

Identifying oncology effectiveness endpoints using administrative secondary databases: An example utilising Hospital Episode Statistics in England

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ABOUT HOSPITAL EPISODE STATISTICS (HES)

- Hospital Episode Statistics (HES) is a real-world data source that provides comprehensive longitudinal information on patient care within the National Health Service (NHS) in England.
- It includes data on inpatient, outpatient and emergency department admissions, as well as various healthcare activities and procedures. Costs of healthcare activities can also be derived.
- HES offers detailed records of diagnoses, treatments and demographics of patients, making it a valuable resource for healthcare research, planning, and policy development.
- The data are pseudonymised with disclosure control applied when published to protect patient privacy and is used for epidemiological and clinical research, healthcare management, and quality improvement efforts.

CONCLUSIONS

- Derivation of oncology-specific clinical characteristics and effectiveness endpoints using diagnoses, treatment patterns and procedures recorded in HES is possible. Nevertheless, data granularity remains lower than data that would be collected in clinical trial, via primary data collection methods (such as chart review) or than recorded within cancer registry data.
- Endpoints except overall survival are derived via proxy measures, they are not directly comparable to the same endpoints measured within a clinical trial setting but should hold insightful concordance.
- The granularity of oncology data recording in HES is available for use cases such as fast and accessible feasibility counts, identifying regional differences in patient care and building initial understanding of treatment patterns and healthcare resource use (HCRU).

ONCOLOGY CARE PATHWAY

PATIENT CHARACTERISTICS

Epidemiology			Patient characteristics at diagnosis			Clinical Characteristics			
Date of diagnosis	Incidence	Prevalence	Age & sex	Ethnicity	Geographic region	Comorbidities	Performance status	Morphology & Histology	Secondary Malignancies
✓	✓	✓	✓	✓	✓	✓	✗	✗	✓

HES uses the International Classification of Diseases, 10th Revision (ICD-10) coding system to classify and code diseases and conditions. In HES we can identify all ICD-10 recorded diagnoses of cancer made in England per year.

DISEASE STAGING

CANCER STAGE AT DIAGNOSIS (E.G. TNM STAGING) IS NOT DIRECTLY RECORDED IN HES DATA...

However, it may be proxied via a combination of ICD-10 diagnostic codes and OPCS Classification of Interventions and Procedures (OPCS-4) codes. The following example demonstrates how an algorithm using ICD-10 diagnostic codes for melanoma, secondary malignancies/metastases and OPCS-4 procedure codes was used to proxy stage 0, I/II, III and IV melanoma and resectable vs. unresectable melanoma at incidence diagnosis. This algorithm was developed with input from clinical experts with practical understanding of both the clinical disease area and medical coding within the NHS and follows the guidance published in the American Joint Committee on Melanoma Cancer 8th edition cancer staging manual¹:

Stage 0 ← ICD-10: D03 Melanoma in situ

Primary ICD-10 Diagnosis

AND at least one ICD-10 diagnosis of a secondary malignancy/metastases (C77.0-C77.5)

>1 ICD-10 diagnosis of a secondary malignancy/metastases (C77.0-C77.5) OR lymph node secondary malignancy of multiple regions

Stage I/II ← NO

Stage III/IV ← NO

Stage IV ← YES

Unresectable ← NO

Resectable ← YES

TREATMENT PATTERNS

Radiotherapy				Surgery			Anti-cancer treatment			
Date of	Presence/Absence	No. of Fractions/Dose	Treatment site	Date of	Procedure undertaken	Speciality of treating clinician	Best supportive care	Stem cell transplants	Systemic treatment	Dosage
✓	✓	✗	✓	✓	✓	✓	✗	✓	✓	✗

METHODS FOR INFERRING LINES OF THERAPY IN HES:

- Initial literature review of standard of care treatment pathways in cancer of interest
- Confirm with a clinician and NHS clinical coder the likely tumour-specific therapies covered by the unique combination of chemotherapy 'banded' OPCS-4 procedural and delivery codes in the data post diagnosis by:
 - Identifying frequency and time intervals between OPCS-4 code recording (akin to number and length of treatment cycles)
 - Identifying healthcare setting of treatment initiation (e.g., transfer of outpatient drug administration to inpatient or day-case setting)
 - Mapping procedures and markers of disease progression (such as stem-cell transplants, surgeries or ICD-10 codes for metastases) that help sequence treatment
- Treatment gaps, changes in OPCS-4 codes or transfer of care will then be attributed as markers of change in line of therapy. Date of latest OPCS-4 code recording + assumed cycle length is used as end date of treatment

ENDPOINTS & OUTCOMES

Healthcare resource use					Mortality		Common trial endpoints			
Inpatient admissions	Outpatient visits by speciality	A&E visit	Costs of care	Palliative care	Date of death	Cause of death	Overall survival	Progression-free survival	Recurrence-free survival	Time to next treatment
✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓

MARKERS OF DISEASE PROGRESSION, RECURRENCE & TREATMENT END DATES ARE NOT DIRECTLY RECORDED IN HES...

However, they may be proxied via a combination of ICD-10 diagnostic codes and OPCS-4 codes. The table to the right describes example proxy definitions of common oncology endpoints of interest in real-world HES data. These examples were derived based on a population of melanoma patients with input from clinical experts.

Endpoint	Example 'event' definition
Progression-free survival	Progression = any of: <ul style="list-style-type: none">Reaching disease next stagePresence of a new metastasesDeath
Recurrence-free survival	Recurrence = any of: <ul style="list-style-type: none">New metastasisNew lymph node removal surgeryDiagnosis of the same primary tumour >30 days after incidence diagnosis
Time to next treatment	Time from date of latest OPCS-4 code recording + assumed cycle length to date of next OPCS-4 code recorded

KEY

Available ✓ Partial availability or via proxy ✗ Not available ✗