

Epidemiology of sexually transmissible enteric infections in men who have sex with men (STEIM): protocol for a longitudinal pilot study in Brighton and Sussex

Holly D Mitchell^{1,2} (holly.mitchell@phe.gov.uk), Caisey V Pulford^{1,2}, Nigel Field³, Kate S Baker^{4,5}, Claire Jenkins^{1,5}, Daniel Richardson^{6,7}, Hannah Charles^{1,2}, Katie Thorley^{1,2}, Xavier Didelot^{5,8}, Katy Sinka^{1,2}, Noel McCarthy^{5,9}, Gwenda Hughes^{2,10}, Hamish Mohammed^{1,2}

1. UK Health Security Agency; 2. NIHR HPRU in Blood Borne and Sexually Transmitted Infections at UCL; 3. UCL; 4. University of Liverpool; 5. NIHR HPRU in Gastrointestinal Infections at the University of Liverpool; 6. University Hospitals Sussex NHS Foundation Trust; 7. Brighton and Sussex Medical School; 8. University of Warwick; 9. Warwick Medical School; 10. London School of Hygiene and Tropical Medicine

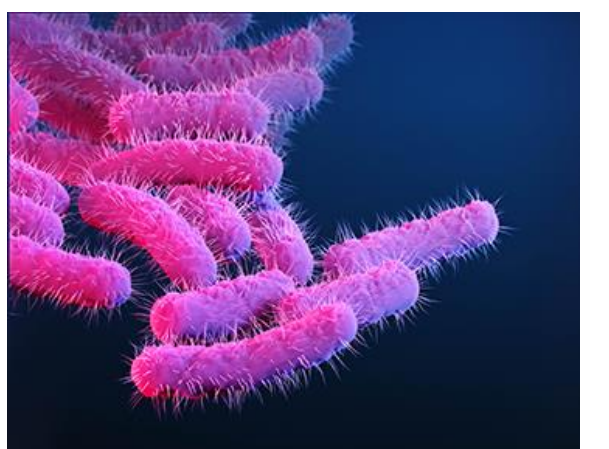


1. BACKGROUND

- Increasing number of enteric pathogen outbreaks reported among men-who-have-sex-with-men (MSM), often associated with high levels of antimicrobial resistance (AMR)
- Evidence suggests that asymptomatic carriage might play an important role in sustaining transmission in specific sexual networks of MSM
- There is a need to better understand the drivers of sustained transmission of, and development of AMR in, enteric infections among MSM to inform the design and delivery of interventions
- Such a study will require the collection of samples and epidemiological data over a period of several months
- Rectal swabs are routinely collected from MSM attending sexual health clinics (SHCs) for routine care and may provide a practical alternative to stool samples

2. PILOT STUDY OBJECTIVES

- To assess the feasibility and acceptability of longitudinal sample and epidemiological data collection among MSM attending NHS SHCs
- To compare rectal swabs with faecal samples for enteric pathogen and AMR detection, and molecular typing
- To provide preliminary data on:
 - Overall prevalence of enteric pathogens
 - Duration of carriage
 - Within-host evolution of pathogens, including AMR



3. STUDY POPULATION

Location and sample size

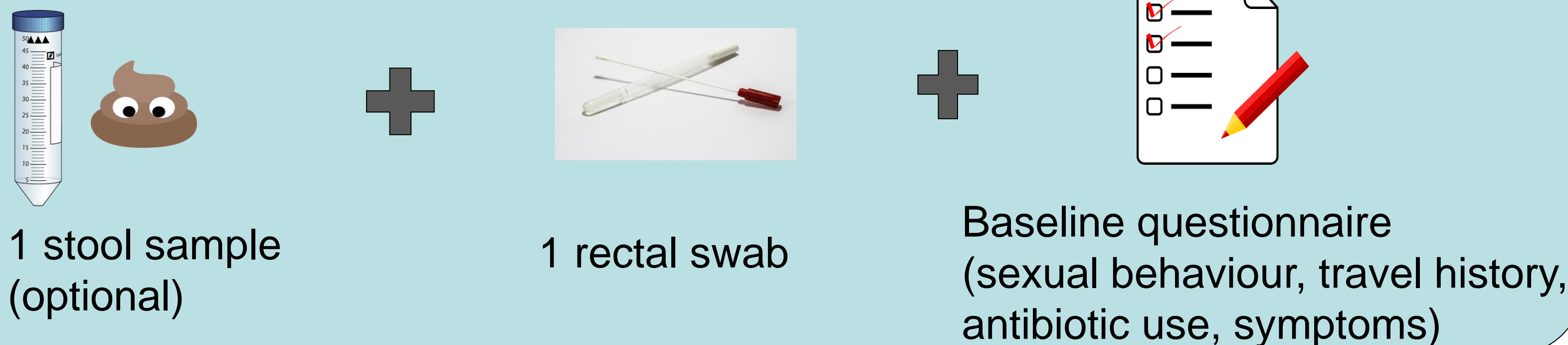
- Individuals attending SHCs in Brighton and Sussex for routine testing and care, regardless of symptoms
- 200 individuals

Eligibility criteria

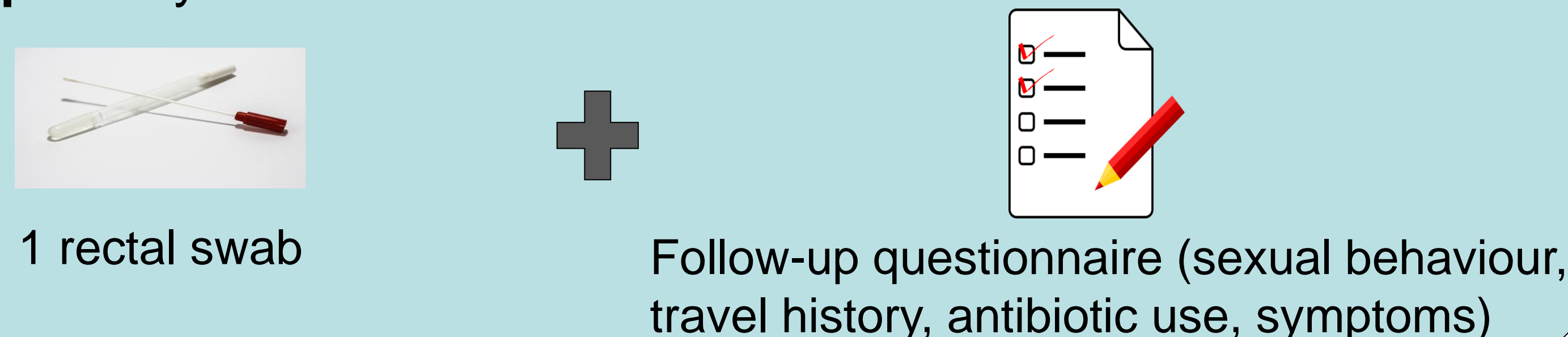
- MSM, including men (cis/transgender), transwomen or gender-diverse people reporting sex with a man (cis/transgender) or non-binary person assigned male at birth
- Report sex with another man in the past 3 months

4. STUDY DESIGN

At enrolment:

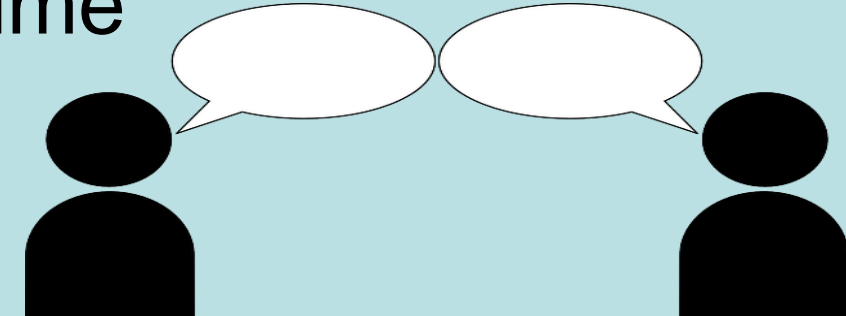


Follow-up: every week for 12 weeks



Qualitative interview (optional)

1:1 interview exploring the barriers and motivators to study participation, and the collection of samples over time



- As part of the Patient and Public Participation and Engagement strategy, cognitive interviews were used to explore general interest and acceptability of the study design and comprehension of participant information; suggestions for improvement were incorporated
- The study has been reviewed and approved by London - South East NHS Research Ethics Committee (21/LO/0891). Recruitment will begin in March 2022.

5. ANALYSES

- Testing and analysis of stool samples and rectal swabs**
 - PCR testing to include *Shigella* spp., *Campylobacter* spp., *Salmonella* spp., *E. coli*, *E. histolytica*, *Giardia lamblia*, hepatitis A virus
 - Culture and whole genome sequencing
 - Metagenomics to compare complete diversity of pathogens and genetic determinants of AMR
- Linkage of test results and questionnaire responses to national STI surveillance data**
 - Information on STI and HIV testing and diagnoses
 - Participants provide consent for data linkage
- Thematic analysis of 1:1 interviews**
 - Identification of emerging themes and exploration of any patterns observed

6. EXPECTED OUTCOMES

- Key analyses will address the following:
 - Willingness to take part in the study and to return samples over a period of several months
 - The characteristics of those who take part in the study compared to those who do not
 - Proportion of participants who agree to the linkage of biological samples and questionnaire responses to STI surveillance data
 - Sensitivity of rectal swabs compared to stool samples to determine whether future studies involving longitudinal sampling can use rectal swabs only
 - Preliminary data on the prevalence of enteric pathogens and duration of carriage, and how these vary according to patient characteristics
 - Genomic comparisons to infer within-host evolutionary dynamics and processes
- The findings will be used to inform the design of a larger study at multiple SHCs involving the repeated collection of biological samples and epidemiological data

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