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A practice level intervention to reduce antibiotic prescribing for self-limiting infections in primary care

Submission date
25/09/2015

Recruitment status
No longer recruiting

Registration date
30/09/2015

Overall study status
Completed

Last Edited
17/08/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background
Since the discovery of the antibiotic penicillin, people have been prescribed a whole host of antibiotics treat whole host of infections. Different strains of bacteria change (mutate) over time, which can lead to strains which are resistant to antibiotics emerging. Strains of bacteria that are resistant to antibiotics have an advantage over those which are susceptible, and so these strains rapidly multiply. It is thought that the overuse of antibiotics in the past played a key role with the emergence of antibiotic resistant strains. In recent years, health organisations across the world, including the NHS in the UK, have been trying to reduce the amounts of antibiotics prescribed, especially for minor illnesses. It is thought that if antibiotics are only prescribed for serious complaints, then bacteria will have a lower chance of developing resistance as they are not exposed to antibiotics as much. The aim of this study is to try to reduce the amount of serious infections that are resistant to antibiotics by using promotional material in GP surgeries.

Who can participate?
General practitioner (GP) surgeries across England that do not take most bookings online and not already doing something similar to what is being tested in the study.

What does the study involve?
The first intervention (or test) is to add a message to the answer phone message which is usually played when patients phone up to make an appointment to see a doctor or nurse. The message tells patients that the doctors are committed to appropriate antibiotic prescribing and suggest that for colds and flu patients should first seek advice at their local pharmacy. The second intervention involves asking GPs to commit to appropriate antibiotic prescribing and make this commitment public by displaying a poster with their name and photo saying so. GP practices are randomly allocated to one of 4 groups. For those in group 1, the answer phone message is played. GP practices in group 2 display the posters. GP practices in group 3 play the answer phone message and display the poster. GP practices in group 4 carry on as normal (control group).

What are the possible benefits and risks of participating?
The benefits for the GP practices participating are likely to be reduced demand for appointments and for antibiotics and support to refuse antibiotics where they think it's not appropriate to prescribe them. Patients will need to wait an extra 10 seconds before the phone is answered to book an appointment. The answer phone message will not be played outside of opening hours so that access to emergency numbers is not delayed.

Where is the study run from?
The majority of GP practices participating are from Commissioning Support Unit in the North East of England but other area are also taking part such as Bedfordshire, Kernow and Liverpool.

When is study starting and how long is it expected to run for?
February 2015 to March 2016

Who is the main contact?
Anna Sallis

Contact information

Type(s)
Scientific

Contact name
Miss Anna Sallis

Contact details
80 London Road
London
United Kingdom
SE1 6LH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Impact of a mixed patient and GP intervention level intervention on antibiotic prescribing in GP practices in England: A cluster randomised controlled trial

Study objectives

Antibiotic prescribing will be reduced by a call waiting intervention and/or a GP commitment poster compared to usual practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Queen Square Research Ethics Committee, 16/09/2015, ref: 15/LO/1662

Study design
Cluster randomised controlled trial with a factorial design (3 intervention arms and 1 control arm)

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
Antimicrobial resistance

Interventions
Randomisation of GP practices will be stratified by Clinical Commissioning Group (CCG) using an even-split-within-strata method, which ensures numerical balance within each CCG. Regression analysis will be used to check for balance on baseline measures of our outcome measure.

Brief recorded message on the GP surgery answer phone explaining to patients that GPs in this practice are committed to prescribing antibiotics prudently and directing patients to their pharmacy for self-care advice for infections that do not usually require antibiotics. This aims to address patient demand for appointments and ultimately reduce access to antibiotics by facilitating an expectation that inappropriate antibiotics will not be prescribed.

Display a ‘commitment poster’ in GP consulting rooms with a photo of the GP and a signed statement of their commitment to appropriate prescribing of antibiotics. This aims to provide a tool to support GPs, during the consultation, in their decision not prescribe antibiotics where it is not clinically appropriate and also to strengthen the GPs own commitment to appropriate prescribing through this public commitment.

Intervention Type

Behavioural

Primary outcome measure
EPACT data (STARPU adjusted) on filled antibiotic prescriptions per 1000 of the population for a baseline period of 3 months and the 4 month intervention period, and for the same intervention period the previous year.

Secondary outcome measures
Percentage of all filled antibiotic prescriptions that are for broad-spectrum antibiotics.

Measured at baseline for a period of 3 months and the 4 month intervention period and for the same intervention period the previous year.

Overall study start date
02/02/2015

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. All or the vast majority of GPs, practice nurses and non-medical prescribers are willing to take part in the study which may involve emailing a photograph and electronic signature
2. Can display the personalised posters in the GP consulting rooms
3. Can implement or amend an existing automated call-waiting message to record and play the AMR message (ideally first or last) and leave in place for the duration of the study

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
175

Total final enrolment
196

Key exclusion criteria
1. Walk-in centres
2. More than 20% of our appointments bookings are made online
3. Those which already display AMR GP commitment posters or play AMR call waiting messages (other AMR related activity and posters are fine, including antibiotic guardian posters)

Date of first enrolment

01/10/2015

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North & East London Commissioning Support Unit
75 Worship Street
London
United Kingdom
TS17 6BL

Study participating centre
NHS Kernow
Sedgemoor Centre
Priory Road
Saint Austell
United Kingdom
PL25 5AS

Study participating centre
Bedfordshire Clinical Commisioning Group
Capability House
Bedford
United Kingdom
MK45 4HR

Sponsor information

Organisation
Public Health England

Sponsor details

80 London Road
London
United Kingdom
SE1 6LH

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Public Health England

Alternative Name(s)
PHE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Study summaries sent to all participating practices
2. Conference presentations
3. Academic publication

Intention to publish date
31/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/08/2020	17/08/2020	Yes	No
HRA research summary			28/06/2023	No	No