

# Adverse Drug Reaction Surveillance Scottish Pilot

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# Adverse Drug Reaction Surveillance – Scottish Pilot

- Undertakes surveillance of adverse drug reactions in Scottish Children
- Collaboration between:
  - Royal College of Paediatrics & Child Health
  - Scottish Neonatal and Paediatric Pharmacy Group
  - MHRA



# Overview

- Medicines for children are frequently provided off label and off licence
- Because of the changing physiology during childhood it is likely that children will have more than average adverse drug reactions (ADRs)
- This project aims to develop and pilot an effective active surveillance system for ADRs in children.



# Aims

- Can an active ADR reporting system be established with Paediatricians?
- What level of reporting of ADRs can a card based surveillance system achieve?
- Can an electronic – email based – surveillance system deliver returns as good or better than a card based system?
- How does baseline reporting using this system compare with that of the MHRA system?
- How many and what ADRs are reported in this group of drugs?



# Case Definition

Any ADR that

- Is severe enough to precipitate admission to hospital  
or
- Occurs because of an outpatient medicine prescription  
or
- Occurs in hospital

specifically for the following drug groups:



# Case Definition cont

specifically for the following drug groups:

- Ibuprofen
- Ceftriaxone
- Fluticasone
- Sodium valproate
- Sedative
- Other please state



# Methodology 1

- This is ACTIVE surveillance – the stimulus coming monthly from the RCPCH Research Division, unlike the MHRA yellow card system which relies on passive reports
- System is based on the highly successful BPSU orange card, which has a compliance rate of over 90%
- Paediatricians and pharmacists will be asked monthly to report ADR seen in a group of drugs listed on the card
- Importantly they will be asked to return the card even if there is NOTHING to report.



# Methodology 2

- Following a positive report the clinician will be sent a short questionnaire to identify a) ADR seen b) the drug involved c) the outcome of the ADR
- After 6 months the methodology will change
- Half the card recipients will be randomly chosen to receive an email version of the green card for the remainder of the surveillance period
- At the end of the year recipients will be asked about their opinions of the reporting system.



# Surveillance Card

RCPCH SCOTTISH PHARMACOVIGILANCE SYSTEM

January 2006 [0601]

Code [    ]

**NOTHING TO REPORT**

Specify in box the number of cases seen

**IBUPROFEN**

**CEFTRIAZONE**

**FLUTICASONE**

**SODIUM VALPORATE**

**ANY SEDATIVE – Please state**

**Other DRUG please state below**

Please add your email address below in caps

**Clinicians Section – Please Keep if Necessary**  
**RCPCH SCOTTISH PHARMACOVIGILANCE**  
**SYSTEM**

For cases seen in January 2006

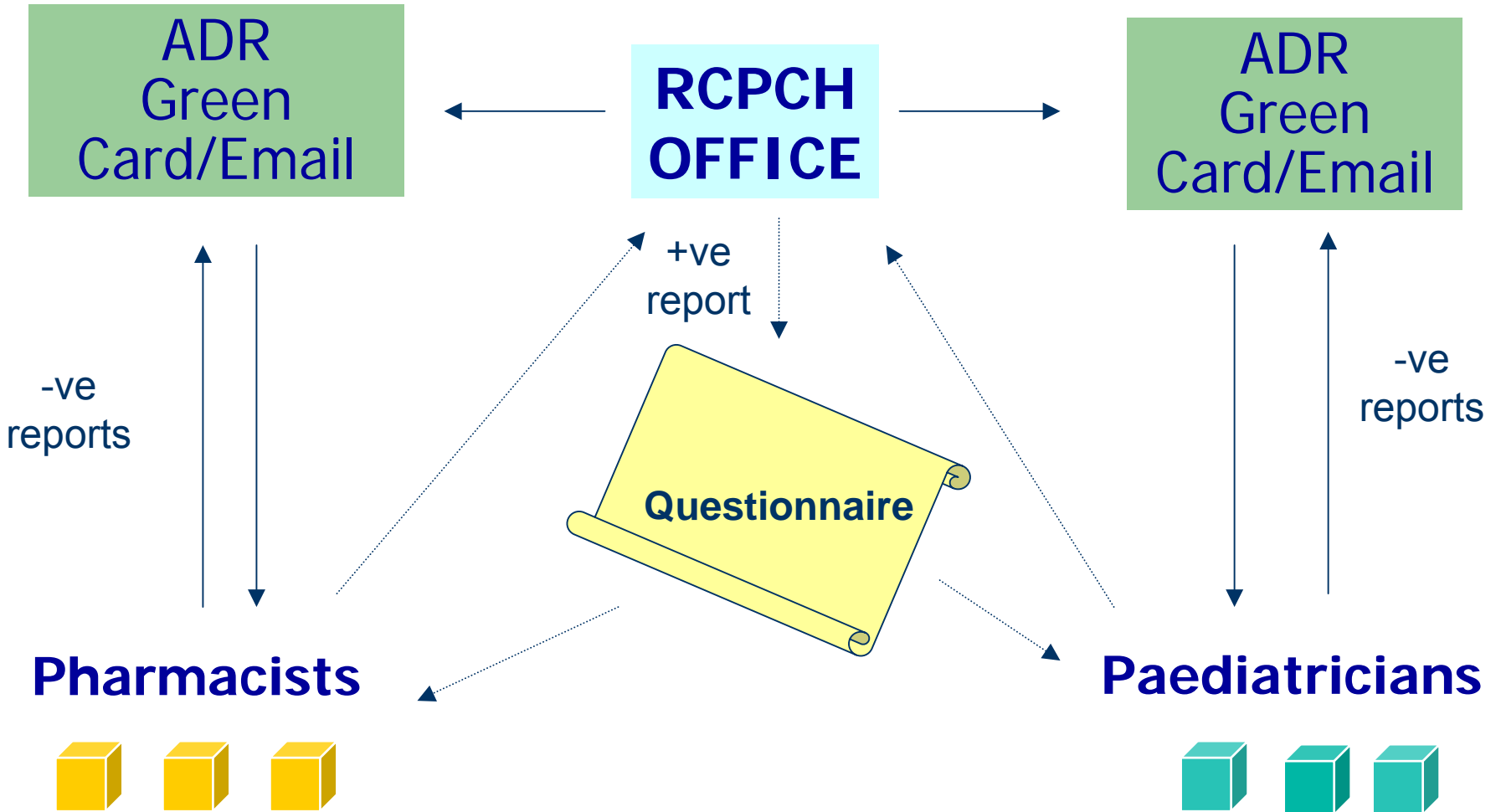
Please **NOTE** the patient's names(s) or other identification and **KEEP THIS SLIP** for easy reference

Adverse Drug Reaction	Patient(s) Sex/Age	Hospital Numbers

**DETACH THIS SECTION BEFORE RETURNING**



# ADR Study



# Reporting Instructions

- Please Report any cases seen within the last month that meet the case definition
- Please note that this surveillance does not replace the statutory surveillance carried out by the MHRA



# Results

From the data collected we hope to answer

- whether an active ADR reporting system using paediatricians is possible
- what level of reporting can be expected
- whether or not an electronic – email based – surveillance system delivers returns as good or better than a card based system?
- we will also compare baseline reporting of this system with that of the MHRA passive system
- what is the age and sex of those presenting with ADRs
- what type of ADR is presented.



# Way Forward

If the pilot meets its aims we will

- Identify the most appropriate surveillance mechanism for monitoring ADRs.
- Consider the development of a web based / email reporting system to supplement a postal system
- Make plans to expand the active surveillance system to cover the UK
- Consider how we can identify denominator data so ADR incidence can be measured.



# Funding and Ethics

- This study is funded by the Department of Health and the Royal College of Paediatrics and Child Health
- This study has been approved by the East London & The City HA LREC 1



# Thank you

We would like to thank

- All Scottish Paediatricians
- All Scottish Members of the Neonatal & Paediatric Pharmacy Group

