SESSION 1: NORDIC ACCESS

Evaluation and market access of high-value medicines in the Nordics

REGULATORY AND CLINICIAN VIEWPOINTS

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As a regulator and a clinician,…

- As chief medical officer for clinical auditing at HUS (1/2021 – >), my primary responsibilities have included conducting hospital-based HTA-assessments of healthcare methods provided by HUCH (including expensive hospital medications and) and developing real-world data production and reporting of the actual effectiveness and cost-effectiveness of the treatments in use with HUCH

Other affiliations and viewpoints ..

- FinCCHTA, in collaboration with the assessment network led by chief medical officers, governs hospital-level HTAs of new drug therapies
- Member of the Medical section for new medicines at Council for Choices in Health Care in Finland (COHERE Finland) 2023-2026 (national level HTAs)
- Member of a working group for preparing the reform of medication evaluation activities for the term 13 May 2024 to 30 September 2025 (Ministry of Social Affairs and Health)
- EU-project Oncovalue (Implementing value-based cancer care at European cancer hospitals) 2023-2026. WP 5: Infrastructure for RWD reporting in regulatory/HTA decision-making with harmonized data (OMOP-CDM) and federated analytics

IMPLEMENTATION OF PHARMACOTHERAPY IN FINLAND

- In Finland, the evaluation and decision-making procedures for pharmacotherapies differ between outpatient medicines (Pharmaceutical Pricing Board; HILA) and so-called hospital medicines (FIMEA/COHERE/FinCCHTA). This difference is linked to the national financing system.
- When a new medicine is evaluated, research evidence on its benefits, harms, costs, and cost-effectiveness is collected, assessed, and summarized in comparison to existing medicines or other treatment options
- Evaluations apply health technology assessment (HTA) approaches
- This dual-channel assessment has been criticized for its lack of transparency, predictability, and efficiency
- According to current government program, the evaluation processes and criteria related to the adoption of outpatient and inpatient medicines in pharmaceutical services will be reformed so that they are harmonized regardless of the form of administration (2026?)

DE-IMPLEMENTATION OF LOW-VALUE CARE (1)

- As healthcare spending continues to rise the concern over low-value care is growing
- Low-value care refers to healthcare practices that do not provide meaningful benefits to patients and also to those that are not cost-effective
- It causes direct harm to patients through adverse effects and costs
- Additionally, low-value care presents an opportunity cost, as resources are no longer available for higher-value care and other critical needs, making it also a threat to the sustainability and quality of healthcare

DE-IMPLEMENTATION OF LOW-VALUE CARE (2)

- Reliable estimates on the total prevalence of low-value care are lacking, but even 20-30% of care could be of low value to patients
- Resources should primarily be allocated to interventions with the strongest research evidence, including real world evidence (RWE) when needed
- De-implementation includes, for example, shared decision-making and informing patients about the harms of low-value care as well as the natural course of diseases

IDENTIFICATION OF LOW-VALUE CARE (1)

- Real-world data is crucial for identifying, monitoring, and phasing out low-value expensive drugs after market approval. De-implementation succeeds best when it combines robust RWE-data, clinician engagement, patient involvement, and policy tools
- HUCH is part of DARWIN EU®- network which is EMA's system for harnessing real-world healthcare data (OMOP CDM) for supporting more effective, timely, and evidence-based regulatory decisions on medicines in Europe

IDENTIFICATION OF LOW-VALUE CARE (2)

- Fimea collaborated with Finnish university hospitals and Sitra to pilot RWE (real-world evidence) generation using the OMOP Common Data Model and federated analytics (2023). This model allowed hospitals to share aggregated data for treatments like multiple myeloma — without transmitting individual-level records. Data were pooled and assessed for health technology assessment (HTA) needs
- The VALO(NSCLC)-project (2025) test in practice and demonstrate the effectiveness of cross-border Nordic cooperation in the use of harmonized health data
- Coming VALO2-project, where the main goal is to demonstrate how real-world research can be conducted across national borders using Secure Processing Environments (SPE), Trusted Research Environments (TRE), or similar controlled data access infrastructures. Jointly prepare for and implement the European Health Data Space (EHDS) legislation in the Nordic countries with using pseudonymised personal health data
- Limitations: the Finnish secondary-use legislation doesn't yet fully support federated analytics; nor does it explicitly prohibit it

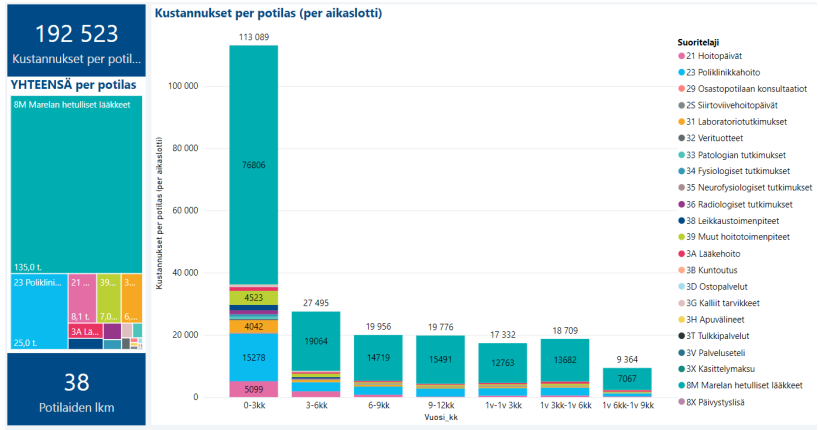
RWE-DATA FOR COST-EFFECTIVENESS

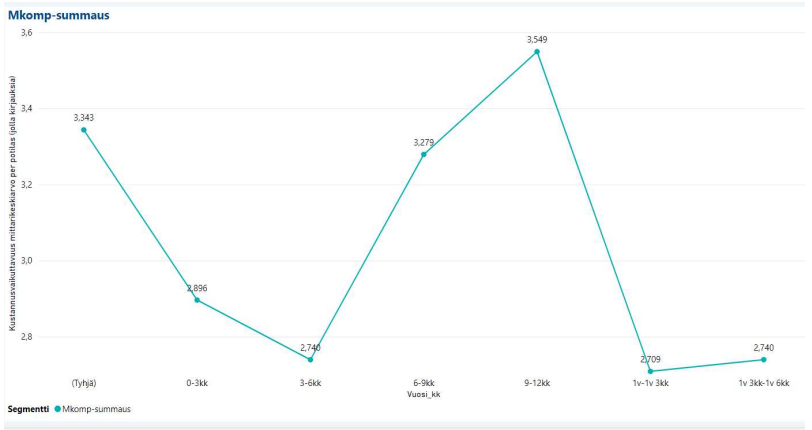
- Observational registry data and post-marketing studies sometimes show that benefits, like survival, seen in clinical trials (e.g. RCTs) are not replicated in everyday practice, raising questions about cost-effectiveness advantages over standard treatment
- In the marketing authorization process of EMA, the therapeutic and economic value of medicines is not assessed. The process does not address the necessity of the medicine, and granting marketing authorization does not always require evidence of patient-relevant outcomes, such as effects on survival or quality of life, nor that the medicine has been compared with other medicines in studies. The marketing authorization system also does not take a position on the price of the medicine
- Current marketing authorization procedures allow a new drug to reach the market more quickly and with less clinical evidence than before, which is why the role of national assessment in decisions on drug adoption and pricing has become increasingly important

HTAR AND JCA (JOINT CLINICAL ASSESSMENT)

- The JCA assessment of medicines is carried out partly concurrently with the centralized marketing authorization procedure by EMA. JCA assessments will be implemented gradually, starting in 2025 with oncology medicines and ATMP treatments (Advanced Therapy Medicinal Products, including cell and gene therapies)
- The JCA report includes the clinical part of the HTA assessment, meaning it systematically summarizes the research evidence on the effects of the medicine and the uncertainties related to the results
- JCA report does not draw conclusions about whether the medicine being assessed is overall more effective than the comparator treatment or whether the treatment outcome achieved is clinically significant. Therefore, the evaluation of the results remains the responsibility of the national level.
- In addition, at the national level, an assessment of aspects other than the clinical ones—such as costs, budget impact, and cost-effectiveness—still needs to be carried out

Clinicians Real time Dashboard for Cost-Effectiveness Reporting of Myeloma Drug Therapies in HUCH





Can be used for data-driven management and with Managed Entry Agreements (MEAs) which are increasingly used in healthcare systems to manage the introduction of high-cost or innovative medications, particularly when there is uncertainty about their clinical or economic value