

Towards consensus for best practice: the use of patients records for research in general practice

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Bournemouth October 2008**

RCGP Use of Patient Records for Research in General Practice

Outline

- Background/Introduction
- Principles underpinning the guidance
- Preconditions for research studies
- Research using:
 - > Existing patient records alone
 - > Identifiable data
- Participatory research
- Informed consent
- Feedback to participants
- Conclusion

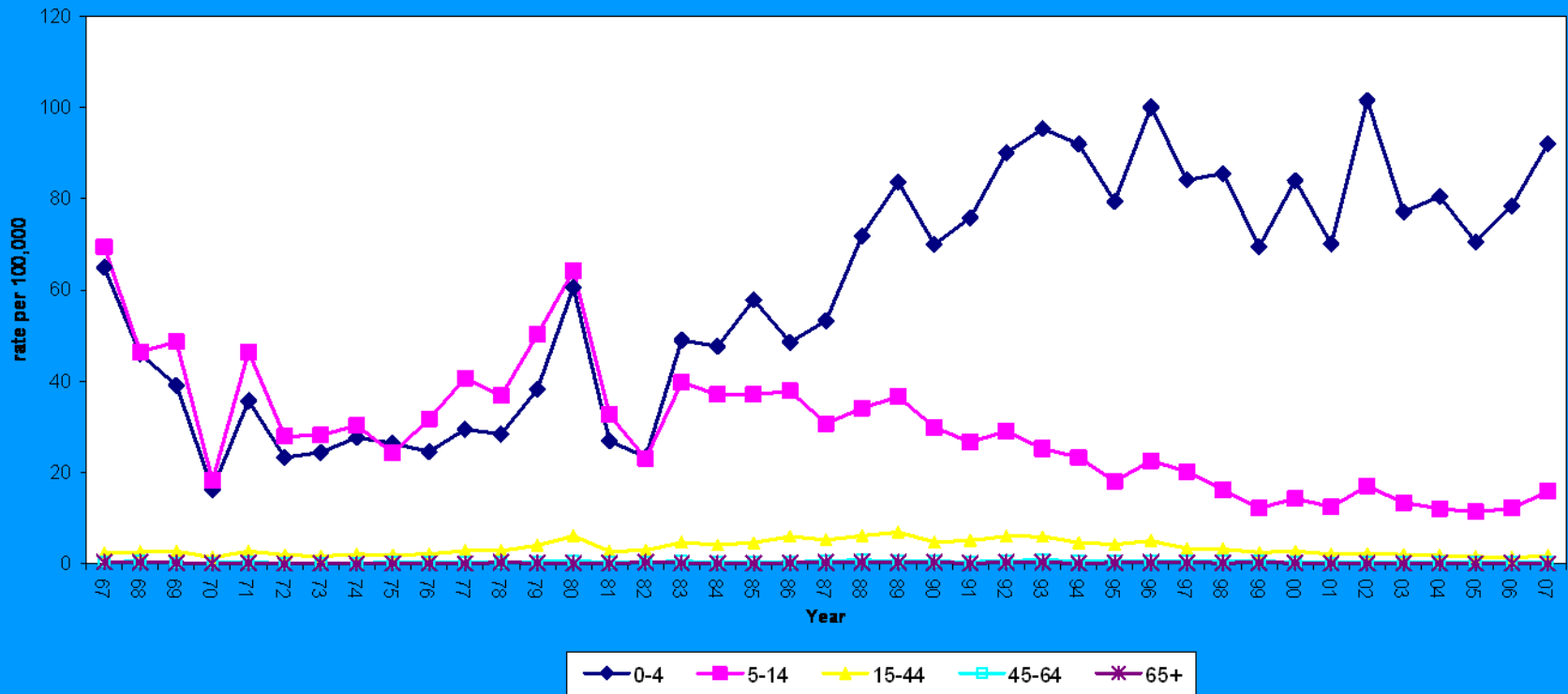
Background / Introduction

1. Use of Patient Records in Research

- Audit
- Surveillance
- Monitoring (Pharmacovigilance)
- Epidemiology
- Clinical Trials

RCGP Birmingham Research Unit

CHICKENPOX
Mean weekly incidence rate by Age Group



2. Identifiability of Data

- Anonymised Information
- Coded Information
- Identifiable Information

3. Context

- Wellcome Trust Conference
- Existing Reports

Principles underpinning the Guidance

- Patient Confidentiality
 - Honest Brokers
 - Safe Havens
- Primary Role of the GP
- Improving Public Awareness and Engagement
 - National Programme
 - Local Provision of Information

Preconditions for Research Studies

- Ethics Review
- Research Governance
- Practice – appropriate setting
- Adequate Resources
- Potential Conflicts of Interest
- Research Ready

Research using existing patient records [No patient participation]

- Using anonymised data

- Consent
- Anonymisation Process
- QResearch [Example]

- Using coded data

- Consent
- Coding Process
- General Practice
Research Database [Example]

- Using identifiable data

- Consent [GMC Guidelines]

Inviting People to take part in Research

GMC Guidelines (Informed Consent) [1]

- What the **research aims** to achieve, an outline of the research method, and confirmation that a research ethics committee has approved the project;
- The **legal rights and safeguards** provided for participants;
- The **reasons** that the patient or volunteer has been asked to participate;
- If the project involves randomisation, the nature of the process and reasons for it and the fact that in **double-blind research** trials neither the patient nor the treatment team will know whether the patient is receiving the treatment being tested or is in the control group;

GMC Guidelines (Informed Consent) [II]

- Information about possible **benefits and risks**;
- An explanation of which parts of the treatment are **experimental** or not fully tested;
- Advice that they can **withdraw** at any time and, where relevant, an assurance that this will not adversely affect their relationship with those providing care;
- An explanation of how **personal information** will be stored, transmitted and published; what information will be available to the participant about the outcome of the research, and how that information will be presented;
- Arrangements for responding to **adverse events**;
- Details of **compensation** available should participants suffer harm as a result of their participation in the research;

Research using patient records as a starting point for participatory research

- Reviewing Records (Eligibility)
- Access to the Records (Formal process of accreditation)
- Screening of Participants
- Informing Patients (Public Awareness)

Inviting Patients to take part in a study

- Contacting Patients
- Best Practice
 - GP involvement
 - Screening of contacts
 - Letter of invitation
 - reassurance about future care
 - opportunity for discussion
 - Practice-headed paper
 - Patients informed
 - Practice responsibility

Feedback of Results

- Use of Results
- Researcher Responsibilities
- Feedback
- GP as Patient's Advocate

Conclusion

- Maximise potential for research
- Clearly defined processes for uses of data
- Principles adhered to