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STEP-UP IMPLEMENT PARTICIPANT INFORMATION SHEET (Workshops - Citizens)

1. **Background and aims of the study**

We are inviting members of the public to take part in the STEP-UP IMPLEMENT study that is part of the 'Improving the uptake and Sustainability of Effective interventions to promote Prudent antibiotic Use in Primary care' (STEP-UP) programme (www.expmedndm.ox.ac.uk/stepup/home) led by the NIHR Health Protection Research Units in Healthcare Associated Infections and Antimicrobial Resistance at the University of Oxford and Imperial College London.

Antibiotics are important medicines for treating infections caused by bacteria. However, bacteria can adapt and find ways to survive the effects of an antibiotic (i.e. develop antibiotic resistance) which means the infection may require an alternative antibiotic, may take longer to clear, or in some cases may cause further harm. While some infections may benefit from treatment with immediate antibiotics, many common bacterial infections such as an acute cough, sinusitis, and ear infections, in the community can resolve without antibiotics. As overuse and misuse of antibiotics contribute to the development of antibiotic resistance, it is important that we preserve antibiotics for treating infections only when necessary. There are a number of ways in which health care professionals have tried to reduce overuse and misuse of antibiotics, these are sometimes referred to as antimicrobial stewardship strategies. However, not all such strategies are used routinely or appropriately.

One of the aims of this study is to understand different people's views on patient materials to support general practice staff in using strategies to support appropriate use of antibiotics, in particular the use of delayed (back-up or 'wait and see') prescriptions, diagnostic tests to use in consultations and communication training. Two workshops with members of the public and two separate workshops with health professionals will be used to guide development of, and gain feedback on, materials to support the introduction and use of these strategies in general practice. This participant information sheet describes the workshops with members of the public. The first workshop will involve exploring views of members of the public on the use of delayed prescriptions, CRP tests and experience of GPs' consultation styles. It will also involve viewing and discussing draft versions of patient materials and suggesting ways these can be improved. The second workshop will involve viewing and discussing later, revised versions of the same materials and providing feedback.

2. **Why have you been invited to take part?**

We are inviting members of the public to take part in two workshops. To participate you must be able and willing to take part in both workshops – the first workshop will take place on **27 March 2019** and the second workshop on **18 June 2019** at Imperial College London. You will need to be over 18 years of age and speak fluent English.

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3. **Do you have to take part?**

No. Your participation is entirely voluntary. You can ask questions about the study before deciding whether or not to participate. You may also **withdraw** at any time without providing a reason. Any data collected during the workshops will still be used. This is due to the nature of group discussions in the workshops where it will not be possible to remove a single person's comments.

4. **What will happen in the study?**

If you are happy to take part, please complete the form online [insert weblink to advert] or email aleksandra.borek@phc.ox.ac.uk. You will then be contacted by a researcher to confirm your place on the workshops within 5 working days of the closing date stated on the advert. We would like to include a total of 10-15 members of the public. The researcher will provide you with further details. Each workshop will take approximately 3 hours. Before the start of the workshop, all participants will be asked to sign a consent form to confirm that they fully understand what taking part in the study will involve and that their questions about the research have been answered. We will audio-record the workshops with your permission. If a participant does not consent to being recorded we will not record workshops and instead will make detailed field notes of discussions. At the beginning of the first workshop we will explain more about the study and the strategies that we will discuss – delayed prescriptions, CRP tests and consultation skills. No prior knowledge or preparation is required. In the first workshop we will show draft patient materials to help introduce and use delayed prescriptions, CRP tests and consultation skills in general practice, and will invite your feedback and suggestions on how these can be improved. In the second workshop we will present revised materials and seek your feedback on them. We will provide refreshments in the workshops.

5. **Are there any potential risks in taking part?**

There are no risks in taking part in this study: we will not be discussing sensitive topics, and detail below how your privacy will be maintained.

6. **Are there any benefits in taking part?**

There will be no direct benefit to you from taking part in the workshops. However, taking part may help us understand how general practices can introduce patient-centred strategies to reduce unnecessary antibiotic prescribing, and help GPs and patients to use delayed antibiotic prescriptions appropriately. Your contributions in the workshops may also help us develop and assess materials to support the use of effective but under-used strategies to improve antibiotic use.

7. **Expenses and payments**

We will offer £25 in high-street vouchers as a thank you for your participation in each workshop (£50 in total). These will be handed out at the end of each workshop. We will also reimburse travel expenses up to a total of £30 based on the receipts you provide, so please keep all your travel receipts and tickets.

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8. *What happens to the data provided?*

The **research data** will be stored confidentially on the University of Oxford and Imperial College London premises and university computer networks. The workshops will be audio-recorded and we will take notes during the workshops. Both the audio recordings and the notes will be stored in password protected computer files. The recordings will be sent securely to an independent transcription company who will type up the recording. The company has been assessed and approved for data security by the University of Oxford. Once the recordings have been transcribed, the recordings will be stored securely until the end of the study and then deleted. **The transcript of the audio recording will be de-identified.** To ensure confidentiality any written records or quotes from the recordings will not include any names or other defining details that can identify the participants. **Personal data** will be stored securely in a locked cabinet at the University of Oxford or in password protected files on secure computers and university networks at the University of Oxford and/or Imperial College London. Personal data will include your name, age, gender, marital status, number of children and ethnicity. This data will include participants' completed consent form, basic demographics and contact details. The research team will have access to all research data. The transcription company will only have access to audio recordings of the interviews (but will not know who the participants or the practice were). We will ask all participants for their permission to use direct quotes when presenting the study findings at conferences and in written reports and publications. All quotes will be de-identified, this means that anyone reading the quote will not know who you are. The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. At the end of the study de-identified transcripts will be stored in an online data repository available for future research where required. We will keep identifiable information such as contact details for 6-12 months after the study has finished. All de-identified research data and any research documents with personal information, such as consent forms will be stored for 15 years after the end of the study. Responsible members of the University of Oxford or Imperial College London may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

We will be using information from you in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>. You can find out more about how we use your information by contacting Dr Sarah Tonkin-Crine (sarah.tonkin-crine@phc.ox.ac.uk).

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9. Will the research be published?

The research may be published in peer-reviewed scientific journals and may be presented at scientific conferences but any quotes used will be de-identified.

10. Who is organising and funding this work?

This work is being funded by the Economic and Social Research Council. It is organised by researchers at the University of Oxford.

11. Who has reviewed this study?

This study has received ethical approval from the University of Oxford Central University Research Ethics Committee (R59812/RE001) and HRA approval.

12. Who do I contact if I have a concern about the study or I wish to complain?

If a participant in University-sponsored research is ever considered to have suffered harm through their participation, the University has arrangements in place to provide for compensation. If you have a concern about any aspect of this study, please speak to the Chief Investigator, Dr Sarah Tonkin-Crine (sarah.tonkin-crine@phc.ox.ac.uk) who will do her best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how she intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, email ctrg@admin.ox.ac.uk who will also inform the chair of the Research Ethics Committee at the University of Oxford.

13. Further information and contact details

If you are interested in taking part or have any questions, please contact one of the study researchers, Dr Aleksandra Borek by email, phone or post (contact details are below). We will then contact you to discuss the study. If you would like to receive a copy of the final report at the end of the study please also contact Dr Borek.

Dr Aleksandra Borek

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THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION



Participant Information Sheet (Workshops – Citizens)

Version 1, 28/09/18

Study title: Improving the uptake and Sustainability of Effective interventions to promote Prudent antibiotic Use in Primary care (STEP-UP): Implementation Study (STEP-UP IMPLEMENT).

IRAS Project number: 251103

Ethics Reference number: R59812/RE001

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