

Data Linkage For Pharmacovigilance Using Routinely Acquired Electronic Health Records

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Background



- Adverse Drug Reactions (ADRs) are a Problem
- High cost to NHS
- Current Pharmacovigilance
 limitations
- Additional methods required
- Data linkage using routine data



<u>Child Me</u>dical Records for <u>S</u>afer Medicines (CHIMES)

 Acceptability and validity of datasets derived from linked routinely acquired NHS data for post marketing surveillance of medicines in children

Work Package 1

User Communities

Work Package 2

Evidence Synthesis

Work Package 3

Pharmacovigilance











<u>Child Me</u>dical Records for <u>S</u>afer Medicines (CHIMES)

 Accuracy and validity of routinely acquired linked NHS data to support a routine mechanism for post marketing surveillance of medicines in children

Work Package 1

User Communities

Work Package 2

Evidence Synthesis

Work Package 3

Pharmacovigilance











- What routine NHS data are available for post market drug surveillance?
- What's the best way to link data to support Pharmacovigilance and Pharmacoepi?
- How accurate are the data?

What routine NHS data are available for post market surveillance?

	DIAGNOSIS		DRUGS
ADMINISTRATIVE	 HOSPITAL Admissions (SMR 1) – 32m records Maternity (SMR 2) – 4m Cancer Registrations (SMR 6) – 1m Mental Health (SMR 4) – 1m Outpatients (SMR 0) – 51m 	GENERAL PRACTICE > HIC (Dundee) > PCCIU (Aberdeen) > GPRD (UK)	DRUG PAYMENT Prescribing Information System (PIS) – 1bn records

Measuring Error in Databases

RELIABILITY

AGREEMENT

VALIDITY (ACCURACY)

Same source used more than once for the same individual

-> Comparison of these results

-> Not validity!

Different sources compared, without one being distinctly 'superior'

-> Not validity or reliability! Different sources compared, one being distinctly 'superior' (gold / 'alloy' gold standard)

-> Sensitivity (aka completeness)

-> Specificity

Measuring Error in Databases

SENSITIVITY

Degree to which inferior data source correctly identifies individuals who, according to the superior data source, have the characteristic of interest

-> Completeness

SPECIFICITY

Degree to which the inferior data source correctly identifies individuals who, according to the superior data source, **don't have the characteristic of interest**

One may be more important than the other, depending on the study

West. Pharmacoepidemiology 2005; 45:709-765.

Number of items dispensed in the community in Scotland



Percentage of dispensed items with a unique patient identifier



Percentage of dispensed items with valid CHI



Reliability

-> Same source

Same shape occurs year on year. Typically, males receive less medication than females...



Number of drug classes dispensed in Scotland (Oct – Dec 2010)



5 YR AGE BAND

% Population

Agreement

-> Different sources

Insulin prescribing can act as a proxy for type 1 diabetes in children



* Short acting; intermediate and long acting insulins

Insulin prescribing compared to T1 diabetes in Scotland



□ PRESCRIBING (2010) □ COMPARISON DATA SOURCE

1. Rangasami. Arch Dis Child 1997;77(3):210-213. | 2. NHS National Services Scotland - ISD Scotland. Inpatient, Day Case and Outpatient Activity. 2011. | 3. The Scottish Diabetes Survey. 2010.

Insulin prescribing compared to T1 diabetes outside Scotland



Pundziute-Lycka. Diabetologia 2002;45(6):783

Validity

-> Different sources (using a gold standard)

Validity – Data Linkage

		Diagnosed diabetes in hospital (SMR1 'alloy' gold)			
		Y	N		
Prescribed insulin	Y	A) 1,020	B) 4,155		
< 20 years old (2007-11)	Ν	C) 38	D) 89,097		

Sensitivity (A/(A+C)) = 96%

Specificity (D/(B+D)) = X%

SUMMARY

- Reliable consistent & expected patterns year on year
- Agreement patterns of insulin prescribing & T1 diabetes
- Valid 96% hospitalised diabetics can be identified via their prescription records
- Routine prescribing data useful for post market surveillance of medicines in children

Future Work

- Repeat measures using different disease sample (e.g. Asthma)
- Assess generalizability of results
- Publish validity of routinely collected national prescribing data in Scotland
- Continue working with ISD to build a platform for national Pharmacoepidemiology



END OF PRESENTATION

CHIMES acknowledges the financial support of the Chief Scientist Office

Brad Kirby – Child Medical Records for Safer Medicines









Index based pharmaco-epi in Scotland (whole pop)



Data flow into the Prescribing Information System:



Data flow into the Prescribing Information System (Detailed):







Routine Datasets (Fields for linkage)

	EVENTS							MEDICINES	
	Hospital discharges	Cancer Reg	Deaths	Mental Health	ΟΡ	Maternity	A&E	Prescr.	E-Pharm
Seeded Chi Number	\checkmark	✓	\checkmark	\checkmark	\checkmark				
CHI Number	\checkmark	\checkmark		\checkmark	\checkmark	✓ (mother & baby)	✓	✓	✓
Surname	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			\checkmark
Forename	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			\checkmark
Date of Birth	\checkmark	✓	✓	✓	\checkmark	\checkmark			\checkmark
Sex	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			\checkmark
Marital status	\checkmark	✓	✓	✓	\checkmark	\checkmark			
Postcode	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark



Routine Datasets (Fields for analysis)

	EVENTS						MEDICINES		
	Hospital discharges	Cancer Reg	Deaths	Mental Health	OP	Maternity	A&E	Prescr.	E-Pharm
Condition	\checkmark	\checkmark	✓	\checkmark	\checkmark	✓	√		
Procedure	✓				\checkmark	✓			
Drug								✓	✓
Demographics	✓	\checkmark	✓	\checkmark	\checkmark	✓	✓	✓	✓

Percentage of dispensed items and hospital episodes with valid CHI



Typically, males receive less medicines than females...



Insulin prescribing compared to T1 diabetes outside Scotland



□ PRESCRIBING (2010) □ COMPARISON DATA SOURCE

Incidence rate / 100,000

1. Pundziute-Lycka. *Diabetologia* 2002;45(6):783. | 2. Imkampe. Diabet Med 2011;28(7):811.