VIVALDI Social Care

Detailed Information for Participants

Overview of the study

Infections like flu, urine infections, diarrhoea and vomiting are really common in older adults in care homes and often cause severe illness requiring hospital treatment. Outbreaks of infections like flu spread rapidly often leading care homes to close, preventing residents from seeing their relatives. The COVID-19 pandemic highlighted why we need better evidence and new ways to protect people who live and work in care homes from infection.

This study aims to reduce the impact of infection and outbreaks in care homes. We plan to do this by measuring the extent of infection and its consequences in residents, and by doing research to find new, better ways to prevent infections and protect residents and staff.

Invitation to take part

We are giving everyone who lives in your care home the chance to take part in this project, including residents who are only staying in the care home temporarily. If you agree to take part we will collect one piece of information about you – your NHS number. You do not need to do anything because we can retrieve this number from the records that are already held by your care home. We will not ask you any questions, or collect any blood or other samples from you in this study.

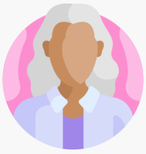
Do I have to take part?

No. If you don't want to take part tell someone who works in your care home and they will make sure you are removed from the list. Alternatively, you can email:

What will happen if I agree to take part?

The company that provides your care home with electronic care records will send a list of NHS numbers belonging to people in your care home to NHS England. If you agree to take part your number will be on this list. NHS England will swap your NHS number for a code that is linked to your NHS number, but cannot be used to identify you. This is called pseudonymisation and will create a pseudonymised number. Once this has been done your NHS number will be deleted from the list.

1. Original Information



NHS Number: 485 777 3456

2. Removal of Personal Information

ID Number: 123456

NHS England will receive NHS Numbers for residents to build the research dataset. Your personal information is removed and replaced with an ID number.

This is done by NHS England in line with the General Data Protection Regulations (GDPR) 2018. The data (which only contains information that cannot be used to identify you) is sent to the VIVALDI study team by NHS England.

Next NHS England will use this pseudonymised number to link to other records that the NHS already holds for you, so we can measure infections in care home residents and what happens to people who get infected. We will link residents' NHS numbers to the following information:

Type of data	**Description of the data**
Hospital admission	Date of the admission. Reason for the admission is recorded as a code. For example the code for ‘pneumonia’ is J18.9 and the code for UTI’s is N39
Attendance at A&E	Date of the attendance. Reason for the attendance recorded as a code.
Death	Date of death and cause of death recorded as a code.
Vaccination	Date of vaccination. What the vaccine protects against (e.g. COVID, flu). What type of vaccine was given e.g. Pfizer. How many doses of the vaccine.
Lab tests done in primary care (GP) or hospitals	Date and results of laboratory tests (blood, swab tests) for bacteria and viruses.
Antibiotics issued in the community (by the GP)	Date the antibiotic was issued. Name of antibiotic. Dose of antibiotic.

This is what two rows of data in our database (for two fake residents) might look like:

Pseudo-ID	CQC-ID	Event source	Event type	Age	Sex	Episode start date	Episode end date	Test result	Reason for admission
19994578	1-45678	APC	Hospital admission	67	F	21/04/23	27/02/23		N39.0
19989999	1-43432	Pillar 2	AgTest	84	F	30/06/23		NEGATIVE	

Lets us link to the correct record for each resident

The care home the resident lives in

The person had a negative COVID-19 test

This person was admitted to hospital with a urinary tract infection

We will use the linked dataset for two purposes:

1. The research team, public health experts from the UK Health Security Agency (UKHSA), care providers and people who live and work in care homes will work together to create a report and/or dashboard that describes the extent of infections and outbreaks in care residents. We will start by measuring 10 outcomes and will prioritise measuring things that residents, relatives, care providers, care staff and policymakers tell us are most important, like the number of flu outbreaks, or the number of people admitted to hospital for a urine infection. Our objective is to assess various aspects of infections and outbreaks within care homes, providing a thorough understanding of their impact. To ensure the relevance and applicability of the measures, we will speak to care home teams, residents, their families, along with policymakers. Together, we will identify the most appropriate measures to ensure participation does not adversely impact care homes. These measures will be shared with care providers and policymakers to improve care. They will also be shared with people who live and work in care homes and the public.

2. We will create a research database made up of anonymised data (NHS numbers removed) which can be used by researchers to generate ideas and evidence on how to prevent and reduce infections. If a researcher wants to use the database, they will have to first get permission from the study Data Access Committee, which will include residents/relatives, care home staff, care providers and policymakers. This will make sure that the dataset can only be used for research that benefits residents. Because the dataset is anonymised, there is no way of linking the records back to the person that are about.

Findings will be published in academic journals, shared with policymakers and care homes, and presented at conferences attended by professionals with an interest in the area. It will not be possible to identify any individual residents, or any individual care homes in these reports. We will also share results with residents and their relatives in an accessible way, as well as with the staff working in participating care homes.

What are the possible benefits of taking part?

- We anticipate that this project will help to reduce the number of infections and severe infections (that require hospital admission) in residents.
- We also anticipate that this project will reduce how often and how severe outbreaks are, therefore reducing how often care homes are closed to new admissions and the impact of home closures due to an outbreak.
- This project should also give people who live and work in care homes the opportunity to shape policies that directly affect them, by working in partnership with academics and policymakers and contributing their views and ideas.

What are the possible disadvantages and risks of taking part?

The only potential risk of this study is a breach of confidentiality. This risk has been minimised because:

1. We are only collecting NHS numbers for residents and no other identifiable information.
2. Data linkage will be undertaken in a secure NHS data environment by NHS England.
3. Only organisations that already have access to residents NHS numbers will access to this information in this study.
4. NHS numbers will be removed before the dataset is shared with the project and research teams.
5. All members of the research and project teams have been trained in information governance (GDPR)
6. The project is overseen by experts in information governance at UCL and at NHS England.
7. All care homes must complete The Data Security and Protection Toolkit which is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian’s 10 data security standards. All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly.

https://www.dsptoolkit.nhs.uk/
https://www.digitalsocialcare.co.uk/

How does consent work in this study?

In research studies we usually seek consent from participants to collect their data. However, there are some special cases where it is acceptable to collect data without consent. In this scenario, there are three requirements:

- The benefits of collecting the data must outweigh any potential harms.
- It is not possible or feasible to obtain informed consent.
- The individuals whose data are being used do not strongly object.

Our engagement work with people who live and work in care homes, and previous experience doing research in care homes in the pandemic has shown us that it is not possible to get informed consent from the majority of people in a care home. This is because many residents have cognitive impairment which means that they cannot provide informed consent to participate. They can still take part if their next of kin or a nominated consultee can act on their behalf, but this would place a huge burden on teams. As a result, care home residents who cannot provide informed consent tend to be excluded from research studies. This really matters, because we want to give everyone the chance to take part in, and benefit from research. Excluding lots of people really reduces the value of our findings for everyone.

In the past people have tried to use residents' addresses to identify who is and isn't in a care home, for example using GP records. The problem with this approach is that addresses are often out of date. Temporary residents are also always excluded using this approach because their address is their permanent place of residence, not the care home. It is essential to include temporary residents in research studies on infection because many of them have recently been in hospital. Hospitals usually have more infections than care homes, so temporary residents are more likely to bring infection into care homes than other residents.

In our discussions with residents and relatives to date, no one has strongly objected to our proposal to use data without consent once we have explained why this is necessary. Overall, we think the need for better data on infection in care homes outweighs the potential harms of sharing data without consent. However, we will continue to review this carefully and seek views from residents and staff throughout the 12-month study.

How long will the study last?

The study will run for a total of 18 months however we aim to collect data from each care home for a maximum of 12 months within this period. Our goal is to start the study in October 2023 and begin analysing data from January 2024.

Who is funding the study? Who else is involved in the study?

The study is funded by the UK Health Security Agency. Members of the research team are funded by the National Institute for Health and Care Research. The project is being delivered by three organisations working together: University College London, the Outstanding Society, and Care England. UCL is the study sponsor and Professor Laura Shallcross is the study Chief Investigator.

Who is the data controller? Who are data processors?

The three organisations that are leading the study are joint data controllers (UCL, the Outstanding Society, Care England). UKHSA and NHS England are data processors. UKHSA will process the data to generate reports and dashboards to visualise our results. NHSE will undertake the data linkage and pseudonymisation.

Where will the dataset be built and stored?

The dataset will be built in a secure environment that is managed by NHS England. This is currently called the NHS Foundry but it will shortly be updated and re-named the ‘Federated Data Platform’. A fully anonymised copy of the ‘research database’ will be extracted and stored at UCL in the UCL Data Safe Haven. The UCL Data Safe Haven has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit.

How will my data be kept confidential?

Your identifiable data will only be accessed by people who already have access to this information. The linked dataset in the secure NHSE environment will only be accessible to named members of the project team, all of whom will have been trained in information governance. Access to the research database will only be permitted for named researchers following approval of their project by the study Data Access Committee. The Data Safe Haven (where the research database will be stored) has robust procedures in place to monitor and review who can access the dataset.

What happens if I don’t want to be in the study any more?

While data collection is taking place, residents or their relatives can opt-out at any time by telling someone who works in the care home that they don’t want to take part, or by emailing their care home lead (see poster in your care home for contact details). If we have finished collecting data, it will not be possible to remove individual residents from the dataset or from any publications that have used the dataset because we will not have access to residents' NHS numbers.

People who have already completed the NHS Data Opt-Out will not be included in our dataset.

Who has reviewed this study? Have residents and relatives been involved?
The plan for this study has been developed over the last 18 months through consultation with residents, relatives, care home staff and care providers from different care homes. The study proposal has been reviewed by the UK Health Security Agency. The proposal to establish the research database has been reviewed and approved by the NHS Research Ethics Committee. The proposal to use the linked data from residents without consent has been reviewed and approved by the Health Research Authority and the Secretary of State for Health and Social Care on advice from the Confidentiality Advisory Group (CAG). The whole project will be overseen by a Stakeholder oversight group which will include residents/relatives, care home staff, care providers, policymakers and academics.

What if something goes wrong?
If you are unhappy about something that has happened in the study and want to discuss it with the project team, please contact:

If you want to make a complaint, please contact the UCL research complaints team: research-incidents@ucl.ac.uk

Thank you for reading this information. If you have further questions, please contact:

Where can I find out more about the project?
You can find out more information about the study from the following website: www.theoutstandingsociety.co.uk

Icons made by Freepik:www.flaticon.com

UK Health Security Agency

THE OUTSTANDING SOCIETY

CARE ENGLAND
Representing independent care providers

UCL