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Towards understanding COVID-19 prevalence and transmission in prisons

Submission date	Recruitment status	[_] Prospectively registered
26/04/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2021	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
COVID-19 remains a large public health challenge within establishments. Partly, this is due to social distancing and infection control measures being hard to implement in custody. This high prevalence and transmissibility in custody compounds the poor lifestyle and complex medical histories of prisoners. As a result, prisoners have three-fold greater COVID-19 death rates compared to the background population. At present, no single factor has been attributed to the rapid spread of COVID-19 in prisons. One such actor is the B1.1.7 variant which has spread rapidly since isolation in Kent in late 2020. Clinical samples isolated from B1.1.7 infected patients had higher viral loads compared to wildtype. Therefore, patients/prisoners infected with B1.1.7 are more likely to have high viral loads, which may explain higher infectivity and rapidity of spread in custody. Also, prisons pose a risk as amplifiers of infection and have been shown to drive local outbreaks within the wider community. With higher viral loads present in the respiratory (breathing) tract and a lack of data on faecal shedding about SARS-CoV-2, infectivity needs to be revisited in custody. To date, there no strong evidence of infectious /viable virus in environmental samples collected to date. As such, detectable SARS virus within wastewater or faecal samples is unlikely. Therefore, this is a point for enquiry the researchers wish to close down considering establishments rather than an area where there is significant evidence of risk.
Accordingly, this study aims to understand whether wastewater may be infectious (faecal-oral, faecal-respiratory) through testing of wastewater grab samples, faecal stool samples, and within-cell surface samples in close proximity to toilets. Although aerosol transmission of SARS-CoV-2 is presently considered the main route of disease spread, a growing body of evidence suggests that virus transmission can occur by wastewater aerosols formed during the toilet flush, building plumbing systems, wastewater systems and direct contact with faeces.

Who can participate?
Incarcerated individuals who have tested positive for COVID-19 within 14 days

What does the study involve?
Prison cell swabs, wastewater, faeces and nose/throat swab samples are tested for SARS-CoV-2 virus.

What are the possible benefits and risks of participating?
Participants will already have undertaken a nose/throat swab test for SARS-CoV-2. This will be a repeat swab test and collection of faeces. Therefore distress and inconvenience should be minimal. This will not result in a change in lifestyle for the patients. Participants will be advised and supervised during nose/throat sample collection. Participants will be shown how to collect a faecal sample from a sample vessel.

Where is the study run from?
Cranfield University and Her Majesty's Prison and Probation Service (UK)

When is the study starting and how long is it expected to run for?
April 2021 to July 2021

Who is funding the study?
The study is not being funded directly and received in-kind support from Cranfield University and support from HMPPS, Department for Health and Social Care and Public Health England (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Severe acute respiratory syndrome coronavirus 2 infectivity in samples obtained from wastewater, stool, respiratory tract and living quarters within custody

Study objectives
This research aims to:
1. Understand the prospect of wastewater derived (faecal-oral, faecal-respiratory) infections through targeted infectivity testing of wastewater grab samples, faecal stool samples, ventilation systems swabs, toilet surfaces and nasal/throat swab samples. Implications of wastewater and faecal aerosols, which can transmit this virus, and how different transmission routes might increase the risk of exposure to COVID-19 in custody. Although aerosol transmission of SARS-CoV-2 is presently considered the main route of disease spread, a growing body of evidence suggests that the virus transmission can occur by wastewater aerosols formed during toilet flushing, building plumbing systems, wastewater systems and direct contact with faeces
2. Undertake targeted infectivity testing on swab, faeces and wastewater samples obtained within custody.
3. Determine whether the SARS-CoV-2 virus can remain infectious in near source/at source within wastewater samples and on faecal contaminated surfaces and therefore present an infection risk in custody.
4. Evaluate the role of the prison ventilation system in transmitting COVID-19.
5. Explore the feasibility of implementing an enhanced surveillance system based on wastewater /surface infectivity monitoring at the prison level.

The null hypothesis: SARS-CoV-2 is not infectious from wastewater, stools or environmental samples only from throat/nose swab/sputum from infected individuals in custody.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Cranfield University Ethics Committee (Research and Innovation, Building 316 (Conway House) Ground Floor, Cranfield University, Cranfield, Bedfordshire MK43 0AL, UK; +44 (0)1234 75 8029; E: M.Carter@cranfield.ac.uk), ref: to be confirmed

Study design
Observational cross-sectional single-centre study

Primary study design
Observational

Secondary study design

Cross sectional study

Study setting(s)
Other

Study type(s)
Screening

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
COVID-19 (SARS-CoV-2 infection) in prisoners within custody

Interventions
This study will involve 12 weeks sampling and analysis of wastewater across a single closed prison in England. This data will be compared to data obtained from a National Prison monitoring program involving wastewater analysis for SARS-CoV-2 "Piloting wastewater surveillance in closed settings: Understanding infection prevalence in custody". Faeces and nose /throat (N/T) swab samples will be obtained from 10-30 individuals from within prisons who consent to the study. No additional medical treatments shall be provided to individuals as part of this study. The inclusion criteria are that prisoners should have tested positive for SARS-CoV-2 within the last 14 days and consent to their faeces and nose/throat samples being tested.

Composite wastewater samples will be collected Monday-Thursday at the prison site from a single sewage system access point that serves the whole prison using auto sampling technology and transported to labs at Cranfield University (SARS-CoV-2 measured by qPCR for wastewater and stools) and Public Health England (PHE) Porton Down (infectivity testing - all samples).

Methodology for environmental samples and wastewater from prisons:
Near source/toilet surfaces within the cells or rooms of infected individuals will be sampled using sterile flocked swabs (FLOQSwabs®; Copan Diagnostics) wetted with a non-toxic solution (universal transport media (UTM)). Samples will be analysed for SARS-CoV-2 and bacterial faecal contaminants. Surfaces will be wiped clean and sterilized before the study team leaves. There will be no interaction between the study team and the prisoner. Prison cell will be fumigated prior to the prisoner being allowed re-entry to minimise the prospect of re-infection. The study team will wear single-use surgical masks, gown and surgical gloves and will change these between.

Methodology for wastewater:
Acquisition of samples and sampling time needed for representative samples: Following identification of suitable private drains (i.e. collects sewage from prison only, is accessible and has space for the safe installation of an autosampler), composite samples will be collected from each prison four times a week. Samples will be transferred to the laboratory on melting ice, stored at 4°C, and analysed for COVID-19 and a viral tracer within 2 days of collection.

A more detailed protocol for SAR-CoV-2 quantification in wastewater is available upon request.

Only aggregate (prison-level) data to be shared between researchers – anonymized data of testing is already processed by Her Majesty's Prison and Probation Service (HMPPS) and will only be shared under password-protected data conditions including multi-factor authentication.

Methodology for the acquisition of clinical samples (faeces and nasal/throat swabs):
Clinical swab samples will be obtained via a sampling protocol from PHE Porton Down. This protocol is available on request.

Week 1-4: convening meetings with prison authorities, contacting patients about inclusion within the trial. Interviews will be conducted with prisoners to gauge appropriateness for inclusion within the trial. Interviews will be conducted in formal settings by a medical professional. Medical professionals from the clinical care team at HMPPS will be asked to read out clearly and explain each of the questions to the prisons. Prisoners indicate permission by initialling each point on the questionnaire.

Weeks 5-8: first round of samples will be obtained from T/N, environment (cells surfaces), faeces and composite wastewater

Weeks 9-12: the second round of samples will be obtained. Final report prepared for HMPPS public health team. Researcher effects will be minimised through a single interviewer undertaking all the interviews. As no qualitative or quantitative data will be obtained from the prisoner, there is limited scope for researcher bias to occur. Observational data will be incidental in origin, anonymised prior to interpretation of the data. Genomic clustering will be used to ascertain the spread of variants within custody. This will only occur should a sufficient number of infected individuals be identified and consent to the study.

Intervention Type
Other

Primary outcome measure
SARS-CoV-2 infectivity measured using integrated cell culture reverse transcription quantitative polymerase chain reaction (RT-qPCR) in wastewater, faecal stool samples, N/T swabs and environmental swabs. Faecal indicator bacteria will be assessed using the plate count method on the environmental swabs. The viral RNA titre for SARS-CoV-2 will be assessed in all samples using RT-qPCR. This data will be collected for each COVID-19 positive prisoner/prisoner cell twice and at least 15 days apart. The date of the first positive COVID-19 test will also be ascertained to estimate where the individual is in the infection cycle and likely shedding profile.

Secondary outcome measures
HMPPS testing data, specifically symptomatic and asymptomatic testing data from HMPPS for COVID-19, influenza-like illness and acute respiratory infections, and any suitable and available mass testing data (e.g. lateral flow, PCR or L-AMP assay data) from within the prison being investigated in the preceding 90 days and in the 14 days post-assessment of the primary outcome measures

Overall study start date
20/04/2021

Completion date
30/07/2021

Eligibility

Key inclusion criteria
Volunteer person in prison who is recovering from SARS-CoV-2 virus (COVID-19 disease)

Participant type(s)
Other

Age group
Adult

Sex
Male

Target number of participants
10

Key exclusion criteria
1. Pre-existing medical conditions which place an individual in a higher risk category for COVID-19
2. Persons requiring significant medical intervention/hospitalisation

Date of first enrolment
01/05/2021

Date of final enrolment
21/05/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HMP Bristol
19 Cambridge Road
Bishopston
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United Kingdom
BS7 8PS

Sponsor information

Organisation

Her Majesty’s Prison and Probation Service

Sponsor details
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HMPPS Public Health/Scientific Advisor
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Sponsor type
Government

Website
https://www.gov.uk/guidance/healthcare-for-offenders

ROR
https://ror.org/03e5xvd80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
To be confirmed

Intention to publish date
26/04/2022

Individual participant data (IPD) sharing plan
The data will not be made available as is held under a client confidentiality agreement. The data shall be held by Her Majesty’s Prison Service and Cranfield University.

IPD sharing plan summary
Not expected to be made available