









WP2: Outcome Driven Healthcare

WP Leads: Dalia Dawoud (NICE) & Eline Vanoverbeeke (Pfizer)

WP2 enables the transition towards outcomes-driven healthcare systems in Europe. This can only be achieved if the EHDEN framework can be used in the context of regulatory approval, health technology assessment (HTA), and for payer purposes. As the EHDEN project is using the OMOP-CDM to build a federated network of data sources standardised to a common data model, WP2 tests whether the OMOP-CDM can be used for said regulatory, HTA and payer activities.







- Enable the transition towards outcomes-driven healthcare systems in Europe
- Extend the OMOP-CDM and vocabularies to include PROM standard outcomes sets (e.g. ICHOM)
- Test whether OMOP-CDM can be used in the context of regulatory approval, health technology assessment (HTA), and for payer purposes





• Use Cases

to test the use of the OMOP Common Data Model in HTA, regulatory and payer purposes

- COPD Modelling
- Cancer survival extrapolation
- COVID-19 treatments (ISPE)
- Surrogate validation

PharmacoEconomics (2021) 39:275–285 https://doi.org/10.1007/s40273-020-00981-9

PRACTICAL APPLICATION

Common Problems, Common Data Model Solutions: Evidence Generation for Health Technology Assessment

Seamus Kent¹ · Edward Burn^{2,3} · Dalia Dawoud¹ · Pall Jonsson¹ · Jens Torup Østby⁴ · Nigel Hughes⁵ · Peter Rijnbeek⁶ · Jacoline C. Bouvy¹

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<u>Common Problems, Common Data Model Solutions: Evidence</u> <u>Generation for Health Technology Assessment (springer.com)</u>

Multi-stakeholder workshops

• EMA, DARWIN EU, EuNetHTA21, RWE4Decisionsc, EPF, HDRUK, GetReal Institute

Oct 2022



Regulators are formally adopting real world evidence, when will health technology assessment?

Joint Virtual Workshop with the <u>GetReal</u> Institute 31 October 2022

EHDEN Academy



^{Methods} Health Technology Assessment

https://academy.ehden.eu/



PRIORITIES FOR HTA

NICE

What are **long-term** cancer survival outcomes in (RW) current practice? Can EHDEN provide economic model inputs, e.g. healthcare resource use?

Are relationships between **surrogate** and final **outcomes** supported by RWE?

> Can RWE inclusion in **network meta analysis** inform relative treatment effectiveness estimation?



Can EHDEN fill common evidence gaps for **rare diseases** (e.g. small or single arm RCTs)?

Can EHDEN inform whole-disease pathway models?



NICE

What are **long-term cancer survival** outcomes in (RW)

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PRACTICAL APPLICATION

between and final supported

Common Problems, Common Data Model Solutions: Evidence Generation for Health Technology Assessment

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Abstract



There is growing interest in using observational data to assess the safety, effectiveness, and cost effectiveness of medical technologies, but operational, technical, and methodological challenges limit its more widespread use. Common data models and federated data networks offer a potential solution to many of these problems. The open-source Observational and Medical Outcomes Partnerships (OMOP) common data model standardises the structure, format, and terminologies of otherwise disparate datasets, enabling the execution of common analytical code across a federated data network in which only code and aggregate results are shared. While common data models are increasingly used in regulatory decision making, relatively little attention has been given to their use in health technology assessment (HTA). We show that the common data model has the potential to facilitate access to relevant data, enable multidatabase studies to enhance statistical power and transfer results across populations and settings to meet the needs of local HTA decision makers, and validate findings. The use of open-source and standardised analytics improves transparency and reduces coding errors, thereby increasing confidence in the results. Further engagement from the HTA community is required to inform the appropriate standards for mapping data to the common data model and to design tools that can support evidence generation and decision making.

Check for

Can EHDEN provide

economic model

inputs, e.g. healthcare

resource use?

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- Data requirements include
 - Baseline distribution of patients by disease severity
 - Transition probabilities
 - Rate of COPD exacerbations
 - Mortality risk
 - Treatment effectiveness
 - Healthcare utilisation and costs
 - Health-related quality of life
 - Extrapolation





Research question

 Estimate annual rate of COPD exacerbations and primary care visits in patients with COPD by disease severity in the UK and the Netherlands



Databases – mapped to OMOP-CDM

- IPCI in Netherlands, ETL/access by Erasmus MC
- CPRD GOLD in United Kingdom, ETL by Janssen (access: Oxford)



Methods

- Characterisation by severity using reported FEV1%
- Estimate resource use by determining annual rates of primary care visits







- Understand the extent to which the OMOP common data model and standardised analytical tools support evidence generation for HTA of chronic diseases
- Assess the extent to which current ETL processes support common HTA use cases
- Assess the ability to generate reliable evidence for multiple jurisdictions at speed using the federated data network
- Identify priority areas for further developments to the common data model or analytical tools to support such applications



CHALLENGES: REPRESENTATION OF HEALTHCARE VISITS



• Where is information held?

- Visit occurrence
- Provider specialty
- Care site
- Vocabularies
 - Visit (OMOP)
 - Provider (OMOP)
 - Others, e.g. HES specialty, NUCC, Medicare specialty, UB04, ...

OMOP Visit concepts v5

- Outpatient Visit (9202)
 - \rightarrow Office Visit (581477)
 - → Ambulatory Rehabilitation Visit (581479)
- Inpatient Visit (9201)
 - \rightarrow Isolation in inpatient setting (32760)
- Home Visit (581476)
- Ambulance Visit (581478)
- Emergency Room Visit (9203)
- Emergency Room and Inpatient Visit (262)
- Intensive Care (32037)
- Laboratory Visit (32036)
- Non-hospital institution Visit (42898160)
- Health examination (32693)
- Home isolation (32759)
- Person Under Investigation (32761)

CHALLENGES: DATA PROCESSING AND MAPPING







Information	IPCI	CPRD
Data pre-processing	Restrict to GP visits	Include all contacts (incl. non-clinical, admin)
Mapping to Visit table	Map to either: Outpatient visit (9202) or home visit (581476)	All mapped to Outpatient visit (9202)
Provider	No further information	Staff roles (~70) in CPRD mapped to 25 std concepts across 4 vocabularies. Unknown Physician specialty (38004514) of Medicare spec vocab used for GPs and non-clinical staff.
Location	All mapped to Outpatient Visit (8677; Medicare PoS)	All mapped to Public Health Clinic (8977; Medicare PoS)



CHALLENGES: AVAILABLE ANALYTICAL TOOLS

- Current OHDSI tools do not easily support estimation of some common HTA outcomes (e.g. costs)
 - Specific model specification
 - Panel data
 - Models for continuous outcomes
 - Prediction for population of economic model

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- Data processing and mapping
 - Ensure use of data for HTA purposes is reflected in data processing and mapping processes and ensure HTA experts are involved in the mapping process
 - Map visits in a way that reflects specific types of healthcare delivery in different settings (eg distinguishing between primary and secondary care)
- Analytical tools
 - Development of analytical tools and dashboards to support common analyses in HTA





What might HTA bodies need to have confidence in RWE?



Types of evidence

- Identify data sources using systematic approaches
- Evidence relevant to key model parameters comparative effectiveness, resource use, quality of life
- Geographically relevant



Data and study quality

- Transparent pre-registered studies
- Reproducible
- Understanding strengths and limitations of the data source missingness, etc
- Analysis risk of bias should be assessed, confounders should be adjusted for where possible and uncertainty should be characterised and quantified if possible







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