



DIAGNOSTIC EVIDENCE WORKSHOP 2015

“ Possibilities of routinely available data ”

Dr Antonis A. Kousoulis

Clinical Practice Research Datalink, MHRA & London School of Hygiene & Tropical Medicine

antonis.kousoulis@mhra.gsi.gov.uk, twitter: @AKousoulis

Abstract: Databases of Electronic Health Records (EHR) are fast becoming an extremely important research tool worldwide. Due to the structure of the NHS, UK records are a valuable resource of information. This session, drawing from the long experience of the Clinical Practice Research Datalink (CPRD), will go in depth describing how to define a diagnosis in EHR, and further exploring ways to validate these diagnoses. We will discuss what evidence are available in routinely collected healthcare records, how these fit with new biomarker adoption, and identify what are the advantages as well as the challenges and limitations of working with EHR data.

Types of databases:

1. Electronic Medical Records for routine medical care (eg. CPRD)
2. Bespoke datasets and registries (e.g. Hospital Episode Statistics, Cancer Registry)
3. Claims / Administrative record linkage databases (eg. Truven Market Scan)

Examples of Databases:

- United Kingdom: primary care (CPRD, THIN, QResearch), Hospital Episode Statistics, registries
- Netherlands: PHARMO, ICPI
- Scandinavia: SCAAR, EPR Corpus
- Germany: GePaRD
- France: Thales, CNAM
- Spain: SIDIAP
- Canada: CPSSN, Saskatchewan
- USA: Kaiser Permanente, Medicaid & Medicare, VA, GE Centricity
- Japan: Claims
- Korea: Health Insurance Claims
- Australia: Veterans' Affairs

Strengths:

- Contain information on large populations
- Routine data collections
- Allow for flexibility in design
- Systematic exposure & Outcome assessment
- Provide a natural sampling frame
- Reduce study time
- Reduce human resources need
- Reduce cost
- Data collection occurs independently of study initiation

Limitations:

- Require highly skilled and experienced human resources
- Raise new confidentiality and ethical issues
- Validity and completeness vary
- Do cost money
- Information lacking (medications, lifestyle, hospital)
- Resource integration is difficult



Things to consider:

- Diagnosis is defined as a codelist. Types of Coding.
 - Download: The CPRD Medical & Product Dictionaries:
https://www.dropbox.com/s/8yl5s3g1ma1lnen/CPRD_sample.zip?dl=0
- Validation of a diagnosis
 - Read: *Herrett E, Thomas SL, Schoonen WM, Smeeth L, Hall AJ. Validation and validity of diagnoses in the General Practice Research Database: a systematic review. Br J Clin Pharmacol. 2010;69(1):4-14.*
- Evidence to support adoption of new biomarkers
 - Case studies:
 - *O'Meara H, Carr DF, Evely J, Hobbs M, McCann G, van Staa T, Pirmohamed M. Electronic health records for biological sample collection: feasibility study of statin-induced myopathy using the Clinical Practice Research Datalink. Br J Clin Pharmacol. 2014 May;77(5):831-8.*
 - *Wing K, Douglas I, Bhaskaran K, Klungel OH, Reynolds RF, Pirmohamed M, Smeeth L, van Staa TP. Development of predictive genetic tests for improving the safety of new medicines: the utilization of routinely collected electronic health records. Drug Discov Today. 2014 Apr;19(4):361-6.*
 - *Tenenbaum JD, Christian V, Cornish MA, Dolor RJ, Dunham AA, Ginsburg GS, Kraus VB, McHutchison JG, Nahm ML, Newby LK, Svetkey LP, Udayakumar K, Califf RM. The MURDOCK Study: a long-term initiative for disease reclassification through advanced biomarker discovery and integration with electronic health records. Am J Transl Res. 2012;4(3):291-301.*
- Stratified Medicine
 - *the grouping of patients based on risk of disease or response to therapy by using diagnostic tests or techniques.* It requires:
 - Research
 - Targeted interventions
 - Effective regulation
 - Health Technology Assessment
 - Standardisation of data collection
 - Linkage of datasets
 - Partnerships
 - Consider which of the above can be addressed by Research Databases.
 - Read: "The stratification of disease for personalized medicines", ABPI Vision paper 2014.