

用藥安全研究之應用

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Pharmacoepidemiology

The study of the use and the effects of drugs in large numbers of people.

理想的用藥安全資料庫必備之條件(一)

- 高品質
 - 信度(reliability)、效度(validity)、代表性(representatives)
- 可由不同資料檔串聯出研究個案之相關資料
- 可依時間找出logitudinal follow-up之資料
- 含暴露(exposure)相關因子
 - drug name, strength, date dispensed, quantity, prescribers

理想的用藥安全資料庫必備之條件(二)

- 含結果(outcome)相關因子
 - diagnoses, procedures, disposition (alive or dead)
- 含病患基本資料(Patients characteristics)
 - Unique patient identifier, age, gender, race
- 潛在的共變項(Potential covariates)
 - Date of birth, gender, prior illnesses, concomitant illnesses

健保資料庫分類

- 系統抽樣檔是以看病人次為基本抽樣單位，無法提供研究學者做長期追蹤之研究。
- 承保抽樣歸人資料庫以保險對象為基本抽樣單位的抽樣檔，納入其歷年完整的就醫資料，持續追蹤數年，可做長期追蹤分析之研究。

健保資料庫之內容

門診處方及治療明細檔(CD)、門診處方醫令明細檔(OO)、住院醫療費用清單明細檔(DD)、住院醫療費用醫令明細檔(DO)、特約藥局處方及調劑明細檔(GD)、特約藥局處方調劑醫令明細檔(GO)

健保資料庫於用藥安全研究之優點

省時、省錢

樣本數夠大

原始資料的發生不是為了做研究，
不會有嚴重的偏差

資料內容包含大多數研究相關欄位

健保資料庫於用藥安全研究之限制(一)

- 缺乏檢驗值
 - 如：warfarin研究之INR
- 缺藥理分類碼
- 複方藥很難歸類
- 資料內容之missing data需處理
 - 如：缺處方天數、用法、E-code
- A-code診斷碼需轉成ICD code

健保資料庫於用藥安全研究之限制(二)

- Confounding by indication難處理
- Compliance無法得知
- 無法獲得OTC藥併用情形

Structure of the Anatomical Therapeutic Chemical (ATC) Classification System

- 1st level —
Anatomical main group, 14 main groups
- 2nd level —
Pharmacological/therapeutic subgroup
- 3rd and 4th levels —
Chemical/pharmacological/therapeutic subgroups
- 5th level —
Chemical substance

例：Acyclovir眼藥膏之ATC為S01AD03，
Acyclovir口服及注射藥之ATC為J05AB01。

Ref: WHO Collaborating Centre for Drug Statistics Methodology. Guidelines for ATC classification and DDD assignment.

可用健保資料庫分析之用藥安全研究

描述流行病學(Descriptive epidemiology)

- Cross-sectional studies
- Drug utilization studies

分析性流行病學(Analytic epidemiology)

- 世代研究(cohort studies)
- 病例對照研究(case-control studies)

Drug utilization studies

❖ Areas of research

- use in specific populations
- patterns of use, both over time and cross-sectional
- use in specific disease states
- detection of adverse outcomes
- use as a surrogate for disease states
- use as a public policy tool
- use across countries
- the effects of demographic variables
- Use different methodologic approaches for quantifying drug use

實例分享

- Low dose warfarin had a low recurrence of thrombotic event in Chinese population
- The Potential Drug-Drug Interactions

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