

# Electronically delivered, multi-component intervention to reduce unnecessary antibiotic prescribing in primary care

<b>Submission date</b> 11/11/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/11/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/03/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Antibiotics are vitally important medicines. They are used to treat infections caused by bacteria, some of which would otherwise kill the person affected. In recent years, however, antibiotic resistance, a situation where an antibiotic no longer works against one or more bacteria, has become a major problem. It has been caused by a number of factors, including general practitioners (GPs) prescribing them for minor illnesses that do not need them or for conditions that antibiotics can't cure (such as the common cold). Here, we are going to test whether an electronically delivered, multi-component intervention can reduce the number of unnecessary antibiotic prescriptions given to patients that go to their GP about a respiratory tract infection (RTI - an infection of the sinuses, throat, airways or lungs).

### Who can participate?

General practices that contribute up-to-standard data to the Clinical Practice Research Datalink (CPRD), the NHS observational data and interventional research service.

### What does the study involve?

Participating CPRD general practices are randomly allocated into one of two groups. Those in the control group continue with their usual clinical care. Those in the interventional group receive an intervention made up of a number of parts. These include feedback on their rate of antibiotic prescribing compared to other GP practices, educational and decision support tools to support the none prescribing or delayed prescribing of antibiotics, and three minute webinars that explain and promote the use of the materials they are given. The study is run for 12 months, after which the antibiotic prescribing rates between the intervention and control groups are made, along with other outcome measures such as RTI consultation rate, health care costs, number of cases of pneumonia and lower respiratory tract infections and hospital admissions.

### What are the possible benefits and risks of participating?

This research looks at inappropriate and unnecessary prescribing of antibiotics to patients with respiratory tract infections (RTIs) in general practice. All management decisions for individual patients remain at the discretion of individual general practitioners. Therefore, we do not

anticipate any potential serious adverse events that could be directly caused by the intervention. However, we will ask general practitioners at participating general practices to tell us of any possible adverse events.

Where is the study run from?  
Kings College London (UK)

When is the study starting and how long is it expected to run for?  
January 2015 to December 2018

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Professor Martin Gulliford

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Martin Gulliford

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers  
13/88/10

## Study information

Scientific Title

Electronically delivered, multi-component intervention to reduce unnecessary antibiotic prescribing in primary care. Cluster randomised trial using electronic health records (eCRT2)

**Acronym**

eCRT2

**Study objectives**

To test the effectiveness, in a cluster randomised controlled trial, of electronically delivered, multi component interventions to reduce unnecessary antibiotic prescribing when patients consult for respiratory tract infections (RTI) in primary care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES London Dulwich, 08/10/2014, ref. 14/LO/1730.

**Study design**

Cluster randomised trial with general practices as the unit of allocation

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

GP practice

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Antibiotic prescribing/respiratory tract infections

**Interventions**

There will be two trial arms.

1. The control trial arm practices will continue with usual clinical care.
2. Practices in the Intervention trial arm will receive complex multi-component interventions, delivered remotely, as follows:
  - 2.1. Feedback of each practices antibiotic prescribing results in relation to peers, through monthly updated antibiotic prescribing reports estimated from CPRD data
  - 2.2. Delivery of educational and decision support tools to support policies of no-antibiotic prescribing or delayed prescribing
  - 2.3. Three minute webinars to explain and promote effective utilisation of the intervention materials. The intervention will continue for 12 months.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Number of antibiotic prescriptions for RTI per 1,000 registered patient years at 12 months follow-up

## **Secondary outcome measures**

1. Number of consultations for RTI with antibiotic prescribed / Total RTI consultations (%) at 12 months follow-up
2. Consultations and prescriptions as defined above during 14 days after the index consultation at 12 months follow-up
3. Number of consultations for RTI per 1,000 registered patient years 12 months follow-up
4. All antibiotic prescriptions per 1,000 registered patient years at 12 months follow-up
5. Number of hospital admission (by category) per 1,000 registered patient years at 12 months follow-up
6. Estimated costs of all health care utilisation per 1,000 registered patient years at 12 months follow-up
7. Broad categories of RTI subgroups including colds, sore throat, cough and bronchitis, otitis media and rhino-sinusitis (NICE, 2008) at 12 months follow-up
8. Number of adverse events ((peritonsillar abscess, mastoiditis, skin infections and bacterial infections) (by category) per 1,000 registered patient years over at 12-months follow-up

## **Overall study start date**

01/01/2015

## **Completion date**

31/12/2018

# **Eligibility**

## **Key inclusion criteria**

General practices will be included in the trial if:

1. They presently contribute up-to-standard data to CPRD
2. Consent to participation in the trial
3. Are located in areas that have given research governance approval for the study

Data for non-trial CPRD practices will be eligible for observational data analysis to gauge the representativeness of practices and patients participating in the trial.

Data for individual participants will be included if they are currently registered with CPRD general practices

## **Participant type(s)**

Patient

## **Age group**

Other

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

No other exclusion criteria

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

30/09/2017

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

King's College London

London

United Kingdom

SE1 3QD

## **Sponsor information**

**Organisation**

National Institute for Health Research (UK)

**Sponsor details**

Evaluation, Trials and Studies Coordinating Centre

University of Southampton

Alpha House, Enterprise Road

Southampton

United Kingdom

SO16 7NS

**Sponsor type**

Government

**Website**

<http://www.nets.nihr.ac.uk/programmes/hta>

**ROR**

<https://ror.org/0187kwz08>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme (Ref: 13/88/10)

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

31/12/2019

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	04/08/2016		Yes	No
<a href="#">Results article</a>	results	01/03/2019		Yes	No

