeing services county of Vantaa and Kerava.

MSc Satu Kouhia (female), MSc (Econ) is an information analyst at HUS. She has recently completed a Bachelor's degree in Business Information Technology (BBA). She has extensive experience in cost accounting and reporting for specialised healthcare services, including analytics.

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