The effect of audit & feedback on prescribing behaviour and engagement with data on OpenPrescribing.net - a randomised controlled trial

Submission date	Recruitment status	Prospectively registered	
Registration date	Overall study status	Protocol Statistical analysis plan	
09/05/2018	Completed	[X] Results	
Last Edited 31/03/2021	Condition category Infections and Infestations	Individual participant data	

Plain English summary of protocol

Background and study aims

Prescribing medications in primary care involves keeping in line with a large number of guidelines. However, decisions are often made locally and can be slow to respond to changes in evidence. OpenPrescribing.net, an openly accessible service which transforms the monthly national prescribing datasets into meaningful charts on key measures of prescribing safety, efficacy and cost-effectiveness, demonstrates the huge variation across (and within) practices and their parent organisations (CCGs). Although CCGs have medicines optimisation teams to facilitate and promote best practice in prescribing of antibiotics is one critical public health issue which varies across the country. This study targets general practices in England who are performing in the worst 20% for prescribing broad-spectrum antibiotics, which have very limited indications in primary care but increase the risk of antimicrobial resistance. The aim of this study is to find out whether giving them feedback on their current prescribing performance has an impact on information-seeking and prescribing behaviour.

Who can participate?

GP practices in England (and any staff involved in prescribing therein) ranking in the worst 20% for prescribing broad-spectrum antibiotics

What does the study involve?

Participating GP practices are randomly allocated to the intervention group or the control group. Those in the control group receive no communication. Those in the intervention group are randomly allocated to receive one of two different styles of intervention (variant A or variant B). Intervention variant A is a series of three different interventions: (1) antibiotic feedback, designed to provide enough information to allow prescribers to assess and change their antibiotic prescribing behaviour without needing to access the website; (2) antibiotic feedback "reminder", plus provision of link to evidence showing how feedback has been effective at changing antibiotic prescribing behaviour; (3) more information about the other

data available at OpenPrescribing.net, potential cost savings highlighted, an example of another measure on which they rank poorly amongst other practices, and inviting recipients to access the site to monitor their prescribing data. Practices in intervention group B receive three interventions which are all similar, highlighting their performance on antibiotics, but also inviting them to use the OpenPrescribing site to monitor their data. The trialists send these interventions approximately monthly for three months and measure their impact on prescribing behaviour over a six-month period. They also measure engagement of recipients with their prescribing data after each intervention: via direct interaction with links provided in the interventions, and via overall usage of the OpenPrescribing.net site related to each practice.

What are the possible benefits and risks of participating?

Benefits include increased awareness of their prescribing behaviour in comparison to national trends and of price variations of drugs they prescribe; increased awareness of national guidelines on prescribed medications; and empowerment to improve the safety, efficacy and cost-effectiveness of their prescribing choices. Risks include the time burden on busy GPs. Participants can choose whether or not to engage with the intervention at all and if so, how much time they wish to spend on it. They are also given the option to opt out of further communications. No individuals will be identifiable and they can opt-out freely. Engagement rates are an important outcome for the study and contacting practices for consent would bias this. In addition, it is not necessary to obtain consent from practices to use practice-level prescribing data because it is already publicly available and licensed for this purpose. No identifiable personal information will be collected directly from the practices beyond that which is already in the public domain. Any feedback that is received will be anonymised so it will not be possible to identify which individual at a GP practice provided it. The prescribers involved in the trial will remain responsible for the safe and appropriate care of their patients using their professional judgement. The intervention will only reiterate existing national guidelines, and not advise changing the care of any specific patients. No additional risk of harm is anticipated in relation to the trial.

Where is the study run from? University of Oxford (UK)

When is the study starting and how long is it expected to run for? March 2015 to May 2019

Who is funding the study? The Health Foundation (UK)

Who is the main contact? Dr Ben Goldacre

Contact information

Type(s) Scientific

Contact name Dr Ben Goldacre

Contact details

Nuffield Department of Primary Care Radcliffe Observatory Quarter Woodstock Road Oxford United Kingdom OX2 6GG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers OPAF1

Study information

Scientific Title

The effect of audit & feedback on prescribing behaviour and engagement with data on OpenPrescribing.net - a randomised controlled trial

Study objectives

The null hypothesis is that feedback on current prescribing performance has no impact on information-seeking or prescribing behaviour.

Ethics approval required Old ethics approval format

Ethics approval(s)

 Medical Sciences Interdisciplinary Research Ethics Committee (IDREC), 09/02/2018, ref: R55595/RE001
UK Health Research Authority (HRA), 20/03/2018, ref: 231358

Study design

Cluster-randomised controlled parallel-group trial

Primary study design

Interventional

Secondary study design Cluster randomised trial

Cluster randomised trial

Study setting(s) GP practice

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Infectious disease

Interventions

Participants will be allocated to intervention or control group in a 1:1 ratio, block-randomised by CCG. Those in the intervention group will be allocated to receive one of two different styles of intervention, block-randomised by CCG. Practices will receive three communications at regular intervals. The trialists are seeking to investigate superiority of any intervention over control, and to explore the relative impact of two different interventions.

The 'intervention' will be the delivery of tailored written feedback to each practice, which details their recent performance on the selected measure in a graphical form and invites recipients to access the other services available at OpenPrescribing.net via a unique link for their practice.

Participants will be randomly allocated to receive no communication, variant A, or variant B: A. Behaviour-change optimised series of three different interventions: (1) antibiotic feedback, designed to provide enough information to allow prescribers to assess and change their antibiotic prescribing behaviour without needing to access the website; (2) antibiotic feedback "reminder", plus provision of link to evidence showing how feedback has been effective at changing antibiotic prescribing behaviour; (3) more information about the other data available at OpenPrescribing.net, potential cost savings highlighted, an example of another measure on which they rank poorly amongst other practices, and inviting recipients to access the site to monitor their prescribing data.

B. All-In-One: practices in this group will instead receive three interventions which are all similar, highlighting their performance on antibiotics, but also inviting them to use the OpenPrescribing site to monitor their data.

The trialists will send these interventions approximately monthly for three months and will measure the impact on prescribing behaviour over a six-month period. They will also measure engagement of recipients with their prescribing data after each intervention: via direct interaction with links provided in the interventions, and via overall usage of the OpenPrescribing. net site related to each practice.

Intervention Type

Other

Primary outcome measure

1. ENGAGEMENT: Difference in the proportion of practices having their dashboard viewed during the 15 week intervention period, between intervention and control groups. Measured using data obtained from Google Analytics and other tracking systems for emails and questionnaire responses. Baseline period: 15 weeks prior to first intervention; follow-up period: 5 weeks following each wave, including day of sending (total 15 weeks).

2. PRESCRIBING: Difference in the proportion of antibiotics prescribed which were broadspectrum, during the follow-up period, between intervention and control groups. Measured using publicly available prescribing data published by NHS Digital. Baseline period: latest available six months of data at start of study; follow-up period: corresponding six month period, one year on from baseline period.

Secondary outcome measures

1. ENGAGEMENT, measured using data obtained from Google Analytics and other tracking systems for emails and questionnaire responses. Baseline period: 15 weeks prior to first intervention; follow-up period: 5 weeks following each wave, including day of sending (total 15 weeks)

1.1. Difference in the proportion of practices having their dashboard viewed during the 15 week intervention period, and in the proportion of broad-spectrum antibiotics prescribed, between groups A and B

1.2. Difference in the mean dashboard views per practice during the 15 week intervention period, for intervention versus control groups, and for group A versus B

1.3. Number of practices accessing at least one link provided in the intervention, as a proportion of all practices contacted, for group A versus B

1.4. Number of links accessed at least once as a proportion of all links delivered by each method of contact (email, fax, letter)

1.5. Proportion of emails opened overall; and total number of links accessed from emails as a proportion of those opened, during the follow-up period, for intervention A versus B

1.6. Exploratory descriptive analysis of browsing sessions arising from each link accessed: number of browsing sessions, number of different IP addresses, and number of pages viewed per session (to explore sharing of links among professionals)

2. PRESCRIBING, measured using publicly available prescribing data published by NHS Digital. Baseline period: latest available six months of data at start of study; follow-up period: corresponding six month period, one year on from baseline period

2.1. From the primary outcome measure the overall effect of the intervention will be estimated on the number of broad-spectrum antibiotics prescribed during the follow-up period. This will be calculated as the total difference between the observed number of broad-spectrum antibiotics per practice and the expected number had they been in the control group, using the regression model

2.2. To assess wider impact on prescribing behaviours, the difference in other national antibiotic prescribing measures (below) will also be calculated during the follow-up period, between intervention and control groups. These will be analysed using multivariable linear regression as per the primary outcome, except where otherwise stated:

2.2.1. Rate of total antibiotic prescribing per adjusted population unit, Antibiotic STAR-PU (Specific Therapeutic group Age-sex Related Prescribing Unit). As this is a rate a poisson regression model will be used for analysis

2.2.2. Mean number of daily doses per prescription for uncomplicated urinary tract infections (UTIs), measured as the mean number of average daily quantities (ADQs) per item, of trimethoprim 200mg tablets, nitrofurantoin 50mg tablets/capsules, nitrofurantoin 100mg M/R capsules and pivmecillinam 200mg tablets

2.2.3. Mean number of trimethoprim items prescribed as a percentage of all nitrofurantoin and trimethoprim items, per practice

Each of the primary and secondary outcomes will also be compared between intervention groups A and B

Overall study start date

01/03/2015

Completion date

08/05/2019

Eligibility

Key inclusion criteria

GP practices in England (and any staff involved in prescribing therein) ranking in the worst 20% for prescribing broad-spectrum antibiotics

Participant type(s)

Health professional

Age group Adult

.....

Sex Both

Target number of participants 1,400

Total final enrolment

1401

Key exclusion criteria

Practices must meet the following criteria:

- 1. Standard GP practices (Setting type 4) in England
- 2. At least one method of contact (postal address, fax number and/or email address)
- 3. Active status
- 4. Opened at least 6 months before start of trial
- 5. >= 500 registered patients
- 6. >= 1000 total items prescribed per month
- 7. >= 60 total antibiotic items prescribed in 6 months
- 8. Individual practices and whole CCGs not involved in preliminary testing

Date of first enrolment

08/05/2018

Date of final enrolment

08/05/2018

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Oxford Observatory Quarter Woodstock Road Oxford United Kingdom OX2 6GG

Sponsor information

Organisation University of Oxford

Sponsor details CTRG, Joint Research Office, Block 60, Churchill Hospital Old Road, Headington Oxford England United Kingdom OX3 7LE

Sponsor type University/education

ROR https://ror.org/052gg0110

Funder(s)

Funder type Charity

Funder Name The Health Foundation

Results and Publications

Publication and dissemination plan

Protocol available at: https://figshare.com/articles /The_Effect_of_Audit_Feedback_on_Prescribing_Behaviour_and_Engagement_with_Data_on_Ope All of the analysis code will also be publicly available. The trialists plan to publish the results in peer-reviewed journals within 12 months of results being available. They will post the results online before 12 months of trial completion if journal publication is not possible within this timeline.

Intention to publish date

08/05/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be shared online openly to all at Figshare following publication of results, if not sooner.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Basic results</u>		07/05/2020	12/05/2020	No	No
<u>Results article</u>		28/07/2021	31/03/2021	Yes	No