Child Medical Records for Safer Medicines

UNIVERSITY OF ABERDEEN

ISD SCOTLAND

NHS Grampian

CHIEF SCIENTIST OFFICE

ScotCRN Scottish Children's Research Network Young Persons Group • Grampian

Who is most at risk from ADRs?

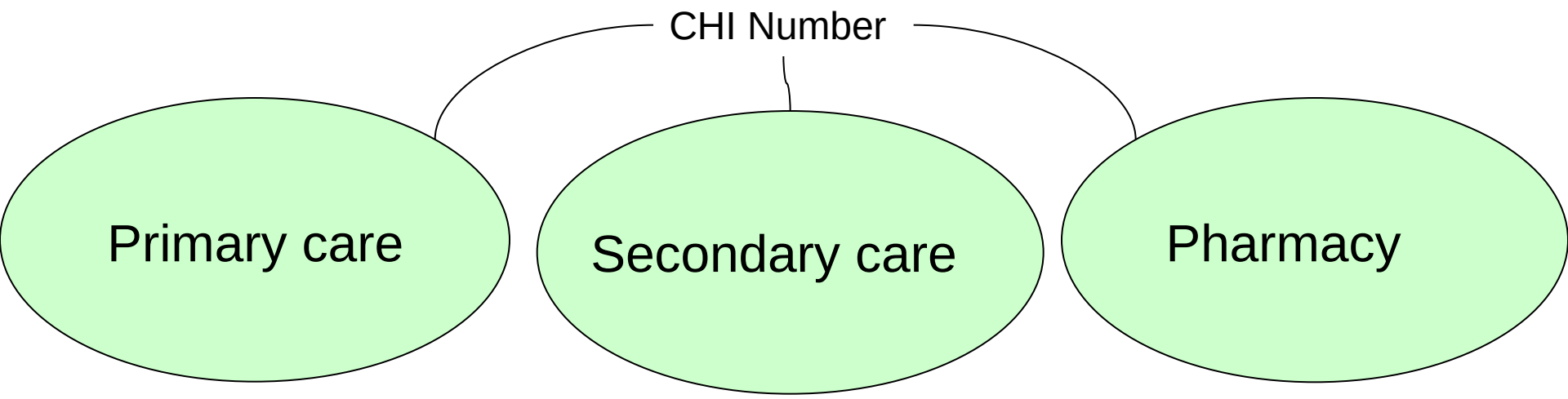
- The elderly
- Children
- Co-existing diseases
- Females
- Atopic individuals
- Polypharmacy
  - 50% of patients on 5 drugs or more

Opportunities for ADR detection

- Routine national (whole population) data
- Data linkage the answer ?
  - Acceptability to public, patients, HCP?
  - Validity and reliability ?
  - Feasibility ?
- CSO programme to answer these questions

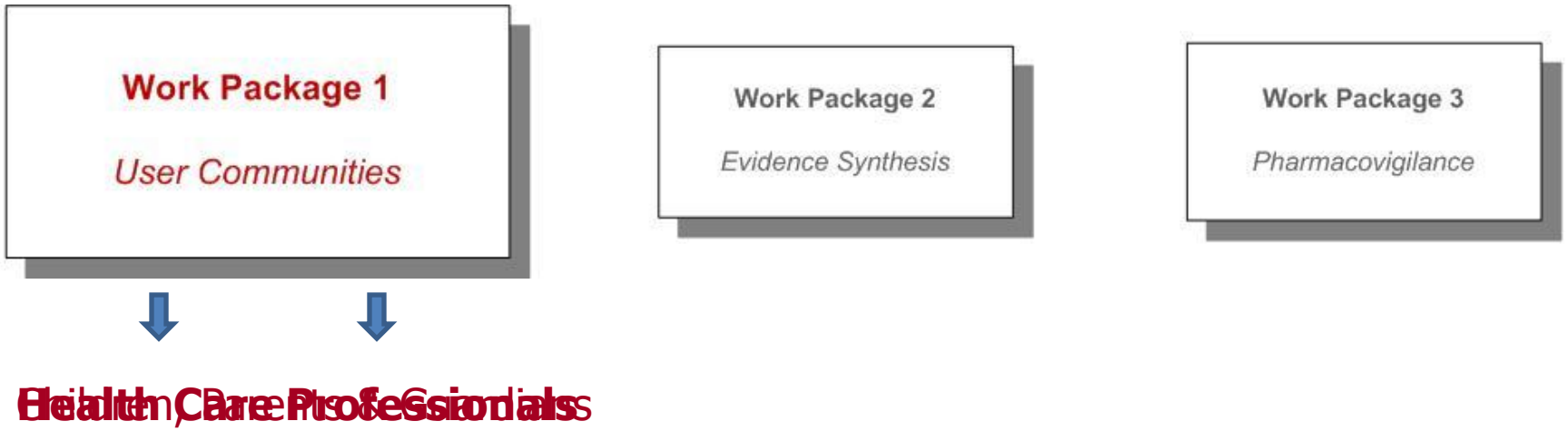
Scottish NHS Population resources

Clinical information systems



Child Medical Records for Safer Medicines (CHIMES)

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



Methods

Literature review

- Data linkage (completed)
- Attitudes of healthcare professionals (ongoing)

Qualitative Study

- Interviews (completed)
- Focus Groups (completed)

Consensus Study

- Delphi Survey (analysis ongoing)
- Triangulation (in progress)

➢Ethical approval granted by North of Scotland Research Ethics Service (NoSRES)

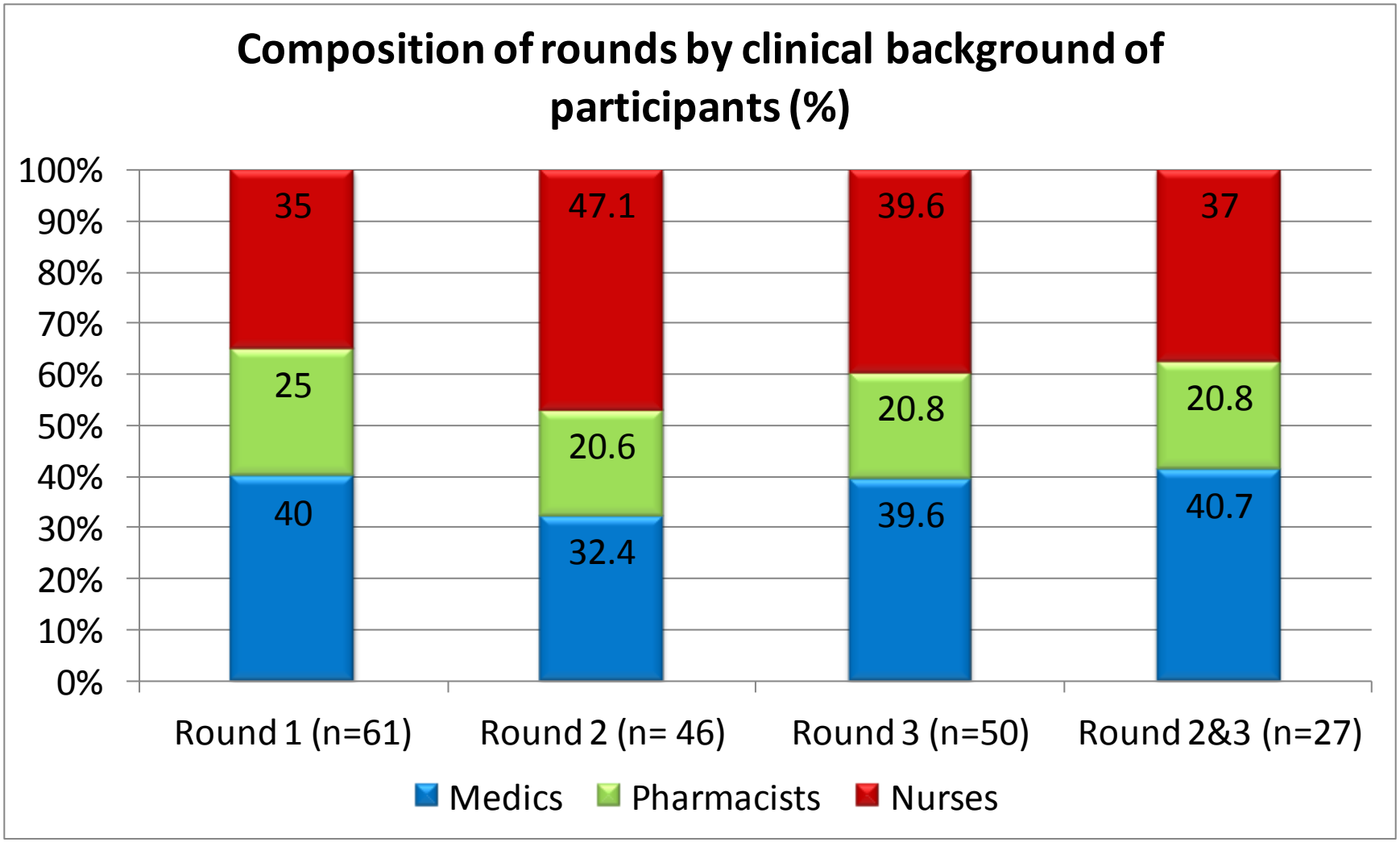
Summary Qualitative Work

- Proposed data linkage seen as beneficial
- General support of data linkage if identified issues are addressed

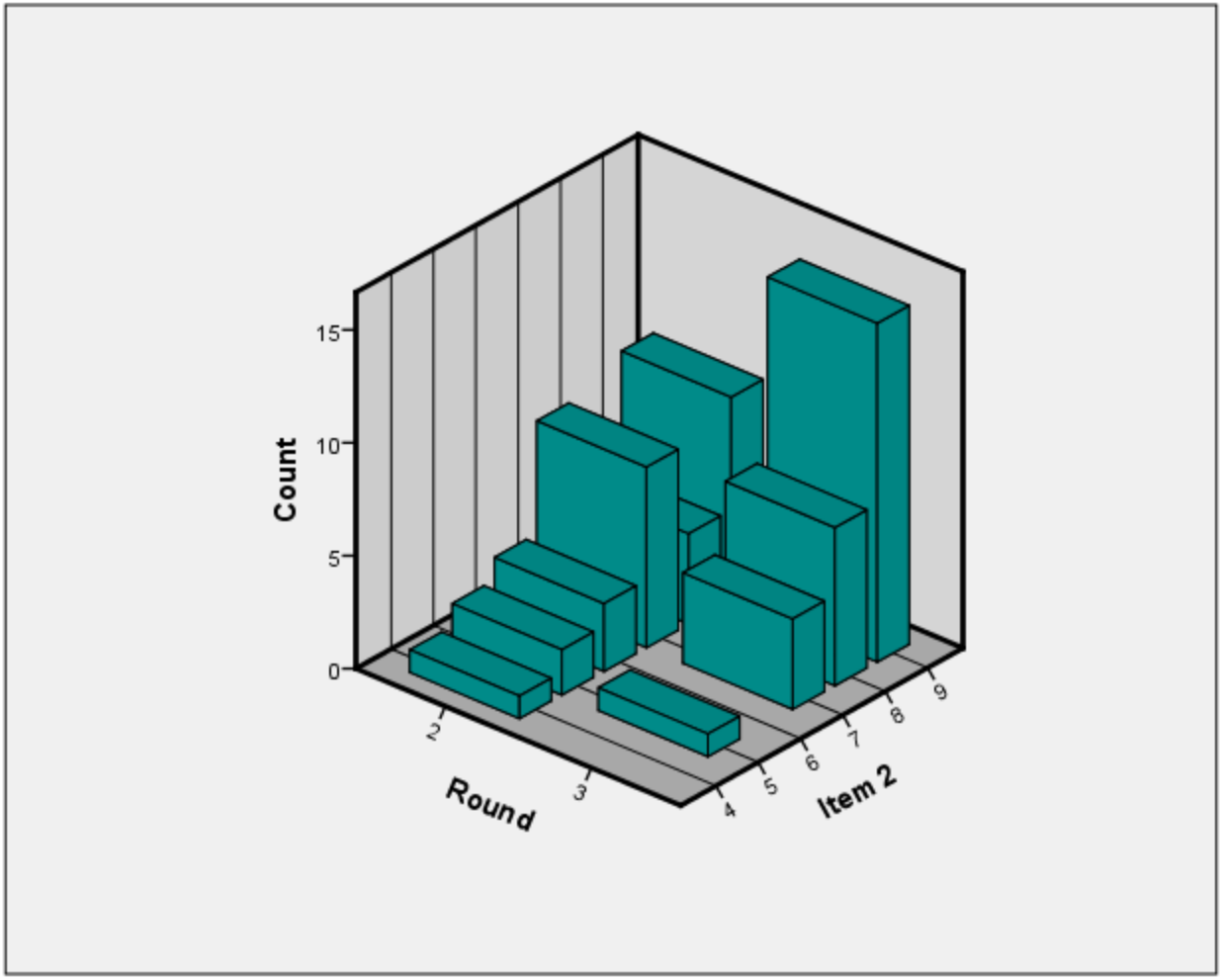
"The benefits are so enormous and the risks are so minimal that denying this activity [data linkage] is unethical." (A04)

"As a professional I can see the huge advantages of linking the data […], I think it would be fantastic if it works." (FG05, Paediatric pharmacist)

Characteristics Participants across Rounds



Facilitating the linkage is not in conflict with my professional standards if the data is anonymised:



- Round 2: median 7 [7-9]
- Round 3: median 9 [8-9]
- p=0.005
- No change 30%

Summary

- Development of linked database supported by health professionals
- Issues, concerns and requirements identified at different levels
  - Governance of database
  - Population Feedback as motivator and control mechanism
- Data to be cross-referenced to a parallel study investigating the views of the public

Child Medical Records for Safer 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

Parents/guardians, young people and their representatives

Analysis: Main Themes Identified

Combined data from Interviews and Focus Groups

Opinions Regarding Privacy and Confidentiality

Awareness and Opinions on Medicine Safety

Opinions Regarding Data Sharing and Linkage

Trust Relationships, and Promoting the Greater Good.

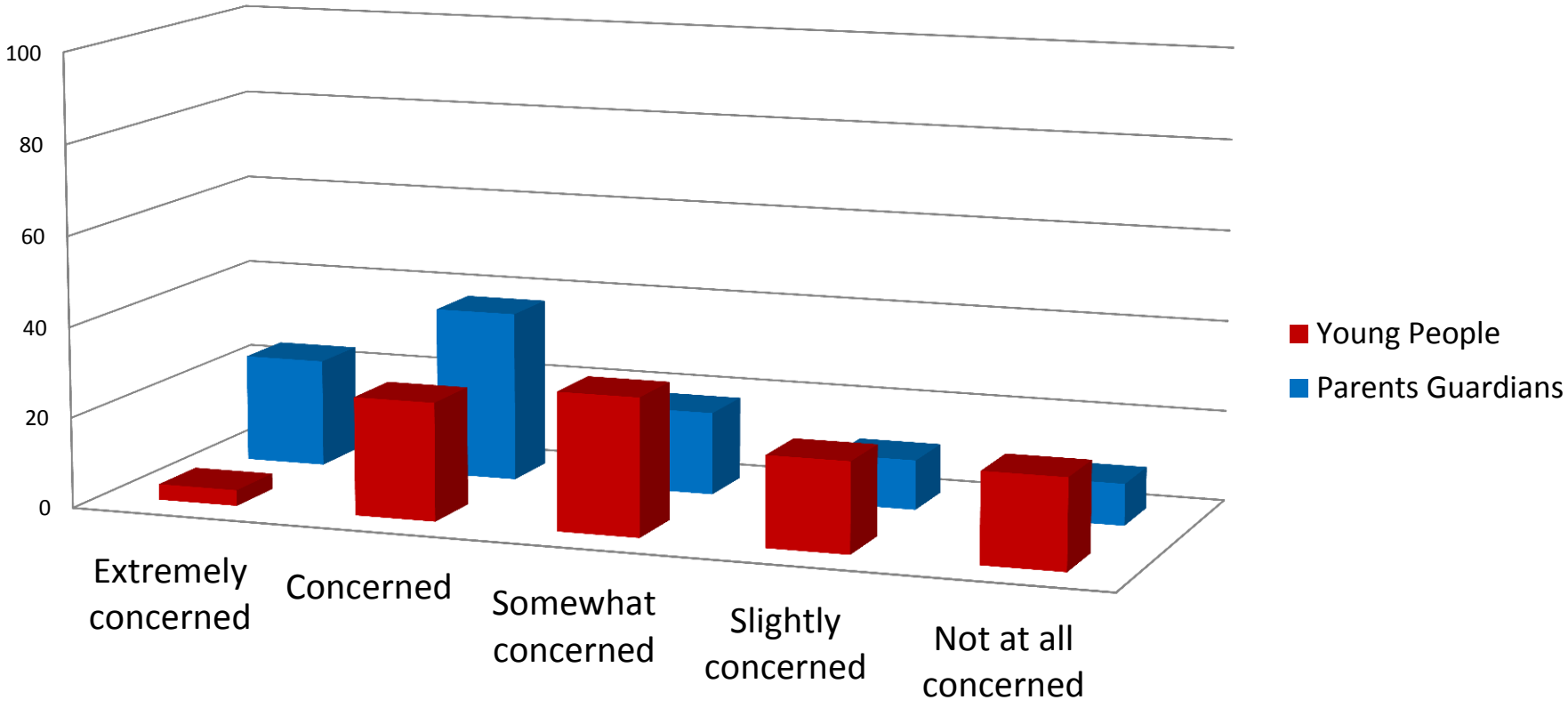
Communication/Public Consultation and Engagement with Proposed Database

I would be comfortable with it (linking data), I'm not sure if parents might be less comfortable... Young Person

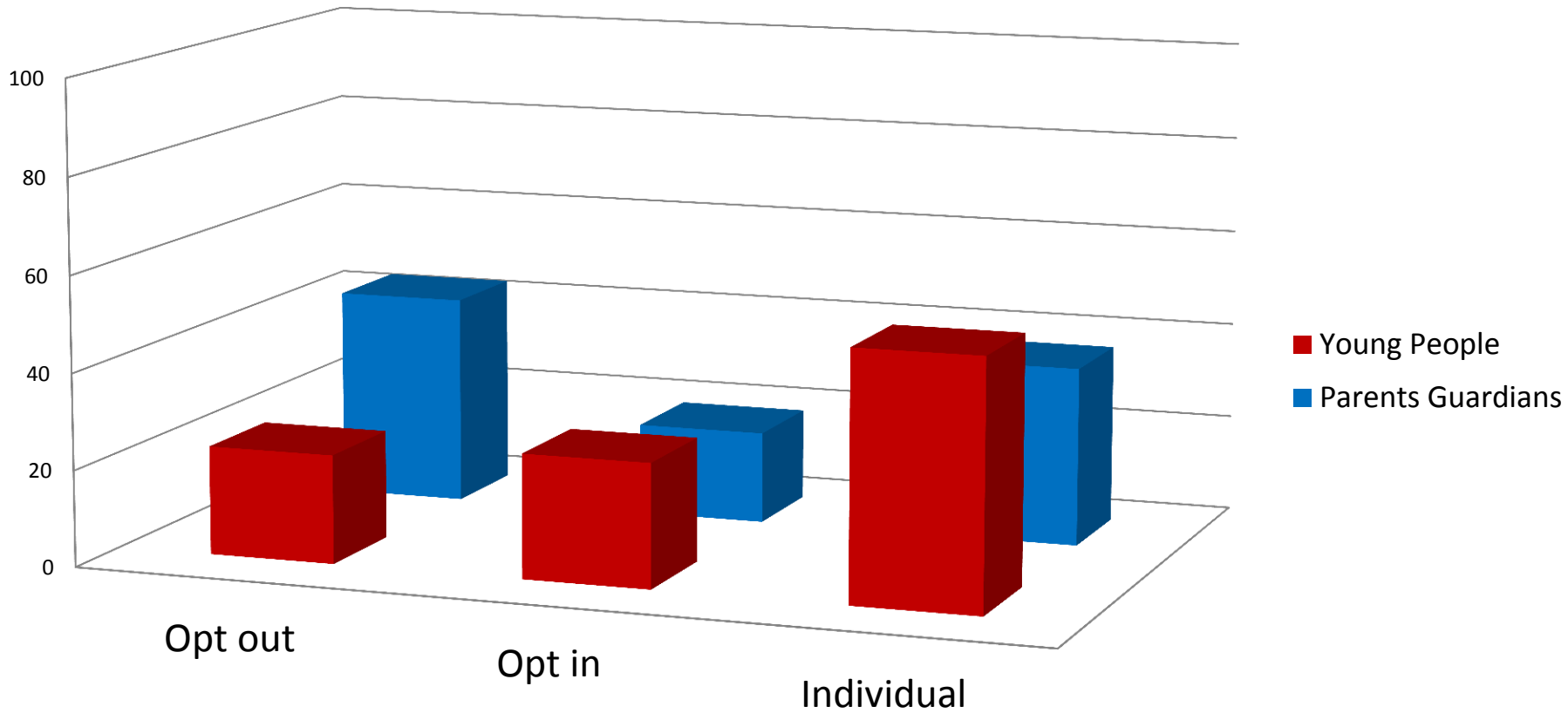
I think a strong and realistic opt-out option makes people feel better about a new system and is actually relatively low risk, 'cos people tend not to opt out, but I certainly think those feelings of having control make people more comfortable with a new data usage...Adult

Questionnaire results

Are you worried about identity theft when using online social networking sites?



If, following a well publicised information campaign about the combining (linking) of anonymised health data to help make children's medicines safer, you were asked to give consent, which method of those outlined below would you prefer?

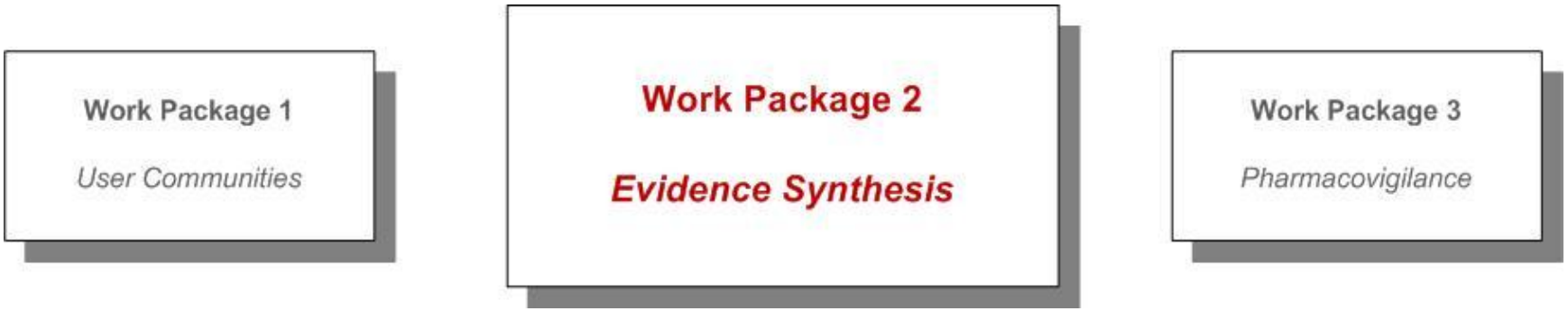


Conclusion

- Although further confirmatory work is required, a pharmacovigilance database derived from linked health care data and managed within an appropriate legal and ethical framework by the NHS would appear to be acceptable to parents and young people.

Child Medical Records for Safer Medicines (CHIMES)

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



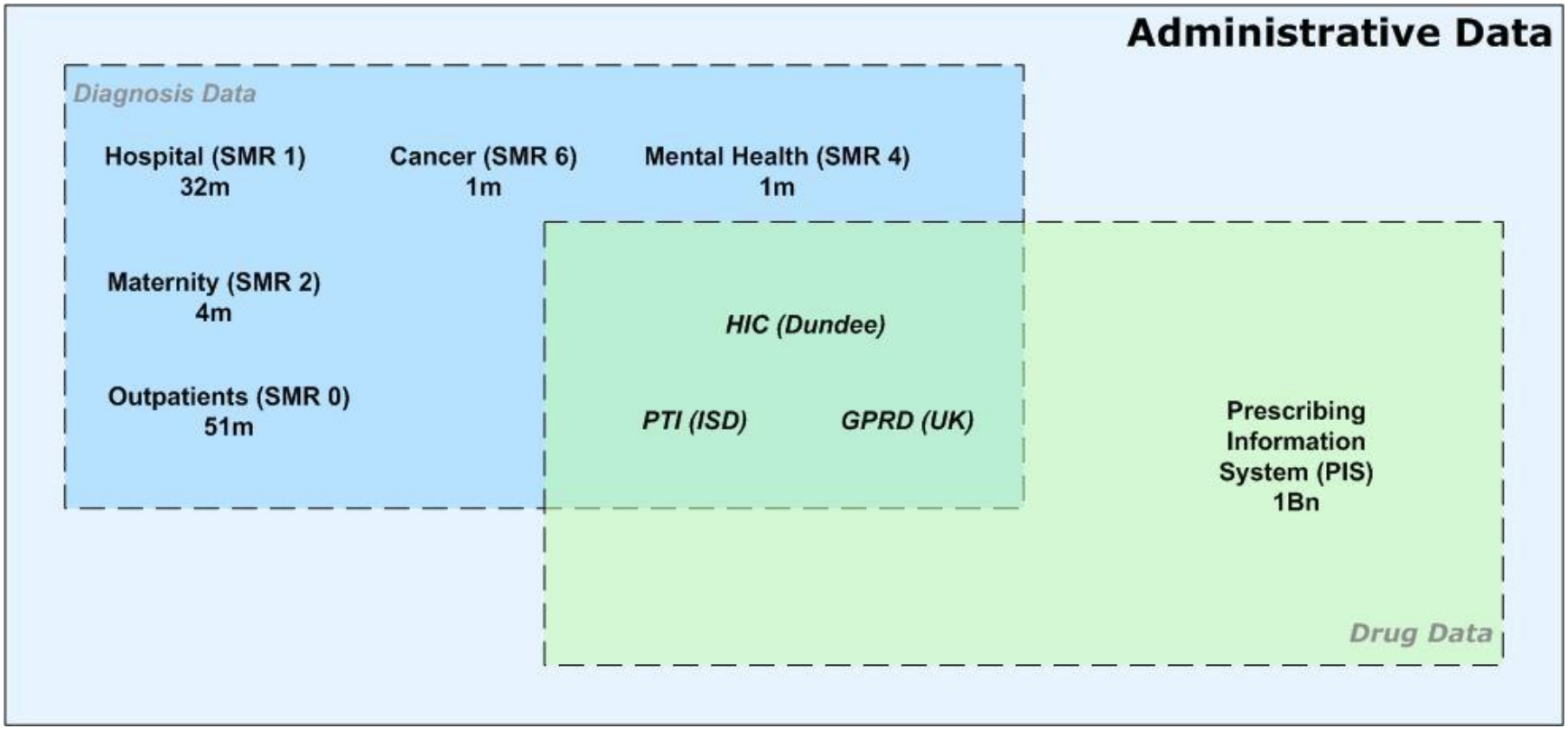
UNIVERSITY OF ABERDEEN

ISD SCOTLAND

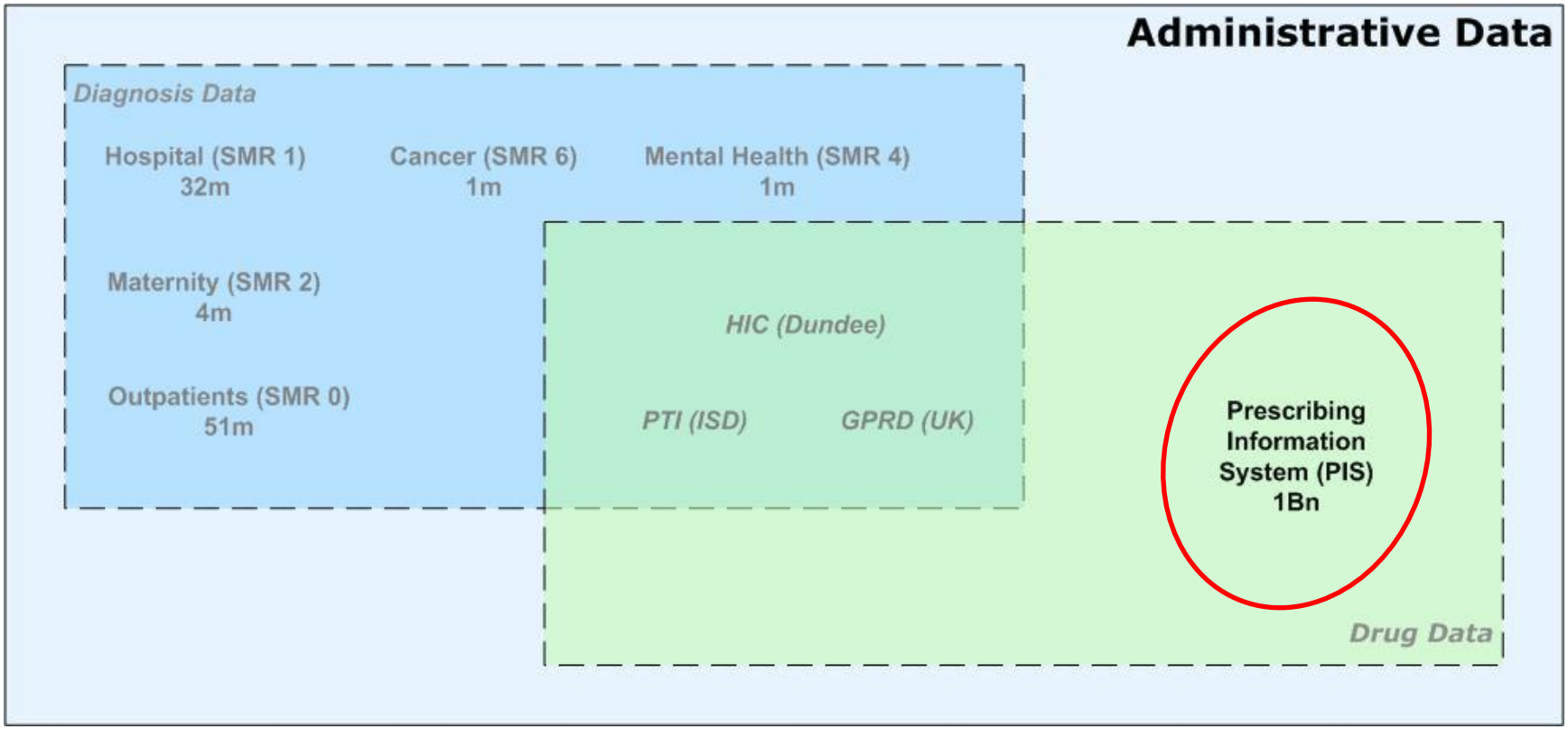
NHS Grampian

CHIEF SCIENTIST OFFICE

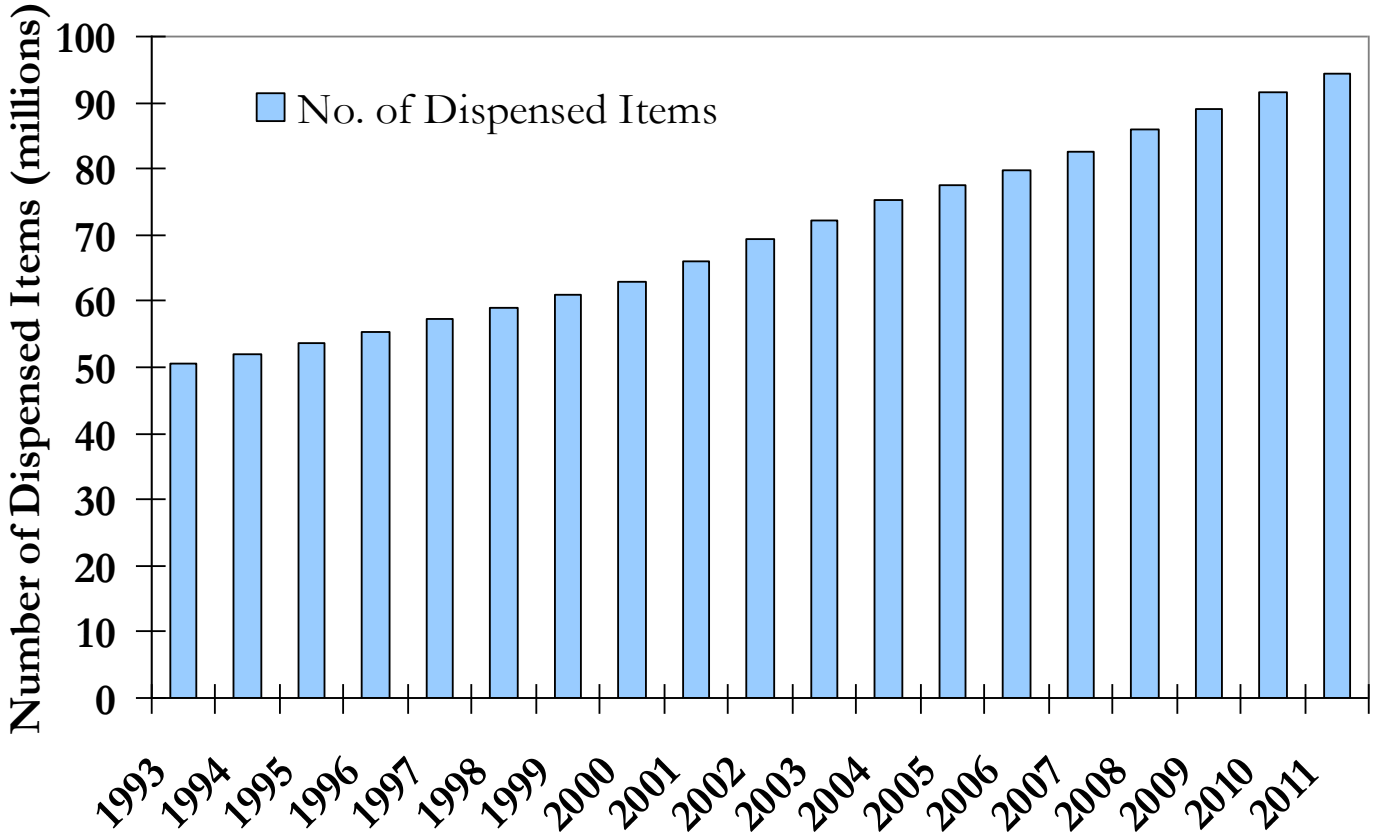
Sampling Frame – Scottish Pop (5m)
Information Services Division (ISD)



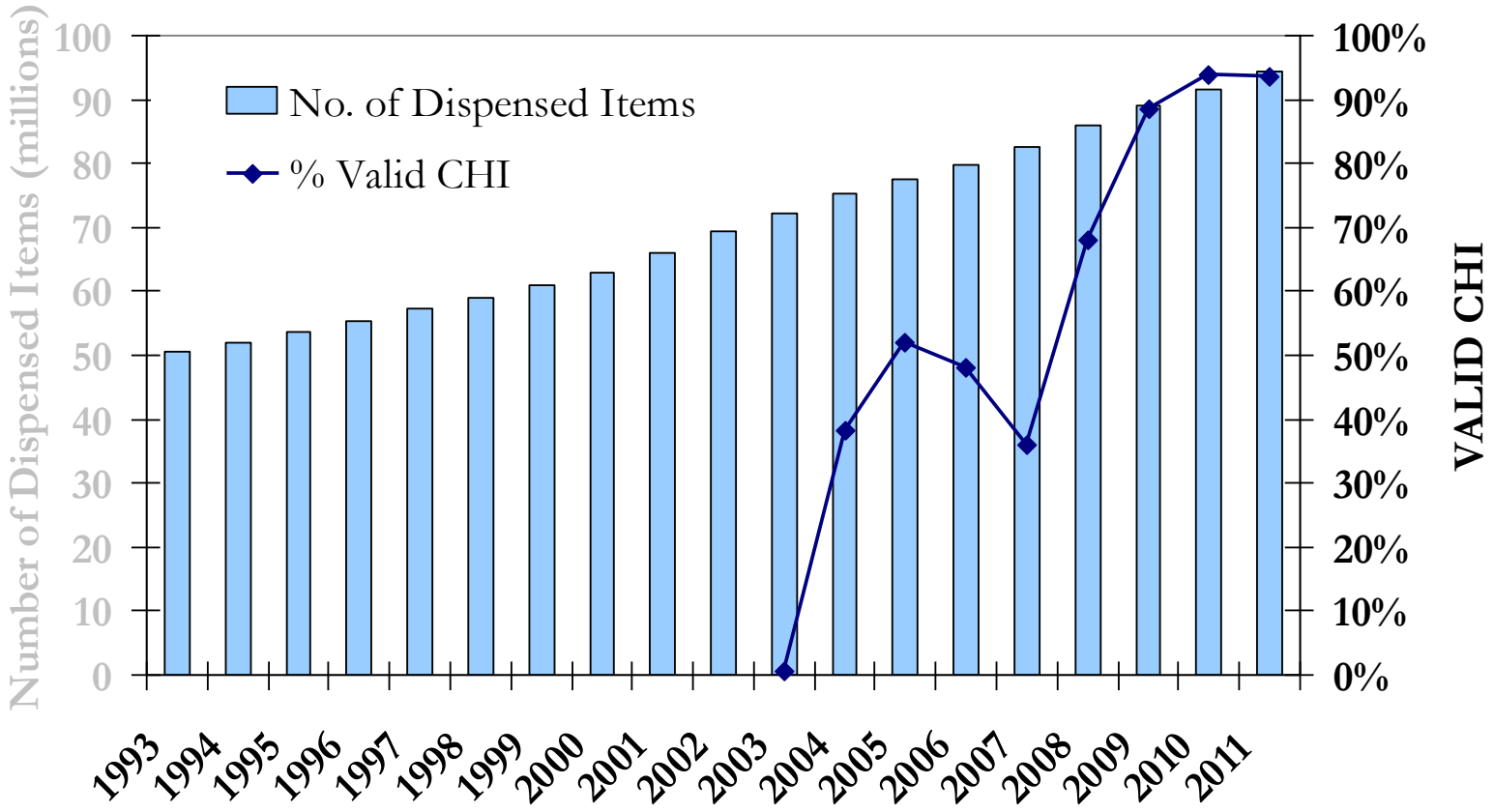
Sampling Frame – Scottish Pop (5m)
Information Services Division (ISD)



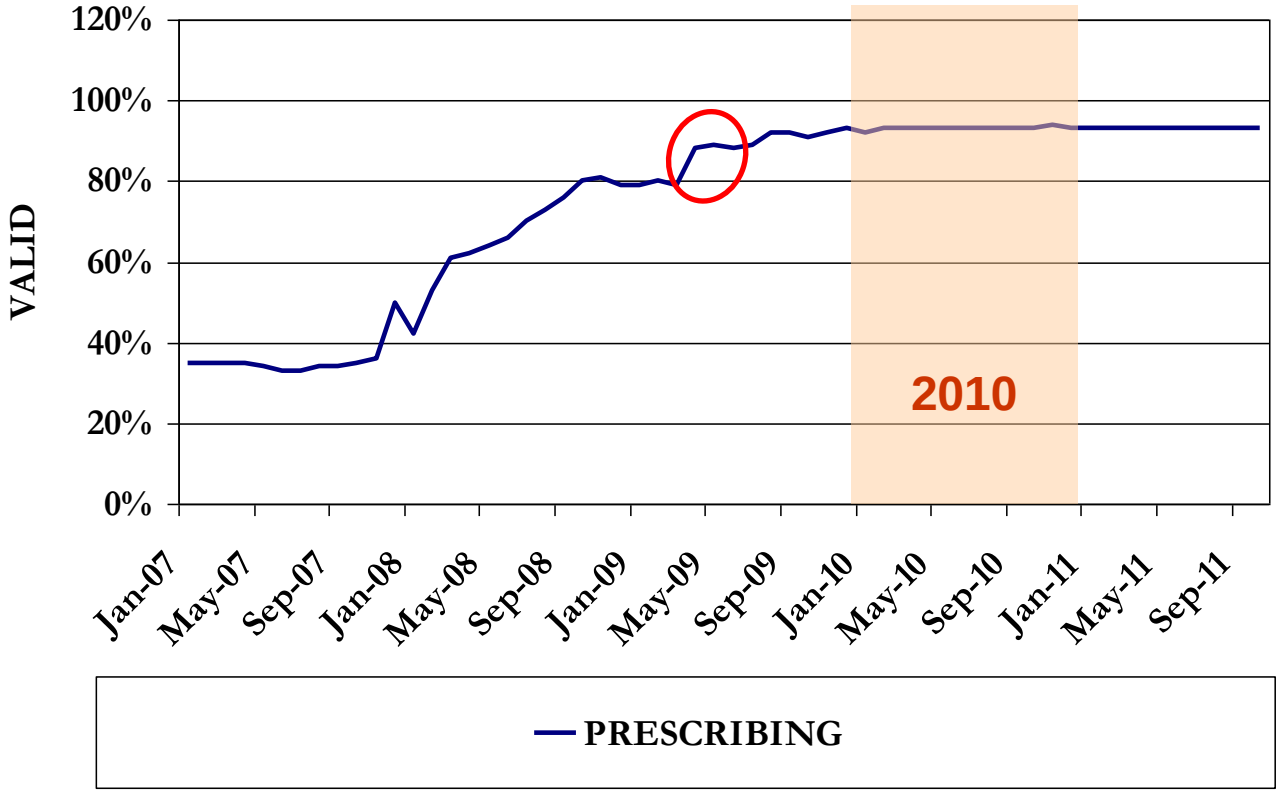
Number of items dispensed in the community in Scotland



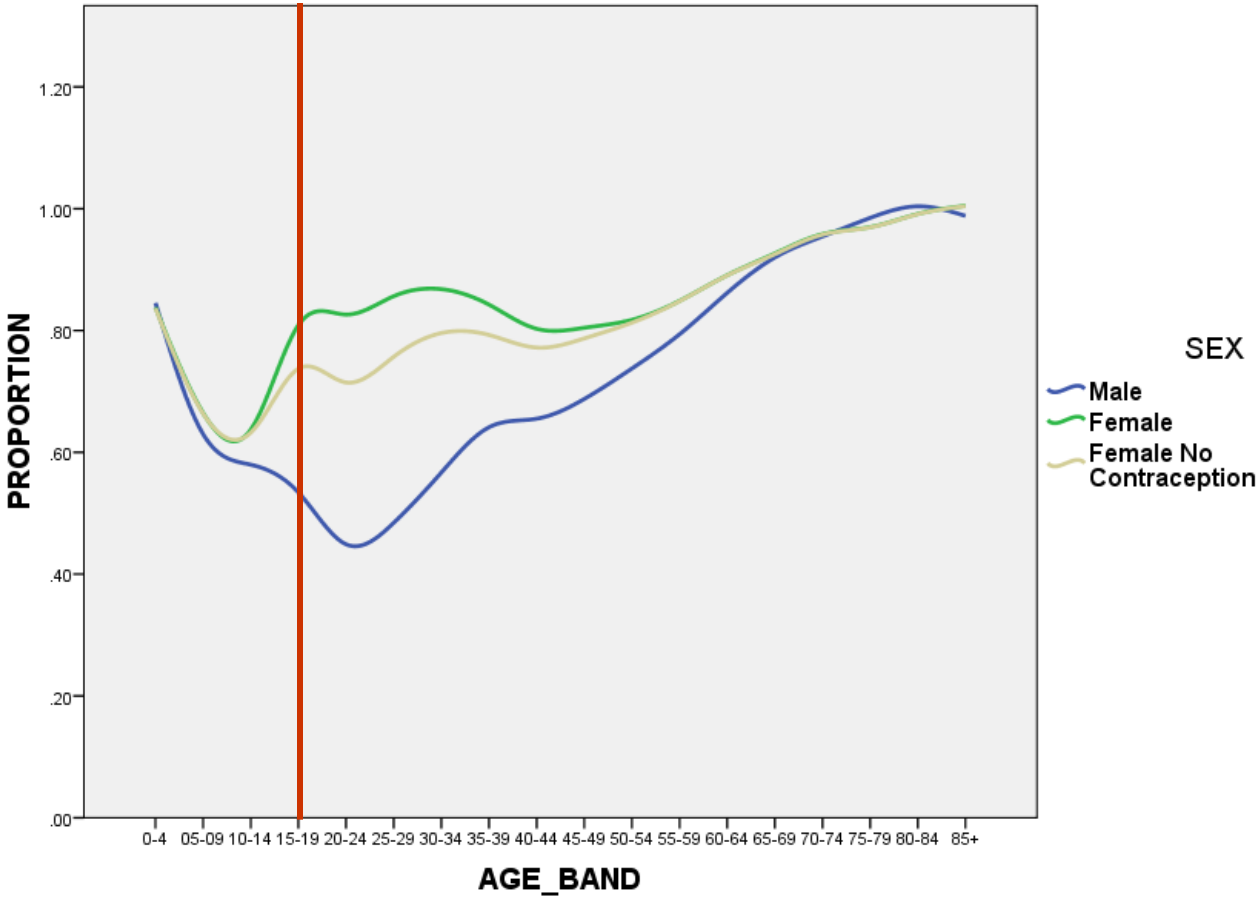
Number of items dispensed in the community in Scotland



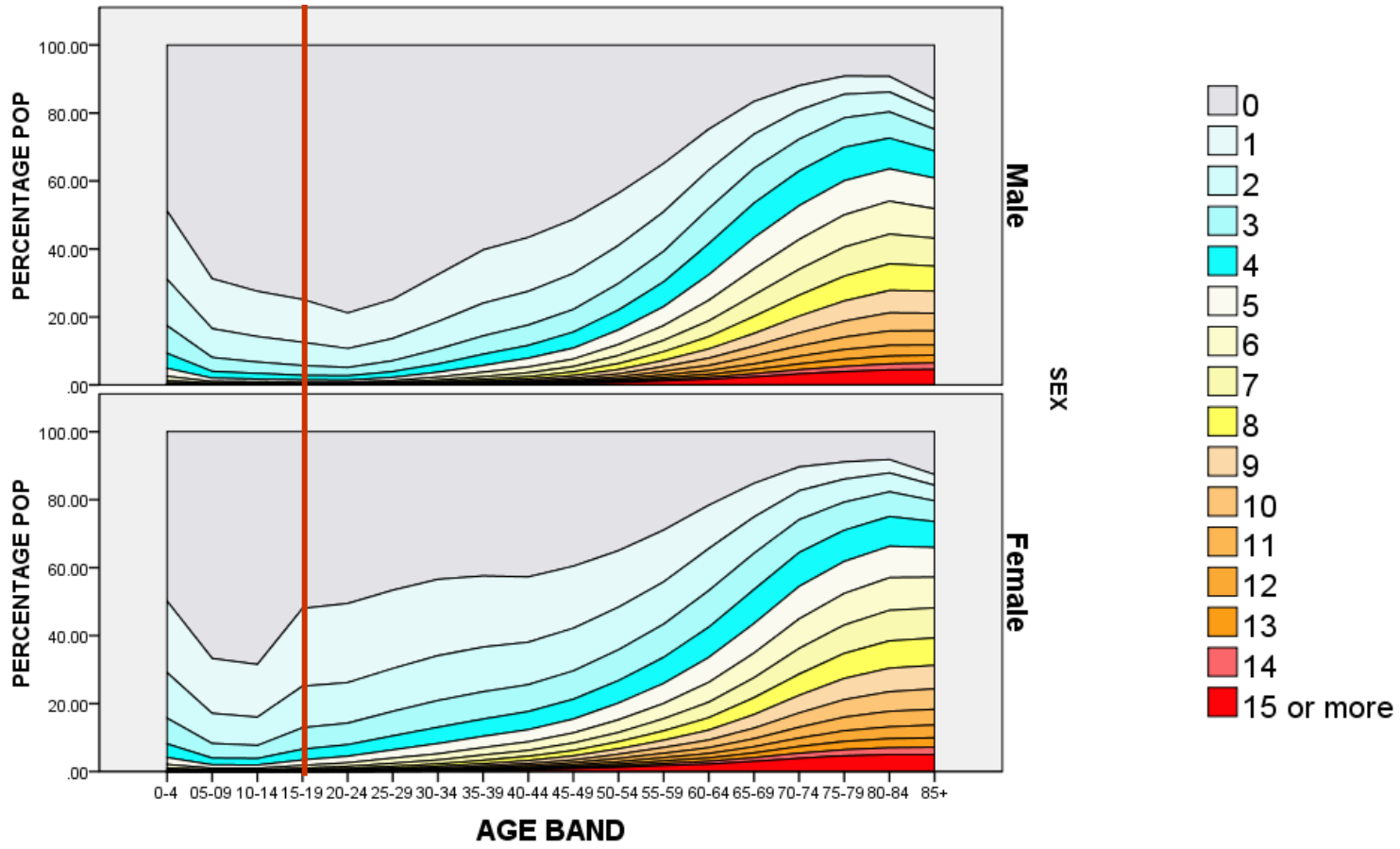
Percentage of dispensed items with valid CHI



Proportion of population receiving prescriptions in Scotland in 2010



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

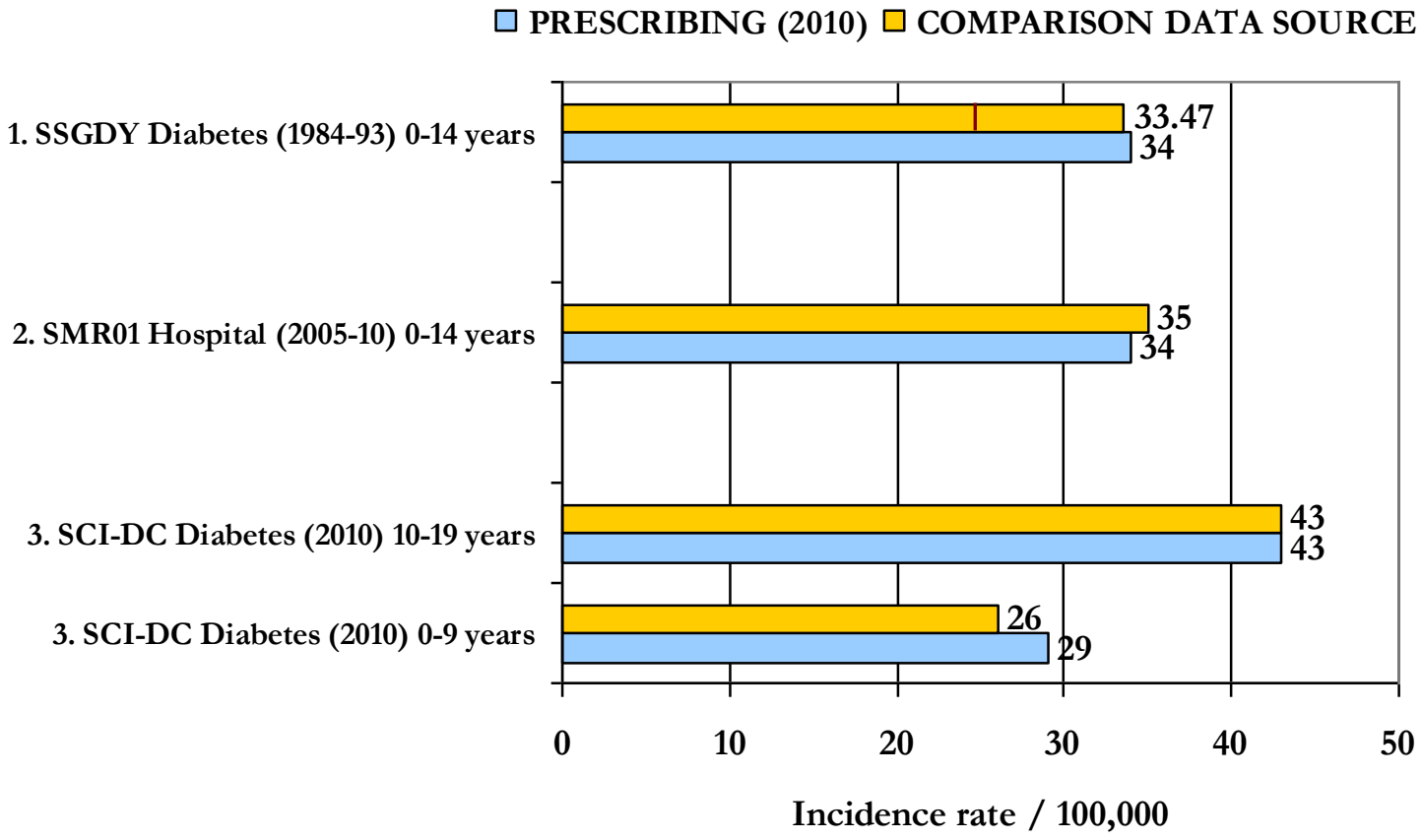


Measuring Error in Databases

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

West. *Pharmacoepidemiology* 2005; 45:709-765.

Insulin prescribing compared to T1 diabetes in Scotland



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.

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

Child Medical Records for Safer Medicines (CHIMES)

- Novel methods for early detection of ADRs in children using routinely acquired health data

Work Package 1

User communities

Work Package 2

Evidence Synthesis

Work Package 3

Pharmacovigilance

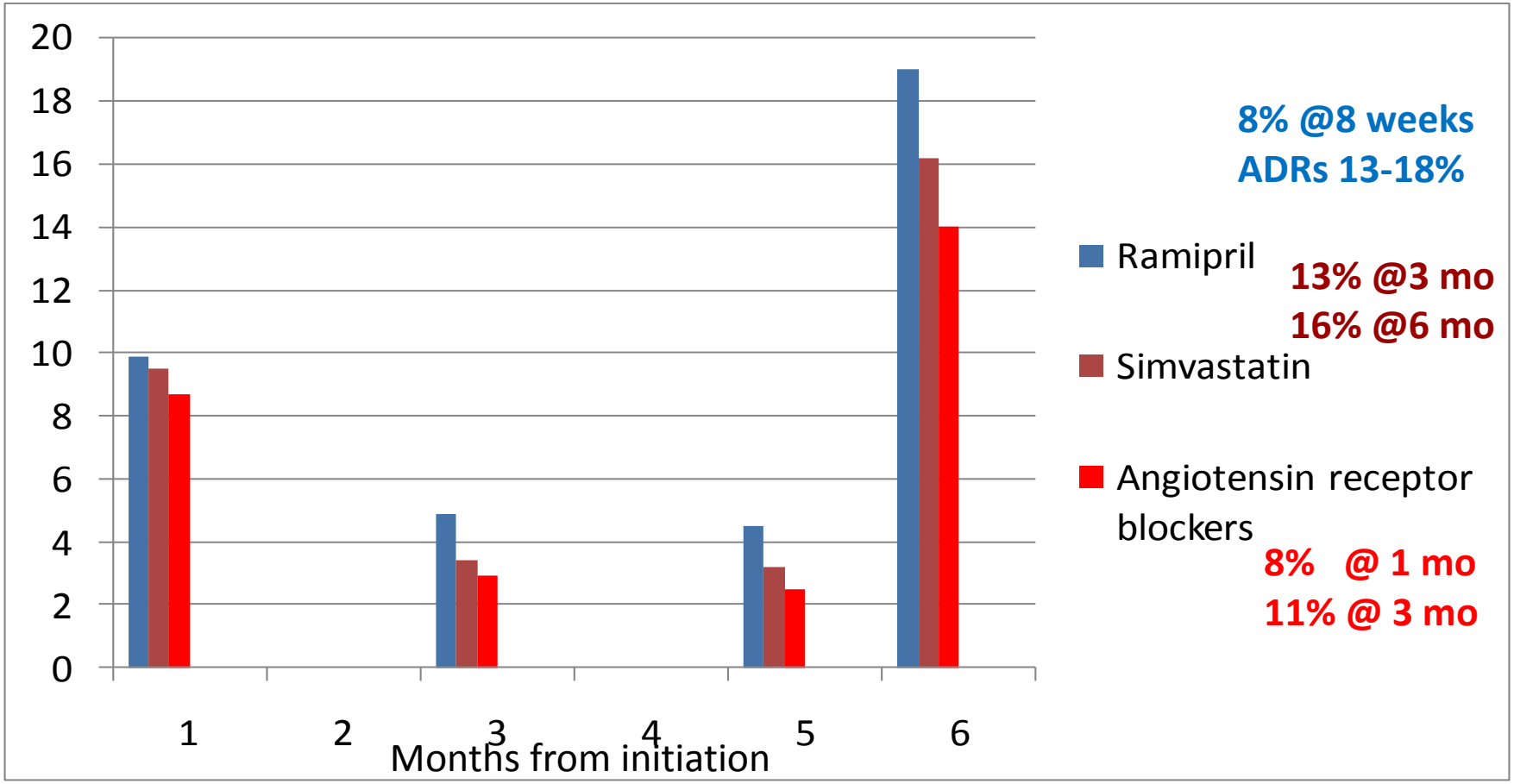
UNIVERSITY OF ABERDEEN

ISD SCOTLAND

NHS Grampian

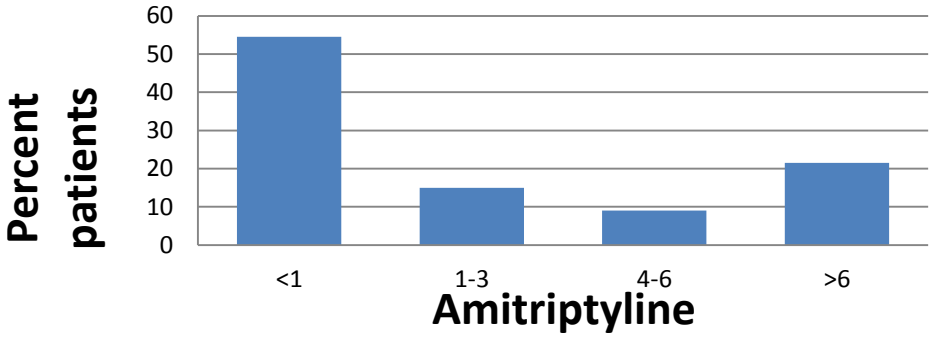
CHIEF SCIENTIST OFFICE

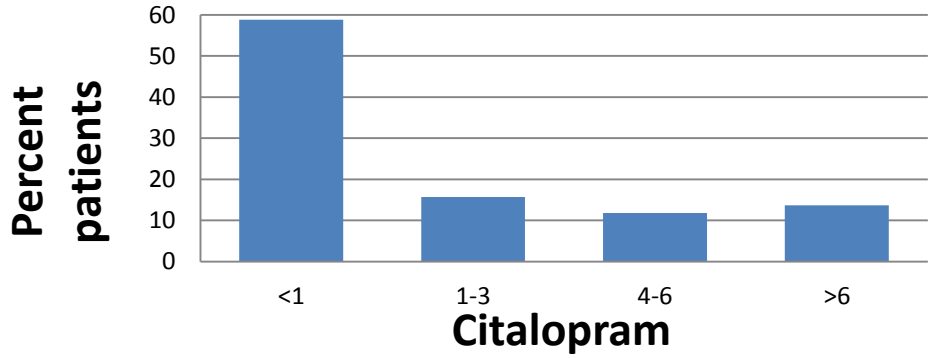
Discontinuations (PTI Primary care data in Adults)

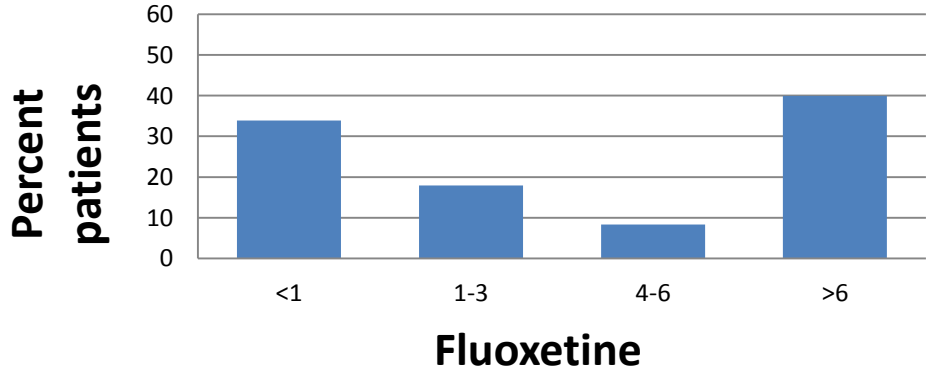


Mohamed, IM et al Br J Clin Pharmacol 2011 71:244–249

Anti depressants







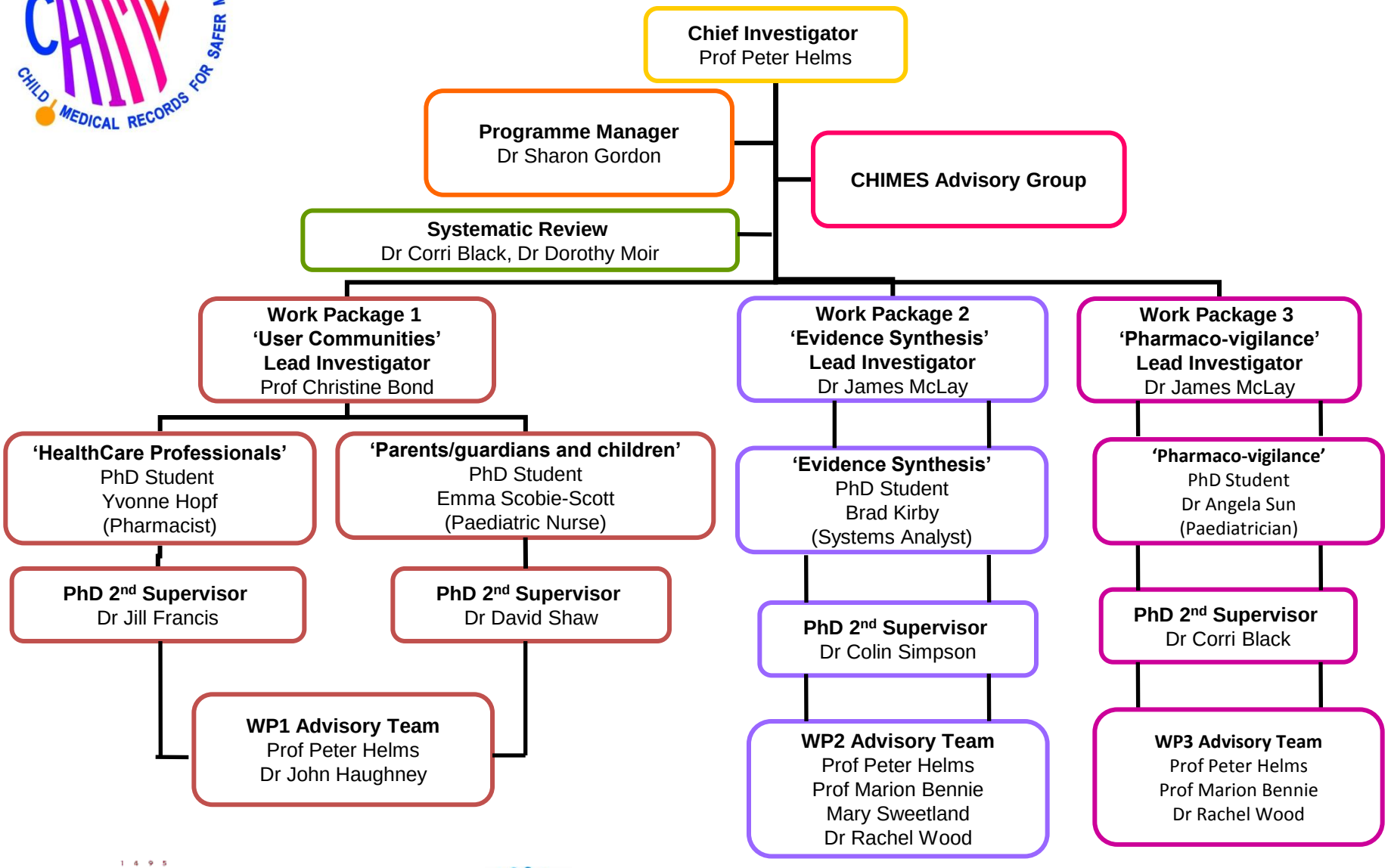
Duration in months

Future plans

- Extend analyses to national Prescribing Information System (PIS) database

- To verify ADRs
  - by linking with SMR01 around the time of drug discontinuation or switching
  - examining GP codes for possible reason(s)

CHIMES acknowledges the financial support of NHS Research Scotland (NRS), through NHS Grampian


Chief Investigator
Prof Peter Helms
Programme Manager
Dr Sharon Gordon
CHIMES Advisory Group
Systematic Review
Dr Corri Black, Dr Dorothy Moir
Work Package 1
'User Communities'
Lead Investigator
Prof Christine Bond
Work Package 2
'Evidence Synthesis'
Lead Investigator
Dr James McLay
Work Package 3
'Pharmaco-vigilance'
Lead Investigator
Dr James McLay
'HealthCare Professionals'
PhD Student
Yvonne Hopf
(Pharmacist)
'Parents/guardians and children'
PhD Student
Emma Scobie-Scott
(Paediatric Nurse)
'Evidence Synthesis'
PhD Student
Brad Kirby
(Systems Analyst)
'Pharmaco-vigilance'
PhD Student
Dr Angela Sun
(Paediatrician)
PhD 2nd Supervisor
Dr Jill Francis
PhD 2nd Supervisor
Dr David Shaw
PhD 2nd Supervisor
Dr Colin Simpson
PhD 2nd Supervisor
Dr Corri Black
WP1 Advisory Team
Prof Peter Helms
Dr John Haughney
WP2 Advisory Team
Prof Peter Helms
Prof Marion Bennie
Mary Sweetland
Dr Rachel Wood
WP3 Advisory Team
Prof Peter Helms
Prof Marion Bennie
Dr Rachel Wood