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© COVID-19: Detecting Indirect Spread in Facilities for Enhanced Care sTudy (COVID-19: DISinFECT). Investigating environmental epidemiology of SARS-CoV-2 in long term care facilities in England. V4.1.

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ABSTRACT

This study aims to investigate the role of indirect transmission of SARS-CoV-2 in care homes, and the potential for environmental surveillance to inform Infection Prevention and Control (IPC) measures and prevent outbreaks. This will be achieved by:

1. In-depth descriptive epidemiology of SARS-CoV-2 during 2-3 care home outbreaks

On notification of an outbreak, environmental swabs and air samples will be taken in parallel with whole-home testing of staff and residents to describe the distribution of SARS-CoV-2 RNA around the facility.

2. Proof of concept: wastewater monitoring for SARS-CoV-2

Autosamplers will be situated at care home sites experiencing an outbreak. Samples will be analysed retrospectively to assess levels of SARS-CoV-2 in relation to case epidemiology within the home and the wider community.

3. Reactive environmental screening in up to 10 care homes, and review of implications for onward transmission

On notification of a single case of COVID-19 (resident or staff), environmental samples will be taken from high-risk areas within the care home. Proportion of sample sites positive for SARS-CoV-2 RNA will be analysed in the context of IPC measures and infection attack rates at 28 days.

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KEYWORDS

infection control, infectious disease transmission, environmental exposure, fomites, disease outbreaks, long-term care, epidemiologic methods

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SAFETY WARNINGS

Health and safety considerations

A risk assessment has been undertaken for this project. Any equipment taken into homes will be cleaned according to the principles described in the PHE guidance. All staff will follow the guidance for donning/ doffing personal protective equipment and other relevant IPC advice. Clinical waste will be disposed of in the appropriate receptacles on site, and the study team will change clothing on exiting the site.

Safeguarding

The study team will all complete level 2 safeguarding training and have enhanced Disclosure and Barring Service checks prior to entering care home sites.

Study team members must work in pairs, or in the company of a carer when in the presence of a resident.

Any concerns about safety or wellbeing raised during the course of data collection should be escalated as follows:

- Notify the care home manager and Health Protection Team of concerns and state that they will be reported to PHE safeguarding team
- Log a safeguarding incident on PHE Trackwise
- If someone's safety is at risk, the Multi-agency Safeguarding Hub (MASH) should be informed

If there is risk of immediate harm, the study lead should act as appropriate to raise the alarm. If in any doubt about the course of action, speak to the PHE safeguarding lead.

BEFORE STARTING

Ethical considerations and information governance

This investigation is being carried out as part of the Public Health England (PHE) response to the national COVID-19 outbreak and addresses a need for microbiological evidence to be used in combination with descriptive epidemiology to inform local and national outbreak control measures in elderly care settings.

The analysis of patient cases is based on routinely collected data, to be supplemented with case and home data obtained in this study. This study will not affect patient care; and will fully align with all existing national guidance. Data collection will be covered under the statutory permissions for data sharing during outbreak investigations and under Section 251 of the NHS Act.

All data will be stored and managed in accordance with PHE information governance policies and procedures for a period of up to 5 years, dependant on the data type.



1 Glossary

COVID-19 - Coronavirus Disease 2019

COG-UK - COVID-19 Genomics UK consortium

CPHI - Consultant in Public Health Infection

IPC - Infection Prevention & Control

FS - Field (Epidemiology) Service

MERS-CoV - Middle East Respiratory Syndrome Coronavirus

NBT - North Bristol NHS Foundation Trust

NHS - National Health Service

N-WESP - National Wastewater Epidemiology Surveillance Programme

PCR - Polymerase Chain Reaction

PHE - Public Health England

PPE - Personal Protective Equipment

RNA - Ribonucleic Acid

SARS-CoV-2 - Severe Acute Respiratory Syndrome Coronavirus 2

WHO - World Health Organization

9 Background

SARS-CoV-2, the aetiological viral agent of COVID-19 is the third highly pathogenic human coronavirus to have emerged in the last two decades. The COVID-19 pandemic is a global health emergency; as of 23^{rd} September 2020 there were 403,551 confirmed COVID-19 cases reported in the UK and 41,862 deaths within 28 days of a positive test. ¹ Care home residents have been particularly affected: over 8,000 COVID-19 deaths occurred in this population over the first 3 months of the UK outbreak (source: Office for National Statistics). Care homes are ideal settings for the proliferation of infectious organisms due to communal living and shared facilities; a population with underlying health conditions; issues such as faecal incontinence and disinhibited behaviours and frequent movement between health and care institutions. ² These are priority settings for improving understanding of and implementation of public health control measures to reduce the spread of COVID-19. ³

The transmission route for SARS-CoV-2 is likely to be via respiratory droplets with direct person-to-person spread. Contact transmission from contaminated dry surfaces has also been assumed to promote onward spread via contamination of an individual's hands with self-inoculation of mucous membranes (nose, eyes or mouth) or via the hands of staff providing personal care and viral RNA has been detected on surfaces in clinical settings, as well as personal items, communal touch sites and multi-use monitoring equipment (personal communication, Porton Down). ^{2,4,5} There is however little evidence to explain whether environmental contamination contributes to the spread of the infection in these settings. No studies have looked at viral deposition of SARS-CoV-2 in care homes in the context of associated risk factors for acquiring the infection (for residents and staff), infection rates and uptake of recommended interventions to reduce the spread of the virus.

Early detection of outbreaks is essential to protect the health of care home residents. Environmental sampling, including wastewater and air ventilation units could be a simple means of detecting SARS-CoV-2 before it causes widespread infection, but the utility of this approach in care homes has not yet been investigated.

There is a need to investigate the environmental epidemiology of SARS-CoV-2 in care homes to inform public health measures and reduce the impact of the virus on residents and staff.

3 Aim, objectives, approach

This study aims to investigate the role of indirect transmission of SARS-CoV-2 in care homes and evaluate the potential for environmental surveillance to inform Infection Prevention and Control (IPC) measures and prevent outbreaks.

The objectives are to:

- 1. Characterise the spread of SARS-CoV-2 within care homes, both between people and in the environment
- 2. Identify environmental reservoirs of the virus within care home settings, and potential means of indirect transmission
- 3. Assess the potential for environmental surveillance using wastewater and/ or surface swabbing in care homes

This will be achieved in three parts:

Part 1: In-depth descriptive epidemiology of SARS-CoV-2 during 2-3 care home outbreaks

On notification of an outbreak, environmental swabs and air samples will be taken in parallel with whole-home testing of staff and residents. Samples will be taken from resident index case(s) bedroom(s), from communal areas and from staff-only areas within the facility. We will request saliva and stool samples from index case(s) as well as fingertip swabs. PCR and Whole Genome Sequencing (WGS) results will be analysed in the context of epidemiological information about the care home and its population.

Part 2: Proof of concept: wastewater monitoring for SARS-CoV-2

Autosamplers will be situated at care home sites involved in step 1, and protocols developed to enable weekly composite sampling up to 16 weeks following outbreak notification. Samples will be retrospectively analysed in relation to infection rates within the home and the wider community.

Part 3: Reactive environmental screening in up to 10 care homes, and review of implications for onward transmission On notification of a single case of COVID-19 (resident or staff), environmental samples will be taken from high-risk areas within the care home to assess the degree of contamination with SARS-CoV-2, likelihood of aerosolisation, and effectiveness of IPC measures. We will review the attack rate 28 days following notification.

Methods

4 Setting

The study will take place in the South West of England for logistical reasons including proximity to PHE Porton Down aerobiology team and Bristol Public Health laboratory.

The term care home refers to a place where personal care and accommodation are provided together under regulation by the Care Quality Commission (CQC). This includes residential and nursing homes, and respite care for people of all ages.

The focus is on a limited number of sites and protocols will align with current guidance on COVID-19 testing and outbreak management, to ensure that participating care homes retain access to public health support and to avoid unnecessary workload for frontline staff.

5 Timeline

The study will take place over 8 months, from mid-January until mid-September 2021.

6 Study participants

The study population is all staff and residents living in a long-term care facility during the study period.

Case definition

Possible case: individual with symptoms consistent with COVID-19 infection, in the absence of laboratory confirmation.

Confirmed case: individual with a positive test for SARS-CoV-2 (point-of-care or PCR test).

7 Recruitment

Care homes across the South West of England will be informed about the study through a regular webinar established by the regional Health Protection Team (HPT), and/ or liaison with local health and social care partnerships. Managers will be provided with literature about the study and on notification of a signal or outbreak asked to consent to enhanced investigation/ environmental sampling as described below.

2 Consent

Consent will first be obtained from the manager to conduct telephone interviews, collect information from care home

records, sample the care home environment and approach residents and staff for involvement. Information leaflets will then be distributed to staff and residents, via the care home manager and prior to a visit from the study team to collect environmental samples and information about the care home and its residents. At the first visit, index cases (maximum 3) will be approached for consent to collect stool/ saliva/ fingertip samples, and to sample their rooms.

Staff will receive invitations to accompany the information leaflet, stating that they will receive an electronic questionnaire via email. Care home managers will be asked to distribute these on behalf of the study team, no less than 7 days after sending out information leaflets. The questionnaire will be preceded by a statement to indicate understanding and consent to take part in the study.

Activity	Consent from	Documentation
Environmental sampling: communal and staff-only areas	Care home manager	Written consent form
Interview with manager/ deputy		
Data collection: care home records		
Invite staff/ residents to participate		
Sampling saliva/ stool/ fingertips	Resident index case, or study lead	Written consent form, or documented discussion with consultee
Environmental sampling: resident room*	after discussion with consultee	
Electronic questionnaire	Staff	Electronic statement of consent prior to entering questionnaire

^{*}Legally, the care home provider can permit access to the premises, however the Health and Social Care Act states that the provider must protect residents' rights to privacy and choice.⁷

Table 1 - summary of activities requiring consent

8.1 Adults who lack capacity

When taking consent from the care home manager the study lead will ask whether there is evidence that any of the index cases lack capacity to consent to sampling. In this case, the study lead will ask the manager to contact a designated consultee and ask permission for the study team to call them to discuss whether the sampling is in their loved one's best interests.

9 Sampling Strategy

9.1 Care home outbreaks

We will investigate up to 3 care home outbreaks. If a care home reports two or more cases of COVID-19 among staff or residents, PHE guidelines for outbreak control dictate comprehensive testing of all residents and staff at the point of notification, and again around a week later using nose/ throat swabs. In addition, stool and saliva will be collected from up to 3 resident index cases. The study team will also sample the environment, and fingertips of index cases: once directly after notification and again around a week later, to correspond with whole- home testing. Sampling will follow a 'stone in the pond' approach: focussing on common-touch items at increasing distances from an infected individual. This is illustrated in **figure 1** and described in detail in the section below on environmental sampling.

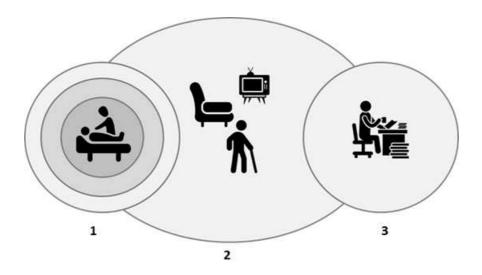


Figure 1 Sampling strategy for care home outbreaks, illustrating the three main zones of investigation, in order of proximity to the index case: 1. the resident's room (3 zones), 2. communal areas and 3. staff-only areas. Images from thenounproject.com

9.2 Wastewater surveillance

On investigation of outbreaks, we will install autosamplers to take composite samples of effluent on a weekly cycle, for up to 16 weeks. These samples will be couriered to National Wastewater Epidemiology Surveillance Programme (N-WESP) laboratories and frozen for retrospective analysis along with clinical and epidemiological metadata.

9.3 Reactive environmental screening

If a care home reports a solitary case of COVID-19 in either a staff member or resident, then environmental sampling will take place as above, and whole-home testing will be arranged at the discretion of the manager via Pillar 2 testing streams.

Up to 10 care home case notifications will be investigated in this way.

Results of environmental sampling will be fed back to the Health Protection Team and care home managers to directly inform IPC measures.

1() Clinical sampling and processing

Nose/ throat swabs will be taken by care home staff or by self-sampling in line with standard procedures for whole-home testing and transported by courier to Pillar 1 or Pillar 2 laboratories. Staff will be provided with instructions for obtaining saliva and stool from index cases: these will be collected as soon as possible following notification of the outbreak, and again between 4 and 7 days later. Stool/ saliva samples will be packed according the UN3373 guidelines and transported by courier to Severn Pathology laboratories.

Nose/ throat samples submitted to Pillar 2 laboratories will be eligible for whole genome sequencing (WGS) through the national COVID-19 Genomics Consortium (COG-UK).

11 Environmental sampling and processing

Environmental samples will be collected by groups of 2 or 3 individuals from a team comprising a Consultant in Public Health Infection (CPHI), Field Service (FS) consultant, and PHE aerobiology unit scientists. We will explore the possibility of care home staff submitting environmental swabs to preclude the need for visits from the study team.

A team at PHE Porton Down is investigating environmental contamination and aerosol generations in hospital settings where COVID-19 patients are located. The same methods and those proposed by WHO for MERS-CoV will be applied to the context of community-based sampling for care home residents.

Initially, air samples will be collected using a Coriolis sampler for a 10-minute period within 1 metre of the resident. This

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may be replaced, for example with a Biospot sampler or other equivalent samplers as they become available. Room temperature, carbon dioxide and humidity levels will be measured over the sampling period using two palm-size monitors.

Wetted swabs will be used to measure surface contamination on hard surfaces at touch sites in the room at 1 metre, 2 metre and > 2 metre distance from the resident, from communal spaces such as reception (visitor sign-in book/ technology) and lounge areas, and from staff only areas (see **figure 1**). Swabs will also be taken from the fingertips of cases, where permitted. Where possible, air ventilation units will also be swabbed. Swabs will be placed in Universal or viral transport medium. Soft furnishes will be sampled using Eurofin sampling devices.

Details about room layout and ventilation will be recorded. Information about cleaning procedures will be collected, however sampling will not disrupt cleaning routines within the care home.

Sample analysis will be performed in Porton Down, using RT-PCR assay. Any positive samples with Ct value < 30 will be retained for viral isolation to demonstrate viability of sampled virus.

Nucleic acid will be retained for up to 100 samples and sent for whole genome sequencing (WGS) to assess relatedness to clinical samples.

A summary workflow is shown in figure 2.

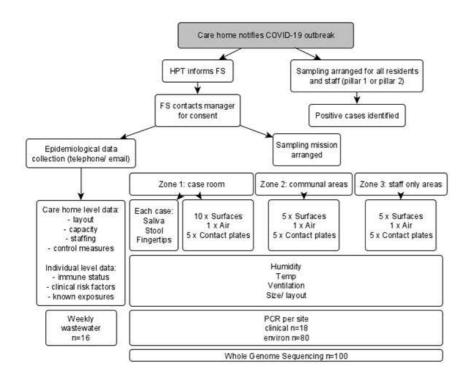


Figure 2 Summary workflow for outbreak investigation

12 Data collection

Laboratory results from both Pillar 1 and Pillar 2 testing streams will be accessed through the Second Generation Surveillance System (SGSS) managed by PHE.

PHE Severn Pathology will liaise with FS to retrieve Whole Genome Sequencing data from CLIMB, a data warehouse used by the COVID-19 Genomics UK (COG-UK) consortium.

Information relating to care homes will be derived from the CQC website, and interviews of up to 30 minutes with care home managers. Interviews will not be recorded, and responses will be captured in Excel logs (see appendix) Information about clinical and epidemiological risk factors for resident infection will be obtained from residential care records whilst on sampling missions.

Information about staff risk factors will be captured in an electronic SelectSurvey questionnaire: care home managers will distribute the link to the questionnaire using a template email provided by the study team. Responses will be downloaded as csv files.

13 Data management

Data management will be undertaken by FS PHE in collaboration with North Bristol Trust (NBT). Data will be collated into the following:

- 1. Care home level data
- 2. Room level data
- 3. Resident level data
- 4. RT PCR results
- 5. Whole genome sequencing and bioinformatic analysis
- 6. Wastewater surveillance results

All data will be held securely on NHS or PHE servers and will be handled and stored in compliance with the Data Protection Act (2018) and guidelines established by the local Caldicott guardian.

During sampling missions, data will either be saved directly on to a PHE secure server or shared with FS from nhs.net email to nhs.net email, or using encryption services for security and data protection.

Samples will be anonymised prior to sequencing at external facilities; PHE Severn Pathology will retain details of the sample unique ID to allow linkage of sequencing data with epidemiological and clinical metadata.

Data analysis

14 Analysis will be done by FS, in collaboration with the University of Bristol Health Protection Research Unit (HPRU), North Bristol NHS Trust, PHE Porton Down and COG-UK partners.

14.1 Descriptive analysis of outbreaks

Setting: The care home will be described in terms of building layout, rooms placement, access to shared facilities, and routine operations. Staff rotas will be summarised by the total number of staff, how many perform each role on a daily basis, and what level of resident contact each role involves.

Interventions: We will outline infection prevention and control measures, and any other changes to the care home environment during the study period.

Cases and characteristics: Data analysis will be undertaken by FS PHE.

Among confirmed and probable cases the proportions recovered (symptom-free), critically ill (requiring intensive care) and died will be described by sex, age group, ethnicity. Any deaths will be presented in the context of comorbidities. and transmission events.

The onset of new cases over the 2 week period will be presented in an epi-curve. Data relating to viral shedding and environmental contamination will be used to construct a temporal-spatial map of the outbreak

Viral distribution: We will describe the distribution of viral RNA about the care home, in the following spatial categories:

- 1. Living quarters of confirmed case(s) of COVID-19
- a) Within 1 metre
- b) At 2 metres and
- c) > 2 metres away from the usual resting place of the individual
- 2. Communal areas within the care home
- 3. Staff only areas within the care home

Viable virus: We will report which samples contain viable virus in the context of proximity to symptomatic and asymptomatic individuals and according to the spatial categories above.

Genomics: Bioinformatic analysis will be conducted for nucleic acid sequences recovered from the

 resident and environment to determine genetic relatedness for nucleic acid recovered and these sequences will be compared outbreak strains with viral sequence data obtained from cases in the locality and wider community.

14.2 Wastewater surveillance

Wastewater surveillance protocols will be drawn up in collaboration with the National Wastewater Epidemiology Surveillance Programme (N-WESP). Samples will be selectively analysed to assess whether trends in SARS-CoV-2 signals reflect trends in the number of clinically diagnosed infections in the care home and surrounding community.

14.3 Environmental epidemiology

We will collate results from environmental screens and look for patterns to a) identify highly contaminated areas/ objects, and b) develop hypotheses about environmental contamination as a predictor of transmission within the care home setting.

15 Outputs

At 3 months, sampling protocols will be established for the surveillance of wastewater on care home sites. To our knowledge, these do not yet exist and should therefore be of use in other areas wishing to pilot wastewater surveillance for respiratory pathogens in long term care facilities.

At 6 months, a report on the epidemiology of SARS-CoV-2 in care home outbreaks will describe the distribution of the virus on surfaces and in air, and identify targets for enhanced IPC measures. It will also assess whether there is evidence of indirect spread of the virus (by means other than close contact), which will inform transmission dynamics models and guidelines for the prevention of outbreaks in care homes.

At 12 months, we will have completed analysis of environmental data to paint a picture of the environmental epidemiology of SARS-CoV-2 in care home settings. Specifically, we will assess the extent of surface contamination and aerosol when the virus first enters the setting in relation to subsequent transmission events. This will reinforce hypotheses about the role of indirect spread in outbreaks of COVID-19 to inform models and guidelines for the prevention of outbreaks. Signals from wastewater surveillance will be presented in the context of background rates of infection and clinical notifications from the care home, to assess how well wastewater reflects risk of outbreak in the care home. This will indicate whether there is value in piloting wastewater surveillance for early warning of outbreaks in care homes.

Throughout the study, our findings will be relayed back to Health Protection Teams and care homes to support public health action and reduce the risk of transmission. We will seek input from service providers and clients to improve the way we collect information and feed back results for surveillance of respiratory illnesses and outbreak investigations

16 Bias and limitations

Findings from this analysis may not be generalisable to other care homes, and we acknowledge differences between care of the elderly homes and other long term care facilities, which tend to have residents with different underling medical and mental health needs. In spite of these differences we feel the study should generate insights and recommendations applicable to other settings.

All assays will generate false positive and negative results. The SARS-CoV-2 PCR is not designed as a screening test and therefore negative results will need to be viewed in this context, as a new test historical performance data are not available and therefore the sensitivity and specificity of these assays are not fully understood. Self-sampling swab collection may be sub optimal for some individuals, dependant on their technique.

Environmental sampling does only provide a snapshot in time and place. Repetitive sampling will help provide additional info regarding presence (and perhaps persistence) in the environment.

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Appendix

18 Data items to be collected

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Category	Variable
LTCF setting	 Type of LTCF i.e. residential, nursing care, EMI (dementia), rehabilitation, psychiatric, learning disability.
	Provider – council, private, name of provider
	Number of beds
	Number of residents
	 Number of empty beds (to be calculated, can use Capacity Tracker)
	Number of single/ shared rooms
	Number of ensuite rooms
	 Care home population by age and sex (number male residents and
	age of admission e.g. over 55 only)
	Use of agency staff
	 Number of staff per shift (day /night)
	 Patient: staff ratio (to be calculated)
	 Staff working pattern e.g. throughout the home, specific floor only.
LTCF layout	Purpose built or conversion
	 Number of buildings/wings/units
	Number of floors
	Number of rooms on each floor
	Number of lounges
	Other shared facilities
Case	How was outbreak identified
information	 Is outbreak restricted to a particular floor/building?
	Number of confirmed cases
	Number of suspected cases
	Number of hospitalised cases
Case	Number of deaths Onset date
	Symptoms
information	Symptoms Confirmed/suspected
for	Type of care required e.g. personal care, nursing, bedbound, dementia
	Room location and room number
symptomatic	Use of communal areas
cases	Contact with staff
	Immunisation status
	Previous infection
Staff	Number of symptomatic staff
information	Dates of onset
mornadon	Symptomatic at work
	Immunisation status
	Previous infection
IPC measures	 Hand hygiene – washing, gloves, alcohol gel
in place	 PPE usage – sessional use or single use?
iii piaco	Visiting restrictions
	 Closed to admissions
	 Social distancing measures
	Isolation
	 Is infected resident wearing a surgical mask?
	Use of communal areas
	Communal activities like bingo, activities.
	Cohorting of symptomatic - location
	Cohorting of symptomatic – staff use
	Sharing of equipment
Classics	Daily surveillance of temperature – residents and staff
Cleaning	Enhanced cleaning Assessment from a protection cleaned lead?
	Are rooms from symptomatic cleaned last? What are distributed as a local feet last and distributed as a local feet last.
V	 What products are used for cleaning and disinfection?