UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

"It's about recognising how many people you've poisoned by giving them medication": thoughts of healthcare professionals on pharmacovigilance

Yvonne Marina Hopf

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Project Team:

Christine Bond

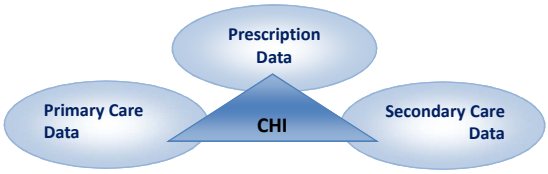
Peter Helms (Child Health)

John Haughney

Jill Francis (Health Psychology)

Context

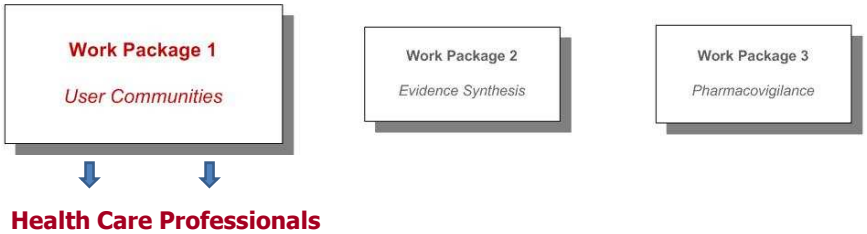
- Off-label prescribing in children linked to higher rates of adverse drug reactions
- Current systems of pharmacovigilance not effective enough
- Improving detection of adverse drug reactions through data linkage



UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Child Medical Records for Safer Medicines (CHIMES)

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



UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Aim of my overall work

To explore the acceptability of linking routinely collected healthcare data to inform the design of a new system for pharmacovigilance in children.

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Study Design

Literature review
- Data linkage (completed)
- Attitude of healthcare professionals (ongoing)

Qualitative Study
- Interviews (completed)
- Focus Groups (completed)

Consensus Study
- Delphi Survey (analysis ongoing)

➢ Ethical approval granted by North of Scotland Research Ethics Service.

Methods

Interviews

- Professional Stakeholders (n=40)
- Purposive sampling, heterogeneous sample
- Semi-structured

Focus Groups

- Frontline healthcare professionals
- n=6 (22 participants)
- Convenience sampling, heterogeneous sample

➢Audio-taped, transcribed verbatim
➢Transcripts and field-notes informed analysis
➢Data management via NVivo

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Identified Themes

Pharmaco-vigilance (PV)	Data	Data Linkage (DL)
Usage of linked data	Dissemination of Findings	Disclosure of personal data*

* Interviews only

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Pharmacovigilance (PV)

Definition of PV	Importance of PV	Current systems
(Dis-) advantages of systems	Issues with PV	ADR reporting
Purpose of PV*	Recognition of ADRs*	Paediatric Prescribing◆

* Focus Groups only; ◆Interviews only

WHO definitions

- Pharmacovigilance[1]:

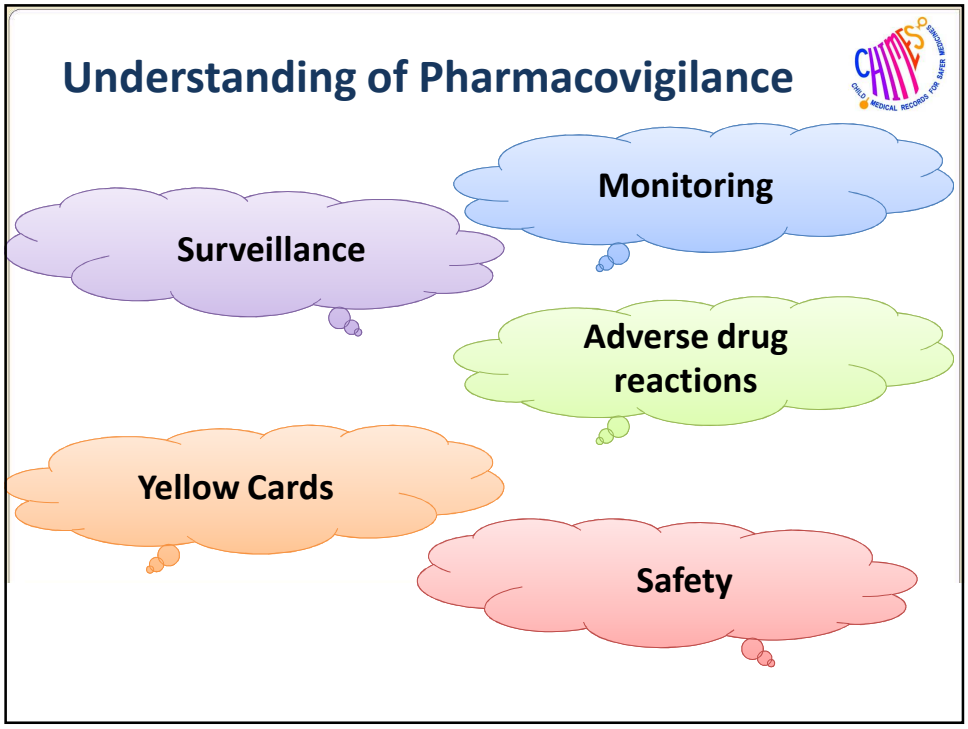
Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.

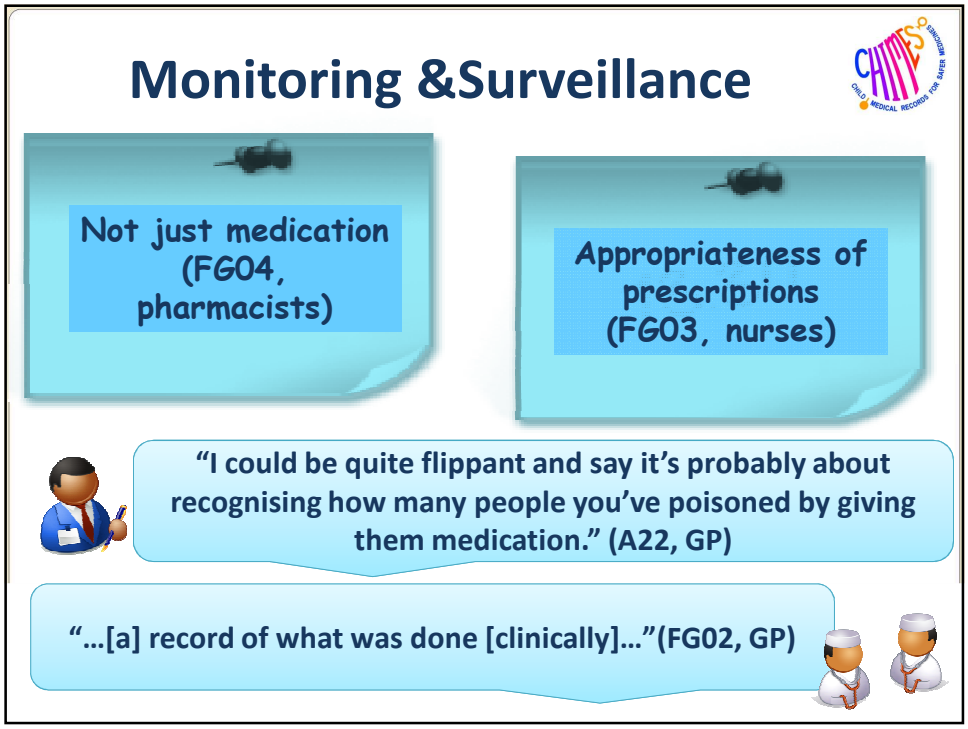
- Adverse Drug Reactions (ADRs)[2]:

An adverse drug reaction is a noxious and unintended response to a drug which occurs at doses normally used in man.

[1] WHO, 2002. The Importance of Pharmacovigilance

[2]WHO, 2002. Safety of Medicines


Understanding of Pharmacovigilance
Monitoring
Surveillance
Adverse drug reactions
Yellow Cards
Safety


Monitoring &Surveillance
Not just medication (FG04, pharmacists)
Appropriateness of prescriptions (FG03, nurses)
"I could be quite flippant and say it's probably about recognising how many people you've poisoned by giving them medication." (A22, GP)
"…[a] record of what was done [clinically]…"(FG02, GP)

Yellow Cards & ADRs

"At least we've got a system…" (A24, pharmacist)

"Opportunity to report adverse reactions"(A34, Caldicott Guardian)

"Who is actually tasked [with] filling out a yellow card?"(FG04, pharmacist)

"I do not think that there is a lot of people that do know about the yellow card scheme..."(FG06, paediatric nurse)

"It [=YCS] should be easy to use but nobody does"(FG07, paediatrician)

Safety

- Main outcome of pharmacovigilance

"Safety and effectiveness {of medication} is the main thing." (FG03, primary care nurse)

- Patient safety

"…even though I'm doing that every day, I'm not thinking 'I'm doing this because of pharmacovigilance', I'm doing it because I'm trying to keep the patient safe." (FG06, paediatric nurse)

- Drug safety

"… enhancing the information […] about that particular drug and if there are any safety concerns, [ensure that] they are addressed […]so it's really a safety measure…" (A36, pharmacist)

Discussion

- Varied understanding of pharmacovigilance
  - Yellow Cards as tool
  - Patient safety as outcome
  - Individual vs population based approach
  - Seen wider than original definition
- Inconsistent understanding as potential limitation for new initiatives

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Next…

- Triangulation of three studies
  - ➢Identification of barriers and facilitators will inform the new system design

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

Acknowledgements

➢The CHIMES programme is funded by the Chief Scientist Office and supported by NHS Research Scotland (NRS) through NHS Grampian.
➢I would like to thank all participants throughout my study for their time and contributions.

THANK YOU

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

	Academia	BMA	CG	CMO	CSO	HIC	ICO	ISD	MD	MEMO	NHS24	IG	ND	PAC	PD	PC	Private	RCGP	REC	RPSGB	ScotMCN	YCS
Pharmaco-vigilance	✔					✔				✔												✔
Prescribing				✔						✔						✔		✔				
Legal issues			✔						✔			✔		✔								
Data Protection			✔				✔		✔					✔			✔					
Caldicott			✔						✔													
IG		✔	✔									✔		✔								
Data linkage						✔				✔				✔			✔					
E-health	✔				✔	✔				✔	✔											
Public health			✔	✔	✔			✔				✔								✔		
Ethics		✔												✔			✔		✔			
Paediatrics													✔								✔	

Composition Focus Groups (1)

Focus Group	Number of Participants	Total
Doctors		
GPs (FG02)	2	
Paediatricians (FG07)	3	5
Nurses		
Primary Care (FG03)	2	
Secondary Care (FG06)	4	6
Pharmacists		
Secondary Care (FG04)	2	
Paediatric Pharmacists (FG05)	9	11
Total Number of focus group participants		22

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

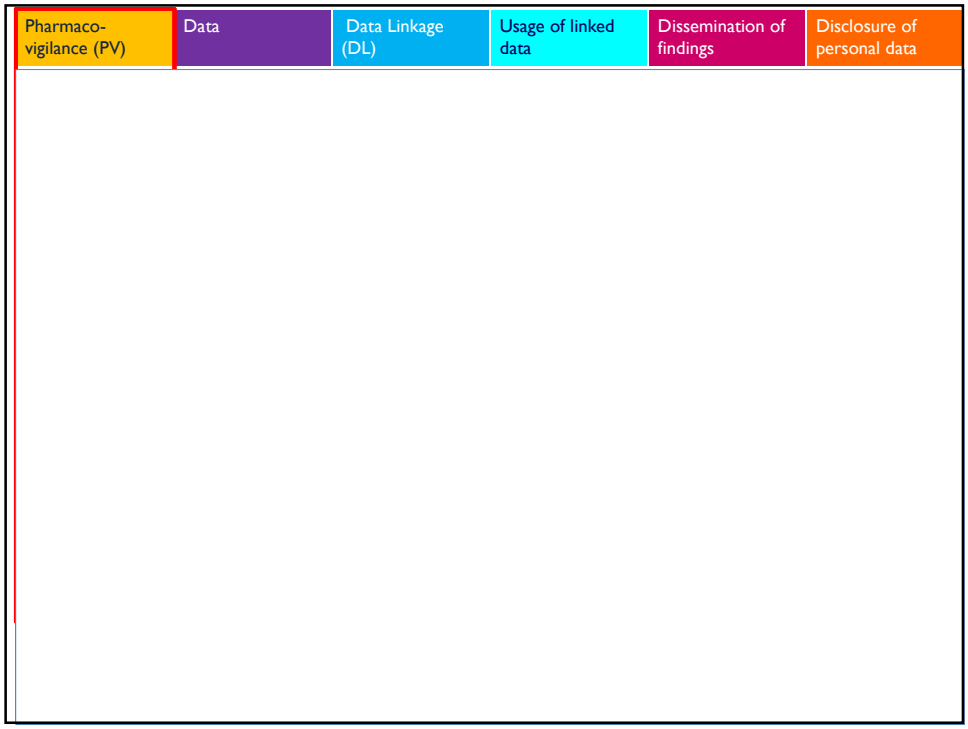
Composition Focus Groups (2)

	Medicine	Nursing	Pharmacy	Total
Male	4	1	4	9 (41%)
Female	1	5	7	13 (59%)
Total	5 (23%)	6 (27%)	11 (50%)	22 (100%)

Clinical Background and gender breakdown of focus group participants

(Qualitative) **Framework**

- Developed during 1980s
- Widely used by qualitative researchers
- Allows to organise “raw” data into categories
- Different stages of analysis
  1) Familiarisation
  2) Identifying a thematic framework
  3) Indexing
  4) Charting
  5) Mapping and Interpretation


Pharmaco-vigilance (PV)
Data
Data Linkage (DL)
Usage of linked data
Dissemination of findings
Disclosure of personal data