Witness Name: Laura Shallcross

Statement No: 2

Exhibits: 37

Dated: 2nd May 2025

UK COVID-19 INQUIRY

WITNESS STATEMENT OF LAURA SHALLCROSS MBE

I, Laura Shallcross MBE, of University College London (UCL) of Gower Street, London WC1E 6BT, will say as follows:

1. I make this statement about the role of the Vivaldi Study in providing evidence on the impact of the Covid-19 pandemic on Adult Social Care, in response to the UK Covid-19 Inquiry's Request for Evidence under Rule 9 of the Inquiry Rules, dated 18 January 2023, in relation to Module 6 of the Inquiry. The facts and matters contained within this statement are within my own knowledge unless otherwise stated, and I believe them to be true. Where I refer to information supplied by others, the source of the information is identified; facts and matters derived from other sources are true to the best of my knowledge and belief.

2. The views outlined in this statement are my own; I am not representing UCL or any other organisation.

Introduction

3. I am Professor of Public Health and Translational Data science, Director of the Institute of Health Informatics at University College London (UCL) and hold a National Institute for Health and Care Research (NIHR) Research Professorship. I was promoted to full Professor in 2021 and became Institute Director in September 2023.

4. I trained in medicine at the University of Oxford and Guy's, King's and St. Thomas's Medical School in London, and qualified as a junior doctor in 2003 (MBBS). Following general medical training I trained in epidemiology and population health through my MSc at the London School of Hygiene and Tropical Medicine (2009) and my PhD at

UCL (2014). I combined my academic training with clinical training in public health and qualified as a UK Consultant in public health in 2017. My GMC registration number is PD and I re-validated in 2021. At UCL, I lead a program of translational research which integrates the application of data science and machine learning to routinely collected data with inter-disciplinary methods (qualitative research, clinical trials) to develop interventions and policies to reduce infections and antimicrobial resistance (AMR) in health and social care. My research has been published in high impact journals such as the New England Journal of Medicine, Lancet Infectious Diseases and PLOS Medicine and informed national policy, and I have accrued > £11.8 million in grant income as Principal Investigator over the last 4 years. I have experience of working with national policymakers, most notably through my leadership of the Vivaldi study. I am deputy chair of the Government's Scientific Advisory Committee for Antimicrobial Prescribing, Resistance and Healthcare Acquired infection (APRHAI) and am a member of the NIHR Health Technology Assessment Programme funding committee and the Wellcome Trust Population and Public Health Discovery Advisory Group.

5. In my current role, I provide strategic leadership for research and education at the Institute of Health Informatics as well as leading my own research group and supporting the development of early career researchers and members of my team. Examples of my published research on infection and AMR (unrelated to Vivaldi) that are of relevance to Adult Social Care include studies on urinary tract infection in older adults [LS2/01 – INQ000544921, LS2/02 – INQ000544922], antibiotic prescribing in care homes [LS2/03 – INQ000544923], LS2/04 – INQ000544924], LS2/05 – INQ000544925], and research on multimorbidity using electronic health care records [LS2/06 – INQ000544926], [LS2/07 – INQ000544927]. Shortly before I was asked to set up the Vivaldi study in May 2020, I obtained research funding (£172,202) the from Economic and Social Research Council (ESRC) to conduct a study to investigate the burden and impact of Covid-19 in care homes called CATCH-19, which used routinely collected data supplied by Four Seasons Healthcare. This study estimated the proportion of residents with symptoms of Covid-19, the proportion testing positive for infection and rates of mortality in residents from 179 care homes [LS2/08 – INQ000544928]. Key findings of the study were that between March and June 2020, 10% of residents had laboratory-confirmed infections for which there was a 36% case fatality rate. High bed occupancy and low staffing levels were independent risk factors of infection.

6. During the pandemic, I set up and led the national Covid-19 in care homes (VIVALDI) study, which was initially funded by the Department of Health and Social Care (DHSC) and subsequently funded by the UK Health Security Agency (UKHSA). My team and I used this study to address a range of research questions with the aim to inform the public health response to Covid-19 in care homes. Examples of the research questions that we addressed included investigating the burden of Covid-19 in care home residents and staff and use of disease control measures in the first wave of infection [LS2/09 – INQ000544929], estimating the risk of re-infection following primary infection with Covid-19 [LS2/10 – INQ000544930], evaluating immune responses to Covid-19 in care home residents and staff following natural infection and vaccination [LS2/11 – INQ000544931]; [LS2/12 –INQ000544932], LS2/13 – INQ000544933] in collaboration with Professor Paul Moss's research group at the University of Birmingham, estimating vaccine effectiveness in residents and staff [LS2/14 – INQ000412930], LS2/15 – INQ000544935], and investigating the severity of emerging SARS-CoV-2 variants [LS2/16 – INQ000544936], LS2/17 – INQ000544937]. I was awarded MBE for services to Adult Social Care during the Covid-19 pandemic in the Queen's Birthday Honours 2021.

The SAGE Social Care Working Group ('SCWG')

7. My first involvement with the public health response to Covid-19 was when I was invited to a meeting that was convened by Health Data Research UK (HDR UK) on Friday 8th May, 2020. The meeting brought together researchers who were undertaking data-driven research in social care with the aim to identify sources of research data and evidence that might inform the response to the Covid-19 pandemic in adult social care. I was invited to take part in the meeting because I had recently been awarded funding from the Economic and Social Research Council for the CATCH-19 study in care homes. Some members of the HDR group became members of the Social Care Working Group. From 19th May 2020 onwards I began attending the SAGE SCWG to report on progress with set up of Vivaldi alongside my colleague Alasdair Donaldson, who was seconded to the Department of Health and Social Care to provide project management support for Vivaldi. I do not recall being formally invited to join the SAGE SCWG until I received an email from Go-Science on 10th July 2020 seeking permission for my name to be listed on the SAGE website.

8. According to my records, the first SAGE SCWG meeting that I attended was on 19th May 2020. To my knowledge, minutes were not recorded, and I do not hold personal records or notes from these meetings. According to documentation that was shared with me by the UK Heath Security Agency (UKHSA), I attended 31 of 38 meetings that took place between September 4th 2020 and April 1st, 2022 [LS2/18-INQ000544938]. My recollection is that I attended the majority of the SAGE SCWG meetings that took place each week until April/May 2021 and then twice per month thereafter. My main contribution to these meetings was to provide timely updates on emerging findings from the Vivaldi study, to describe the strengths and limitations of our data, to work with the group to consider how our findings were relevant for policy, and to ensure that all potentially useful information was shared. Beyond Vivaldi, I helped to identify research and data gaps, and worked with the SAGE SCWG to present a balanced assessment of the evidence that was presented to us (based on Vivaldi and other sources) to inform policy, for example in relation to Covid-19 testing frequency. I contributed to discussions informing the development of a range of documents that were developed by the SAGE SCWG, and I have collective responsibility for these outputs alongside all the other members of the working group. However, I did not lead any documents which were produced by the SAGE SCWG.

The Vivaldi study

9. There are no systems which routinely monitor infections or hospital admissions in individual care home residents or staff. Care homes are expected to notify their local public health teams if they have an outbreak of an infection, but lack of access to testing for SARS-CoV-2 in the first wave of the pandemic undermined the effectiveness of this reporting mechanism. Establishing a research study was arguably the quickest way to address the gap in evidence on the burden of Covid-19 in staff and residents to inform public health policy. The initial plan was to establish a study that was similar to the Covid Infection Survey which was led by the Office for National Statistics (ONS) and Oxford University. However, there were legitimate concerns that it would be very difficult to apply this model in care homes and the decision was made to identify researchers with experience of care home research to support the design and delivery of this study.

10. I was first approached about the need for a national care home study by Professor Susan Hopkins, who was employed by Public Health England (PHE), on 8th May 2020.

Professor Hopkins and I have collaborated on research studies since around 2006 and she was aware of my research on AMR in care homes and the CATCH-19 study. From memory we discussed the need for a care home study and whether I might be interested in leading or co-leading this with my senior colleague Professor Andrew Hayward, who at that time was also working at UCL and leading the VirusWatch study. Professor Hayward and I agreed that we were keen to support the set up and delivery of a national care home study, so I communicated this to Professor Hopkins. I have not discussed this with Professor Hopkins, but I believe that Professor Hayward and I were approached because we have a background in infectious disease epidemiology and public health and have experience of establishing community-based research studies on infection and working with care homes.

11. Professor Hayward and I were invited to attend a virtual meeting entitled 'ONS Care Home study' on Sunday 10th May, 2020. I do not hold minutes from this meeting, but the list of invitees comprised: Professor Jeremy Farrar, Professor John Bell, Professor Ian Diamond, Professor Iain Bell, Professor Susan Hopkins, Professor John Edmunds, Will Warr, Alex Cooper, and Ben Warner. The email invitation stated: "*We are very keen to sort out the ONS care homes study and Jeremy Farrar is going to chair a meeting to ensure the study can progress at pace, now under the auspices of the Pillar 4 of the Testing Programme".* The invitation was sent by Tamsin Berry from the Office for Life Sciences. During the meeting Prof Hayward and I outlined a high-level proposal for a care home cohort study involving antibody testing and long-term follow-up. By the end of the meeting I had been tasked with setting up the cohort study (as study Chief Investigator), with project management support from Alasdair Donaldson at the DHSC. I was also strongly encouraged to work with the Office for National Statistics (ONS) to support the design of a care home survey, building on their experience setting up the Covid-19 Infection Survey with the University of Oxford. Following this meeting, I started to put together a small team at UCL to draft a protocol for the cohort study and obtain research ethical approvals from the NHS Research Ethics Committee. In parallel, I worked with Professors Hopkins and Hayward to draft a protocol and ethics application for the care home survey for submission to the Public Health England Research Ethics and Governance Group (REGG).

12. Leading on from this meeting two Vivaldi studies were established - the Vivaldi survey and the Vivaldi cohort study. The survey was designed to provide rapid but limited information on the burden of infection in care homes by collecting data from care home managers using a one-off telephone questionnaire. The aims, objectives and methods

of this study are outlined in the study protocol [LS2/19 – INQ000544939]. The study was completed by July 2020. The cohort study, which was complex and required more time to set up, was designed to provide detailed information on the burden and outcomes of SARS-CoV-2 infection over time. It involved serial blood sampling in residents and staff and ran from May 2020 – March 2023. Whereas the Vivaldi survey aimed to estimate rates of infection based on polymerase chain reaction (PCR) test results derived from nasopharyngeal swabs, the Vivaldi cohort study used blood testing to assess the proportion of staff and residents with antibodies, which indicate prior infection. Antibodies usually remain detectable for several months following infection so this approach provides a more accurate assessment of the proportion of surviving staff and residents who had been infected in the first wave because many staff and residents had not had access to PCR testing. The cohort study protocol [LS2/20 – INQ000544940] was updated at intervals during the pandemic in response to emerging research questions.

13. Different organisations were involved in the delivery of each of the two Vivaldi studies. The survey was a collaboration between UCL, the ONS and Public Health England. PHE acted as study sponsor. The listed study investigators were Professor Hopkins from PHE and myself from UCL. I provided academic expertise to inform the design of the study and the content of the survey questions with input from Professor Hopkins at PHE and Professor Hayward at UCL. The ONS were responsible for formulating the survey questions, designing the questionnaire, and identifying the sample of eligible care homes. They also oversaw delivery of the telephone survey by Ipsos MORI. I developed the analysis plan with the ONS; ONS analysts undertook the data analysis in NHS Foundry. I worked with ONS analysts and Alasdair Donaldson to interpret the data and consider implications for policy and was usually the person who presented the research findings. Alasdair Donaldson from the DHSC acted as formal project manager for this work, overseeing the multi-institutional team. He also played a key role in disseminating findings to policymakers in DHSC and UKHSA. The press release announcing initial research findings was led by the ONS. To my knowledge, the data controllership arrangement were not formalised for this study.

The Vivaldi cohort study was delivered using a more traditional model in which study design and delivery were primarily the responsibility of the academic team at UCL, with project management support from the DHSC. This support was essential to ensure the study was prioritised, for example to expedite the process of research ethical review and that we had access to the necessary equipment (e.g. personal protective equipment for

phlebotomists, blood bottles). Through my interactions with the SAGE SCWG and the DHSC Data Debrief Group, conversations with other academics and policy colleagues at PHE and DHSC, and interactions with care homes in Vivaldi, I kept up to date with emerging policy questions. Wherever possible I identified ways in which Vivaldi data could be used to generate timely and relevant evidence to inform policy. The study sponsor was UCL. UCL and the DHSC acted as joint data controllers for the study. The ONS had no role in the cohort study.

14. There were two 'formal' mechanisms by which findings from Vivaldi were shared with DHSC, PHE and the SAGE SCWG. From 11th May onwards I was expected to attend the DHSC Data Debrief Group which was chaired by John Hatwell from the DHSC. This weekly meeting brought together the Chief Investigators from each of the 'Pillar 4' surveillance studies including the Imperial led REACT study, and the Oxford/ONS led CIS with senior individuals such as Professor Sir Jeremy Farrar and Professor Sir John Bell to review Covid-19 infection trends. Investigators from other studies such as the UKHSA led SIREN study in healthcare workers and the Schools Infection Study (SIS) also attended when they had new data to present. A report summarising key findings from this meeting was shared with Ministers each week. I also attended the weekly meeting of the SAGE SCWG, often with my colleague from DHSC Alasdair Donaldson. This was the main way in which I interacted with PHE, because these meetings were usually attended by a range of PHE staff and were co-chaired by senior individuals within this organisation such as Professor Dame Jenny Harries and Professor Eamonn O'Moore. Once the Vivaldi study was established we provided regular updates on our findings to the SAGE SCWG whenever we had new information to report. I also attended meetings of the Social Care Taskforce and presented findings from Vivaldi to this group, which was chaired by Sir David Pearson.

Key findings from the Vivaldi survey and the Vivaldi cohort study

15. The Vivaldi survey and cohort study generated a range of findings which were relevant for policymakers. For example, the Vivaldi survey provided evidence that care homes that did not pay full sick pay were more likely to have infections in residents and staff. This supported the Government's policy decision to establish the Infection Control Fund providing care homes with flexible funding to support sick pay so staff could afford to self-isolate when unwell. The survey also indicated that care homes where staff worked across site were more likely to have infected staff. This informed the policy decision to limit movement of staff across sites to limit the spread of infection. These

research findings are described in full in our peer reviewed paper [LS2/09 – INQ000544929]. The Vivaldi cohort study provided the first estimates of vaccine effectiveness in residents in England [LS2/14 – INQ000412930], showed that immunity waned from 12 weeks following primary vaccine course and provided ongoing monitoring of waning immunity following booster vaccination [LS2/15 – INQ000544935]. This information informed guidance from the Joint Committee on Vaccinations and Immunisations regarding the need for and timing of booster vaccines for care home residents. Data from the Vivaldi cohort provided insights into the emergence and spread and severity of SARS-CoV-2 variants in care homes from autumn 2020 onwards as described in these two published papers [LS2/16 – INQ000544936, LS2/17 – INQ000544937], informing policy decisions regarding the ongoing need for disease control measures in care homes.

Operational delivery of the Vivaldi studies

16. The availability of linked individual-level data on care home staff and residents in NHS Foundry was fundamental to the research that we undertook in the Vivaldi study, which relied heavily upon the use of routinely collected data. To my knowledge, in the early stages of the pandemic, NHS Foundry was the only environment which provided timely access to accurate, individual-level test results on care home staff and residents, with linkage to NHS datasets to monitor infection-related outcomes such as hospital admission and mortality. This type of data is essential if you want to monitor outcomes of infection, or monitor the effectiveness of treatments or vaccinations, particularly in settings where it is challenging to obtain informed consent. Through the Vivaldi studies I had access to the SARS-CoV-2 testing data in NHS Foundry for all care home staff and residents. My understanding is that we were the only group that was accessing this data in Foundry in May/June 2020. Although the data had significant limitations, it was clearly an important source of information, and I was surprised it was not being used for surveillance by other teams. As the only epidemiologist in our team at that time, I worked with my DHSC colleague Alasdair Donaldson and individuals from Palantir who were working in NHS Foundry to develop short reports based on this dataset, highlighting potential biases in the data and its limitations, and trying to draw evidence-based conclusions. This information formed part of the reporting to the DHSC Data Debrief Group. I supported the development of these reports because I thought they were important, but from my perspective this work was separate from the Vivaldi survey and the Vivaldi cohort study, and distinct from the research studies that I had

been asked to set up. In this statement I have endeavoured to make the distinction between the Vivaldi survey as reported on the .Gov website [LS2/21-INQ000106159] and reporting of testing data for residents and staff that were held in NHS Foundry.

17. The Vivaldi study was initially commissioned by DHSC, with later waves of the study being commissioned by the UKHSA. My interactions with policymakers in the first phase of the study (2020) were primarily with DHSC although we obviously sought to make our findings available to PHE. My 'line of reporting' was to John Hatwell and the Data Debrief Group in DHSC.

18. We were able to set up both the survey and the cohort study very quickly with strong project management support from the DHSC which helped to expedite processes such as ethical review. However, there was a lack of clarity about how the commissioning and funding processes would work for the study. This was particularly important for the cohort study because of the need to contract with other organisations (e.g. laboratories, care homes), and to fund members of the research team. Fortunately, UCL were willing to accommodate this financial uncertainty in the short term. I was given freedom to design the cohort study in collaboration with academic colleagues, and I do not recall being given a list of policy questions to address, either by DHSC or PHE. Instead, it fell to the research team to identify research priorities and emerging policy questions based on our knowledge and networks, and previous experience of conducting community infection surveys such as the Medical Research Council funded FluWatch study, which began in 2006 and aimed to estimate the community burden of influenza and influenza-like illness. When Vivaldi began the priority was to estimate disease burden based on antibody testing, which is why 'The proportion of staff and residents who have previously been infected with SARS-CoV-2 based on presence of antibodies in serum at baseline, 6 weeks and 3 months' was listed as the primary (main) outcome in the first version of the study protocol. A set of secondary outcomes were also listed, which included investigating rates of asymptomatic and symptomatic infections, estimating mortality, investigating the duration of the antibody response, and investigating disease transmission between care homes. Many, but not all these objectives were ultimately addressed in the cohort study. For example, it was not possible to investigate transmission of SARS-CoV-2 between care homes in Vivaldi because of the low proportion of PCR samples that were submitted for whole genome sequencing by the national network of laboratories that processed samples from care homes (this was beyond the control of the study team). Importantly, the study protocol was revised and resubmitted for research ethical approval at intervals during the study to permit new

analyses in response to emerging policy questions. The only direct request from the DHSC regarding the design of the cohort study was to expand it to more care homes and include a wider range of care providers.

19. A key operational challenge was to put funding contracts between DHSC and UCL in place. The study was funded on a 12-month cycle with no option for 'no cost extensions', which are common practice in academia, and allow for flexibility when delivering complex research studies. The DHSC/UKHSA contracting teams were unfamiliar with costing models that are commonly used by Universities, which led to many queries about overheads and other costs that would be included as standard in a research grant. We wasted a lot of time re-applying for funding, particularly following the first year of the pandemic, which could have been avoided if we had been funded for a longer time period at the outset. There was a sense that there was no template or model for DHSC and Universities to work together in order to respond to a public health crisis. The UCL team worked very effectively with our DHSC project managers (first Alasdair Donaldson, then Aidan Irwin-Singer), but beyond these individuals there was little organisational support from either DHSC or PHE/UKHSA for activities such as establishing data sharing or data processing agreements, or getting access to new data sources (e.g. detailed PCR test results to monitor emerging SARS-CoV-2 variants) that were absolutely critical to the delivery of the Vivaldi cohort study. We received helpful guidance from NHSE and ultimately were able to secure legal fees to employ a lawyer at UCL to support the large number of contracts that were required in this study.

20. The Vivaldi study and testing data that were available in NHS Foundry were respectively new sources of research and surveillance data. At the start of the pandemic, I recall that it took some time (estimated 2 weeks, but I cannot recall this with any certainty) for policymakers at PHE and the DHSC who were not involved in the Data Debrief Group to become aware of this information stream and its potential value. My colleague Alasdair Donaldson at the DHSC would be better placed than I am to comment on this matter as he took responsibility for ensuring that our findings were disseminated rapidly. Based on information supplied by the UKHSA, Alasdair Donaldson and I had started reporting findings to the SAGE SCWG by 10th July 2020 [LS2/22 – INQ000544941]. However, my recollection is that we provided weekly updates to the SAGE SCWG shortly after we began reporting to the DHSC Data Debrief Group (DDG) on 11th June 2020.

21. Our interactions with care homes regarding the delivery of the Vivaldi survey were relatively straightforward because Ipsos MORI was responsible for the telephone interviews, data collection was overseen by the ONS, data was collected from care home managers, and there was a single round of data collection. I recall that the ONS experienced some challenges in getting a list of eligible care homes (those that provided care to the > 65s) and contact details for their care home managers. This information was ultimately supplied by Lang Buisson. The National Care Forum and some care providers raised initial concerns about the survey, largely because they were concerned about additional demands being placed on care home staff. We were able to largely overcome this problem by explaining the purpose of the study.

22. Working with care homes to set up the Vivaldi cohort study was substantially more challenging, largely because of the increased complexity of the study and the need to obtain blood samples from residents and staff during a period when care homes were closed to visitors. Collection of blood samples required informed consent, which is challenging in residents because many lack capacity due to conditions such as dementia. We could have excluded residents who lack capacity to consent, but those with and without dementia are likely to be systematically different, and we wanted to know if certain types of residents were at increased risk. Residents with dementia are likely to be older, more frail and may have different patterns of comorbidity, potentially impacting on their immune function. They are also more likely to display behaviours, such as difficulty complying with disease control measures such as self-isolation, which may increase their risk of both acquiring and transmitting infection. Consequently, if residents with dementia were systematically excluded from the study this could lead to an underestimation of the burden of Covid-19 in care-homes. It would also mean that our findings would not be relevant for the large proportion of care home residents who have dementia. The only option to overcome this issue was to identify personal (e.g. a family member) or nominated consultees (e.g. staff) who could act on residents' behalf. As we were in a pandemic we couldn't send researchers into care homes to support the consent process because homes were shut to visitors. We therefore needed care home staff to contact residents' next of kin on our behalf. This represented a substantial additional workload at a time when the sector was under immense pressure. A further challenge is that we wanted to link the results of blood testing in residents and staff to PCR test results and NHS datasets (hospital admissions, vaccinations, deaths) that were held in NHS Foundry. To do this we needed to ensure that all blood samples were labelled with resident and staff members NHS numbers, but many care homes did

not hold NHS numbers for all their residents pre-pandemic. We used a range of strategies to overcome these problems:

a) We began by working with an organisation (Four Seasons Healthcare) that had previously worked with my research team. Before starting the study, I asked Alasdair Donaldson to investigate if we could get support for the study from Helen Whateley, the Minister for Social Care. She met with me, Alasdair Donaldson and Jeremy Richardson, the CEO of FSHC, on May 14th, 2020, with the aim to get support from FSHC's senior leadership team to aid study delivery, recognising that it would cause significant additional work and potential disruption for staff and residents.

b) Recognising the substantial workload associated with contacting next of kin/ consent, and the need to capitalise on existing organisational infrastructure, we funded an existing FSHC employee to act as the local project manager (rather than providing study support from UCL which is a more traditional research model). We worked closely with this individual to design and operationalise the study in a way that would be feasible for the care sector.

c) We worked with the data lead at FSHC and the team at NHSE to ensure the NHS numbers that were submitted by FSHC were accurate. Over time we modified our study design to ensure we were collecting accurate information on NHS numbers as part of the blood sampling process.

23. When we started the study we sought informed consent to link the results of blood testing to routinely collected NHS data. This meant we could only collect follow up data on the subset of staff and residents who had consented to blood sampling. We sampled a median of 6.8 residents and 14.3 staff per care home. For comparison, the median number of beds for care homes in our cohort was 51 (I do not hold accurate data on the number of residents per care home at the time of blood sampling). The introduction of the Coronavirus (Covid-19: notice under regulation 3 (4) of the Health Service (Control of Patient Information) Regulations 2002 (the 'COPI notice'), which was introduced on 17th March 2020, provided the legal basis for the research team to access data on all staff and residents in participating care homes without consent, for the purposes of responding to the Covid-19 pandemic. This combined with the fact that almost every resident and staff member was being regularly tested for Covid-19 created the opportunity to create a 'registry' of staff and residents in participating care homes and thus establish a much larger study comprising c. 70,000 care home staff and

residents, linked to data on vaccination status and outcomes of infection. I spoke to NHSE's information governance team to confirm that the COPI notice could be relied upon as the legal basis for accessing data from residents and staff in the Vivaldi research study, and from this point onwards sought to use this mechanism rather than informed consent to collect data from care home staff and residents. These developments fundamentally changed the scope of what could be achieved in the Vivaldi cohort study, enabling us to generate research evidence on policy timescales.

The Vivaldi Survey [LS2/21-INQ000106159]

24. As stated in the study protocol [LS2/19 – INQ000544939], the aim of the Vivaldi survey was to estimate the prevalence of SARS-CoV-2 infection, use of disease control measures and population at risk (staff and residents) in each care home in England, by surveying care home managers. This aim was achieved, with full results published in the Lancet Healthy Longevity [LS2/09 – INQ000544929]. In the study, we estimated the proportion of staff and residents who had tested positive for SARS-CoV-2 in the first wave of the pandemic, we described the use of disease control measures in care homes, and we investigated associations between the use of different disease control measures and four outcomes: infections in residents, infections in staff, outbreaks and large outbreaks.

25. The study was a cross-sectional survey which used telephone questionnaires to collect data from care home managers on infections in staff and residents in their home. This approach was used because at the time it was not possible to reliably identify test results from care home staff in routine data or to link PCR test results to specific care homes (this changed as the Covid-19 testing infrastructure matured). In addition, the availability of 'in care home testing' was extremely limited. We concluded that care home managers were likely to have the most comprehensive information on who had been infected in their home and thus surveyed them. Homes were eligible to take part in the survey if they provided dementia care or care to adults aged 65 years or older in England.

26. The survey collected data on care home characteristics, such as the number of beds, the use of disease control measures, and the number of confirmed cases of infection in staff and residents in each home between the 1st March 2020 and the date of the survey. Candidate risk factors for infection were identified from the published literature

and from previous knowledge of disease control measures. Experts from the ONS designed and piloted the survey questions using cognitive interview methods to test comprehension, accuracy, and question acceptability. In the weeks before the survey began, managers of eligible care homes were sent an invitation letter by PHE explaining that they would shortly receive a telephone call from Ipsos MORI. The letter outlined the purpose of the survey, listed the information that would be requested (so that it could be collated in advance of the interview), and explained that the survey should be completed by care home managers. Incentives for managers to participate in the survey were not provided. Subject to obtaining informed consent from managers, the finalised 30-min survey [LS2/23 – INQ000544942] was delivered by telephone by Ipsos MORI who also recorded survey responses electronically. Survey responses were transferred securely to and stored in the NHS Foundry.

27. The survey was conducted between May 26th and June 19th, 2020. Early findings were communicated online by the ONS on 3rd July, 2020 [LS2/24-INQ000346701]. The main findings from this study (primary outcome) was an estimate of the proportion of care home residents (10.5%) and staff (3.8%) who had tested positive for Covid-19 based on the number of cases of Covid-19 in staff and residents reported by care home managers. The ONS also reported that 56% of care homes in the survey had had at least one case of Covid-19. More details on the findings from the Vivaldi survey are described in paragraph 30. Survey responses were also linked to individual-level SARS-CoV-2 RT-PCR test results obtained between April 30 and June 13, 2020, through the national testing programme, which aimed to test all residents and staff of LTCFs in England. It is important to emphasise that testing capacity in care homes was very limited during the first wave of the pandemic so many individuals who were infected with Covid-19 did not undergo PCR testing.

28. Researchers from Ipsos MORI attempted to contact 8634 (95·1%) of 9081 eligible care homes at least once and 6164 (67·8%) of care homes were telephoned three or more times. Three care homes that participated in the survey but subsequently withdrew were excluded from analyses. Data were included for 5126 care homes, representing 56% of eligible care homes. In my view this was a good response rate for this survey, given the short period of the data collection and the fact that the study was taking place during a pandemic. Survey respondents and non-respondents were similar in terms of care home characteristics such as size, membership of a care home group, postcode based deprivation, and region. There was also substantial variation in the prevalence

of Covid-19 infection between homes, which provides some evidence that the number of infections did not strongly influence participation. However, it is possible that other factors that were not captured in the survey might have influenced the decision of managers to participate thus introducing bias due to survey non-response.

29. As a general rule, Alasdair Donaldson our Vivaldi project manager from DHSC and I attended meetings together to report findings from the Vivaldi survey; he summarised results of the testing data (derived from NHS Foundry, which was separate from the Vivaldi survey) and I reported on findings from the Vivaldi survey. In the first wave of the pandemic, this included presenting to the SAGE SCWG (which was held weekly on Fridays 9.30-10.45am), and to the DHSC Data Debrief Group (held weekly on Thursdays 4-5 pm). I do not hold minutes or notes regarding what was discussed at these meetings, but my recall is that we presented an update on findings from Vivaldi every week during this period. A weekly report was submitted by the DHSC Data Debrief Group to Ministers, which would include a summary of key findings from both the testing data in NHS Foundry and the Vivaldi survey, alongside findings from the other Covid-19 surveillance studies.

Key findings from the Vivaldi survey

30. We used data from 160 033 residents and 248 594 staff members in 5126 care homes to estimate the proportion of staff (3.8%) and residents (10.5%) who had tested positive for SARS-CoV-2 in the study period (1st March to June 19th, 2020). We emphasised that this would be an underestimate because it was based on manager recall of PCR test results, and many people who were infected in the first wave were not tested. 2724 (53·1%) care homes reported outbreaks, and 469 (9·1%) reported large outbreaks (defined as care homes with more than a third of the total number of residents and staff combined testing positive, or with >20 residents and staff combined testing positive). From this, we concluded that almost half or all care homes remained vulnerable to Covid-19 in July 2020 because they had not had cases in the first wave.

31. With regard to the use of disease control measures to reduce transmission of infection, the final conclusions based on all the data were that reduced transmission of SARS-CoV-2 from staff was associated with adequate sick pay, minimal use of agency staff, an increased staff-to-bed ratio, and staff cohorting with either infected or uninfected residents. Increased transmission from residents was associated with an

increased number of new admissions to the facility and poor compliance with isolation procedures. However, given the urgent need for data to inform policy, we also shared preliminary findings with policymakers, with the caveat that these results were work in progress and might be subject to change. Preliminary results were reported to the DHSC data debrief committee on 11th June 2020 [LS2/25 - INQ000544943], 18th June 2020 [LS2/26- INQ000544944] [LS2/27 – INQ000544945], 25th June 2020 [LS2/28 – INQ000544946] and to the Social Care taskforce on 1st July 2020 [LS2/29 – INQ000544947]. Final conclusions were presented to the DHSC data debrief group on 30th July 2020 [LS2/30 – INQ000544948] and published in the Lancet Healthy Longevity in March 2021 [LS2/09 – INQ000544929]. It is also important to note that the Vivaldi survey was a cross-sectional survey, which can identify associations between risk factors for infection and outcomes, but cannot be used to infer causality.

32. My records suggest that I had started sharing preliminary findings from the Vivaldi survey with the DHSC Data Debrief Group by 11th June, 2020. From memory all findings that were shared with the Data Debrief Group which met on Thursdays were also shared with the SAGE SCWG / PHE at their weekly meeting on Fridays.

33. I presented work in progress findings from the Vivaldi survey to the DHSC Data Debrief Group on 11th June, 2020 [LS2/25 – INQ000544943], based on data from 2,297 homes. The main message was to highlight the risk that staff working across multiple sites posed to residents.

34. I presented work in progress findings from the Vivaldi survey to the DHSC Data Debrief Group on the 18th June 2020 [LS2/26 – INQ000544944, LS2/27 – INQ000544945]. Survey results were available for 3,605 homes. Findings suggested that staff working across multiple sites might increase residents' risk of Covid-19. Early data also indicated that staff working across sites increased the risk of outbreaks.

35. I presented emerging findings from the Vivaldi survey on 25th June 2020 to the DHSC Data Debrief Group [LS2/28– INQ000544946], highlighting that regular use of agency staff was likely to be an important risk factor for infection in residents and staff. The data suggested that infections in staff were a risk factor for infection in residents and vice versa, but the magnitude of this effect suggested staff were more likely to transmit infections to residents than the other way around. Emerging data also suggested that the number of new admissions and return of residents to the care home from hospital

were important risk factors for infection in residents and staff. On 30th June 2020 I emailed the presentation that I had given to the Data Debrief Group to the Social Care Taskforce which was chaired by Sir David Pearson. The taskforce requested a briefing note which I shared on 1 July 2020 [LS2/29 –INQ000544947]. I attended a meeting of the Taskforce on 3rd July 2020. I do not have notes from this meeting but based on the slides that I shared, I believe that I highlighted the risks of using agency staff and staff working across multiple sites to the Taskforce. I also suggested there was some evidence that paying sick pay reduced the risk of infection.

36. On 29th July 2020 I presented finalised estimates of the proportion of staff and residents infected with SARS-CoV-2 to the Data Debrief Group [LS2/30 – INQ000544948]. I also recall presenting the finalised findings from the Vivaldi survey to the SAGE Social Care working group, [LS2/09– INQ000544929]. I believe this presentation took place on 18th September, 2020, but I have been unable to find any records to confirm this.

Impact and conclusions from the Vivaldi survey for policy

37. The Vivaldi survey had a significant impact on policy because we were able to generate results quickly, and at the time there was an absence of evidence on which to base policy decisions in care homes from the UK or internationally. Our preliminary findings suggesting that staff were more likely to infect residents than vice versa informed the decision to focus limited testing capacity for SARS-CoV-2 in the first wave of the pandemic on residents, rather than staff. The set-up of the Adult Social Care Infection Control fund was supported by two of the recommendations from the Vivaldi survey to minimise Covid-19 transmission in residential adult care: that movement of care workers between sites should cease and that care worker sick pay should be topped up by government. Findings from the Vivaldi survey were also cited in the final report and recommendations from the Social Care Sector Covid-19 Support Taskforce [LS2/31 – INQ000544949].

The decision to discharge people from hospital into care homes

38. An important question that is being addressed by the Inquiry and has been raised repeatedly by the care sector is whether the decision to discharge people from hospitals into residential care and nursing homes without testing in March-April 2020 seeded infection into care homes. The questionnaire used in the Vivaldi survey collected data from care home managers for the relevant period (1st March – June 19th

2020) on the number of new admissions to their care home, the number of residents who had been discharged back to the care home from hospital, and the subset of these that tested positive for Covid-19. Our intention was to use these data to explore the risks associated with new or returning residents entering the home. Unfortunately, these questions were poorly completed by care home managers. Only 80% of the 5126 care homes responded to the question about the number of admissions since 1st March 2020 and only 40% of care home managers answered the question on the number of residents returning from hospital and the subset with Covid-19. We did not collect data on the reasons why these questions were poorly completed, but I would speculate that it is because this information was not immediately accessible to care home managers, and that collecting data for a survey was likely to be a lower priority than providing care to residents, recognising that care homes were under extreme pressure during the period of data collection. These data quality issues were highlighted in my presentations to the Data Debrief Group on 25/6/20 [LS2/28 – INQ000544946], my briefing note submitted to the Social Care Taskforce on 1st July 2020 [LS2/29 – INQ000544947], and described in detail in the supplementary appendix which was published alongside our academic publication describing the Vivaldi survey in March 2021 [LS2/23 – INQ000544942].

39. Our preliminary analyses indicated that the number of new admissions to their care home, the number of residents who had been discharged back to the care home from hospital, and the subset of these that tested positive for Covid-19 might be associated with increased risk of infection in residents and staff, however it was my strong view that this was not a question we could answer reliably using our data for a number of reasons. We had a very high proportion of missing data in the two key variables (number of discharges from hospital, number of Covid-19 cases discharged from hospital to the care home). We considered using statistical methods such as multiple imputation to address the problem of missing data, but these work best when there is not a large amount of missing data. I was also concerned that our study design meant there was a risk of recall bias (e.g. managers in homes with outbreaks may have been more likely to remember residents who were discharged from hospital with Covid-19 compared to homes that did not have outbreaks). Testing for Covid-19 was extremely limited during the period of data collection which means there was significant under-ascertainment of Covid-19 cases in residents and staff. This made it difficult to investigate the relationship (directionality) between discharge of residents from hospital into the care home and onward transmission of infection to other residents and staff. We were also unable to account for other routes of transmission such as ingress of

infection from staff or visitors. Finally, our small study team was overstretched with limited analytical capacity and we were under significant pressure to produce results. I therefore prioritised addressing our primary and secondary research questions in the Vivaldi survey, and setting up the Vivaldi cohort study to get a more accurate assessment of the burden of infection based on antibody (blood) testing. I discussed the limitations of our data as outlined above with our DHSC project manager Alasdair Donaldson, with the expectation that this would be communicated to policymakers within DHSC. When the question of whether the decision to discharge people from hospitals into residential care and nursing homes without testing in March-April 2020 seeded infection into care homes was discussed at the SAGE SCWG, I explained why were unable to address this question directly using data from Vivaldi.

40. To comprehensively address the question of how Covid-19 infections entered care homes, and the relative importance of different routes of transmission would have required a longitudinal and complex research study, comprising comprehensive and regular testing of residents, staff and ideally visitors, collection of detailed data on the timing of infection, and ideally whole genome sequencing to estimate the directionality of person-to-person transmission. It was not possible to conduct this type of study during the first phase of the pandemic, and to my knowledge there have been no examples of this type of study in the UK or internationally. The ability to stand-up a study like this would require considerable investment in research and data infrastructure in 'peacetime', but in the event of a future pandemic it would transform our ability to 1) monitor infections and their severity in care homes in near real time and 2) rapidly evaluate (via pragmatic clinical trials) the benefits and harms of new drugs or interventions (e.g. point of care testing) which seek to prevent disease transmission. Better surveillance in this setting could also benefit the general population by acting as a 'canary in the mine' providing early warning of emerging infections or other threats that are likely to manifest first in vulnerable populations such as care home residents. Building on our experience conducting research in the Covid-19 pandemic, we are working towards establishing the research and data infrastructure that would be required for such a study in the Vivaldi Social Care project which is described in paragraphs 62-64. In my opinion, there are three outputs from the Vivaldi survey that are of relevance to the question of how Covid-19 infections entered the care home: 1) data on new admissions, 2) data on the relative importance of staff-to-resident versus resident-to-staff transmission, 3) data on staff behaviours associated with increased infection transmission. However, it is important to emphasise that the Vivaldi survey involved collecting data from care home managers at a single point in time, so we lack

data on the specific timing of infections relative to events such as admission to the care home.

41. The first output relates to collection of data from care home managers on the total number of new admissions to the care home since 1st March 2020. Our finalised analysis showed there was a statistically significant association between the number of admissions to the care home and 1) infections in residents, 2) infections in staff, 3) outbreaks. This suggested that new entrants to the care home were a source of infection, but it provides no insight into the relative importance of this route of transmission compared to ingress of infection from staff or visitors. Our cross-sectional study design also introduces the risk of reverse causality: homes with large number of cases and outbreaks had more admissions because they had more empty beds. The second output also relates to preliminary analyses which were shared with the DHSC Data Debrief Group, the SAGE SCWG and the Social Care Taskforce [LS2/28 – INQ000544946]. Survey data suggested that the prevalence of infection in residents was a risk factor for infection in staff, but that this effect was weaker than the effect of staff infection on residents. This was based on the finding that "*Every one unit increase in the total number of resident infections increases the odds of infection in staff by 4%, but every one unit increase in the total number of staff infections increases the odds of infection in residents by 11%.*" This provides some evidence on the relative importance of staff in driving transmission of infection. Thirdly, we identified a number of staff related risk factors that were associated with increased risk of infections and outbreaks, such as lack of sickness pay and movement of staff between care homes. These factors pointed to the important role of staff in transmission of infection.

42. As outlined in 'Figure 1: schematic showing potential routes of ingress of Covid-19 into care home settings' in the SAGE Consensus statement on the association between the discharge from hospitals and Covid in care homes [LS2/32-INQ000215624], there are seven potential routes by which infection might have entered the care home. Findings from the Vivaldi survey pointed to the important role of staff in transmission of infection and highlighted that new admissions to the care home were a potential source of SARS-CoV-2 infections. However, we did not collect data on all seven routes of transmission in Vivaldi, so I am unable to comment on the relative importance of each of these sources. It is my view that our findings were compatible with SAGE's 'Consensus statement on the association between the discharge of patients from hospitals and Covid in care homes' dated 26 May 2022 [LS2/32-INQ000215624] and

the following statement in the CMOs' 'Technical report on the Covid-19 pandemic in the UK' dated 1 December 2022 [LS2/33-INQ000203933_0298] "*Epidemiological and genetic evidence from across the UK suggests that for COVID-19 while some care home outbreaks were introduced or intensified by discharges from hospital, hospital discharges does not appear to have been the dominant way in which COVID-19 entered most care home*".

43. In my opinion, findings from the Vivaldi survey partially support the statements made by the Right Honourable Matthew Hancock on page 231 of 'Pandemic Diaries' entry for 16 July 2020 ("*The main takeaway is that the virus is primarily being brought in by staff, not elderly people who've been discharged from hospital")* and Paragraph 49 of the Right Honourable Matthew Hancock's M2 Witness Statement [INQ000232194] *"a widespread concern has been that patients who were discharged from hospitals were the main cause of infections in care homes. While I understand why so many people hold this view, we now know that this is not the case. During the summer of 2020 I was made aware of initial evidence showing that movement of staff between care homes was the main source of transmission, and asked for urgent work to be undertaken to place restrictions on such movements."* Whilst it is accurate that Vivaldi provided evidence supporting the important role of staff in transmission of infection, and particularly the risks associated with movement of staff between care homes, the survey did not provide evidence on the relative importance of different modes of transmission. It is therefore in my view going beyond what can be concluded from the Vivaldi survey to state that 'movement of staff between care homes was the main source of transmission'.

Key findings from the Vivaldi cohort study

44. As mentioned in paragraph 12, my team established the Vivaldi cohort study alongside the Vivaldi survey to get an accurate estimate of the proportion of surviving staff and residents who had been infected with SARS-CoV-2 based on antibody (blood testing). I also wanted to track what happened to residents and staff over successive waves of the pandemic. The study began in 100 care homes that were owned by Four Seasons Healthcare. At the request of the DHSC we expanded the study to more than 300 care homes from October 2020. As described in paragraph 23, the introduction of the COPI notice created the opportunity to use data on all residents and staff in participating care homes. This gave us the flexibility and sufficient analytical power to address emerging

public health questions over successive waves of the pandemic. The linked dataset, which was established and stored in the NHS Foundry underpinned all of our subsequent research studies. I have summarised the most important research outputs from the Vivaldi cohort study below. I regularly presented preliminary and finalised results at the weekly meetings of the DHSC Data Debrief Group and the SAGE Social Care Working Group. I also presented findings from the cohort study on multiple occasions to scientific advisory groups such as the New and Emerging Respiratory Viruses and Threats Advisory Group (NERVTAG).

45. Following the survey, our first priority in the cohort study was to estimate the proportion of staff and residents who had been infected in the first wave of the pandemic based on antibody testing and to quantify the risk of reinfection in those with antibodies. These findings are described in detail in our academic paper entitled 'Incidence of SARS-CoV-2 infection according to baseline antibody status in staff and residents of 100 long-term care facilities (VIVALDI study): a prospective cohort study', which was pre-printed on Medrxiv on 10th March 2021 and published in The Lancet Healthy Longevity in June 2021 [LS2/10 – INQ000544930]. Using data stored in NHS Foundry and blood samples collected through the cohort study from more than 2000 care home residents and staff, we estimated that 33% of surviving residents and 29% of staff had antibodies showing they had been infected in the first wave. The estimate for residents was approximately three-fold higher than that reported in the Vivaldi-1 survey, which was based on PCR test results. This difference is not surprising. It shows that many people who were infected in the first wave did not have access to PCR testing, whereas antibodies remain detectable for many months post-infection. To investigate rates of (re) infection, we compared rates of PCR positive infection (between October 2020 and February 2021) in residents and care home staff who had evidence of a previous infection up to 10 months earlier (antibody positive), with those who had not had an infection (antibody negative).

Residents with a previous infection (antibody positive) were 85% less likely to be infected than residents who had never been infected (antibody negative), while staff with past infection were 60% less likely to get infected than staff who had not had the infection before. These findings were presented to the DHSC Data Debrief Group, the SAGE SCWG and to NERVTAG. Findings provided insights about the risk and characteristics of re-infections. They also provided reassurance to care providers, policymakers, residents and staff that people who had survived Covid-19 were at lower risk of reinfection.

46. In England, cases and hospital admissions for SARS-CoV-2 increased rapidly in autumn 2020 associated with the emergence of the first (alpha or B.1.1.7) SARS-CoV-2 variant. Care homes were subject to stringent disease control measures at this time, so it was hoped that this would be sufficient to prevent ingress of infection from the community. Our research study investigating this issue entitled 'Spread of a Variant SARS-CoV-2 in Long-Term Care Facilities in England' was published in the New England Journal of Medicine on March 21, 2021 [LS02/16 – INQ000544936]. The study demonstrated that the new variant was rapidly entering care homes by using detailed information on PCR test results to differentiate 'old' and 'new' SARS-CoV-2. The proportion of infections caused by the new variant rose from 12% in the week beginning 23 November to 60% of positive cases just two weeks later, in the week beginning 7 December. In the South East of England, where the variant was most dominant, the proportion increased from 55% to 80% over the same period. In London, where the variant spread fastest, the proportion increased from 20% to 66%. Findings were presented to the DHSC Data Debrief Group, the SAGE SCWG, to the New and Emerging Respiratory Viruses and Threats Advisory Group and were also shared by email with the Chief Medical Officer and the Chief Scientific Advisor. My understanding is that these findings were discussed at the SAGE meeting on 22nd December and informed policy decisions about the ongoing need for disease control measures in care homes.

47. Vaccines against viruses such as influenza are often less effective in frail care home residents compared to the general population and the clinical trials that evaluated SARS-CoV-2 vaccines did not include care home residents. There was significant concern that the SARS-CoV-2 vaccines might not provide residents with adequate protection, and an urgent need to evaluate the effectiveness of vaccination in residents to inform policy. We addressed this question in our paper entitled 'Vaccine effectiveness of the first dose of ChAdOx1 nCoV-19 and BNT162b2 against SARS-CoV-2 infection in residents of long-term care facilities in England (VIVALDI): a prospective cohort study' which was pre-printed in MedRxiv on March 26, 2021 and was published in the Lancet Infectious Diseases in November 2021 [LS2/14 –INQ000412930]. Using our Vivaldi cohort and linked data, our analysis looked at the effectiveness of a single vaccine dose (Pfizer or Oxford/AstraZeneca) against infection with SARS-CoV-2, using routine PCR test results for 10,412 residents (aged 65+ years) from 310 care homes across England. We observed vaccine effectiveness to be 56% between four and five weeks after vaccination, and 62% between five to seven weeks, with similar timing and level of protection for both vaccine types. Additionally, we found that people with prior infection

were already well protected irrespective of vaccination status; and average Cycle Threshold (Ct) values of PCR-positive tests were higher from 28 days after vaccination compared to before vaccination (31.3 vs 26.6) - suggesting lower viral load, and therefore potentially reduced transmissibility, due to vaccination. I presented these findings to the Minister for Social Care on 10th March 2021 and to the DHSC Data Debrief Group and the SAGE SCWG during the same time period. My colleague and I presented our findings in the week commencing 15th March 2021 to the Joint Committee for Vaccinations and Immunisations (JCVI), and the Medicines Healthcare Regulatory Agency (MHRA) on 18th March 2021. My understanding is that these findings informed JCVI policy on vaccination of care home residents and staff by providing estimates of the effectiveness of vaccines that were being used in this population in the UK.

48. Having assessed the effectiveness of primary course vaccination in residents, our next priority was to investigate the duration of vaccine-induced protection in residents and staff. We did this in two ways, first by assessing the immune response following vaccination and natural infection, working in collaboration with Professor Paul Moss at the University of Birmingham and second using the Vivaldi data infrastructure to estimate the risk of infection, hospitalisations and deaths in people who were vaccinated compared to those who were not vaccinated. We assessed the immune response post vaccination in our paper entitled 'The Profile of humoral and cellular immune responses to single doses of BNT162b2 or ChAdOx1 nCoV-19 vaccines in residents and staff within residential care homes (VIVALDI): an observational study' [LS2/11 – INQ000544931]. The paper was pre-printed on 4th May 2021 and subsequently published in The Lancet Healthy Longevity in September 2021. This study aimed to assess the magnitude of protection of a single dose of Covid-19 vaccine in care home residents and staff given the extended interval between vaccines doses that was adopted in the UK. Blood samples were collected from residents and staff before and after they received their first dose of vaccine. We found out that after a single dose, residents without a prior infection made lower antibody response and were much slower at generating an antibody response to vaccine, taking >21 days for them to catch up to the younger staff members. However, residents made comparable cellular immune responses to younger staff members after a single vaccine dose. Those with prior infection status showed strong immune response to variants of concern. We also used the Vivaldi data infrastructure to monitor the duration of vaccine effectiveness in residents and staff in our paper entitled "Duration of vaccine effectiveness against SARS-CoV2 infection, hospitalisation, and death in residents and

staff of Long-Term Care Facilities (VIVALDI): a prospective cohort study', which was pre-printed on March 18th 2022, and published in the Lancet Healthy Longevity in July 2022 [LS2/15 – INQ000544935]. This study investigated the effectiveness of one, two, and three vaccine doses against PCR-confirmed SARS-CoV2 infection and against hospitalisation and death related to Covid-19 in residents and staff from more than 330 VIVALDI care homes between December 2020 and December 2021. Results demonstrated high effectiveness of two doses, irrespective of vaccine type, for 3 months after receiving the second dose; however, protection appeared to decline substantially over time. The significant waning of protection against more severe outcomes in residents was especially notable as this had not been observed for other population groups, and was not observed for staff within our study. Reassuringly, however, a third booster dose restored very high levels of protection against all outcomes across all groups, including for staff and those previously infected, illustrating the benefit to everyone of receiving three vaccine doses. Findings from these studies were shared widely including with the DHSC DDG, with PHE and with the SAGE SCWG. My understanding is that findings contributed to the accumulating body of knowledge on waning immunity and informed decisions about the need for and timing of booster vaccination in care home residents and staff.

49. Following the emergence of the highly transmissible Omicron variant, there were major concerns that there could be a rapid and significant increase in hospital admissions and deaths in care home residents. We used the Vivaldi cohort study to compare rates of hospitalisation and death in residents in the period before and after the arrival of the Omicron variant, as described in our paper entitled: 'Outcomes of SARS-CoV-2 Omicron infection in residents of long-term care facilities in England (VIVALDI): a prospective, cohort study', which was pre-printed on 27th January 2022 and published in the Lancet Healthy Longevity in May 2022 [LS2/17 – INQ000544937]. In this study data were included from over 1600 residents with confirmed Covid-19 infection. The study found that people infected with the virus after 13 December 2021 (when Omicron was dominant) were 50% less likely to be admitted to hospital after infection than those infected before 12 December 2021 (when the Delta variant was dominant) and were less likely to die following infection. This was reassuring because it suggests that although Omicron infections were more transmissible than Delta, the infections that were caused by Omicron in residents were not as severe as Delta. These findings were shared widely including with the DHSC DDG, with the SAGE SCWG, and with PHE. My understanding is they informed decisions about the scale of disease control measures that were required in care homes.

50. We also undertook a clinical trial called VIVALDI-CT which was funded by the National Institute of Health and Care Research (NIHR) in autumn 2022 and began recruiting care homes in January 2023. The trial aimed to investigate the benefits and harms of regularly testing care home staff for SARS-CoV-2 (with provision of sickness pay for those that tested positive and funding for agency staff backfill) to protect residents from severe outcomes following infection. I have not described the trial because it took place after 28 June 2022, but further information is available in the published protocol [LS2/34– INQ000544950]. I have mentioned the trial in my witness statement because learning from this study is relevant for future research, surveillance and pandemic preparedness in care homes.

Lessons learned

51. When we started the Vivaldi study, there was no pre-existing research or data infrastructure in care homes to support the setup of a care home research study. The network of care homes that participated in Vivaldi and all the data, data linkages, ethical and information governance approvals and contractual arrangements (e.g. funding, data sharing agreements) had to be created from scratch. This was a very significant amount of work which was delivered almost entirely by the UCL research team, with support from individuals working in NHS Foundry, NHSE (in relation to information governance) and our DHSC project manager (initially Alasdair Donaldson, then Aidan Irwin Singer). In my view the project was highly dependent on the knowledge and skills of the UCL researchers. This emphasises the important role that academics and those outside Government play in responding to a pandemic or other public health emergency. Rapid set up of a future study such as Vivaldi would have been facilitated by strong, pre-existing relationships between policymakers in DHSC and PHE and researchers so that we all had a better mutual understanding of each organisations culture and ways of working, rather than being forced to 'skill up' very quickly in a pandemic. For example, it would have been much easier to set up funding contracts if DHSC finance colleagues had been familiar with how University finance systems operate. As a researcher, I was totally reliant on my DHSC colleague Alasdair Donaldson to gain access to relevant meetings and information and to ensure our research findings were reaching the relevant audiences across Government. Prior experience of working with policymakers would have helped, but it is also essential that

academics are paired with individuals within Government who have the experience and networks to communicate important research findings quickly.

52. Care home residents, staff and family members have often had no exposure to research, and there is no established culture of research in care homes, unlike the NHS. To expedite set up of research studies in care homes in future there is a need for investment in research training and capacity building for care home staff to increase their research awareness, and ensure that they have the knowledge, skills and confidence to communicate the importance and benefits of research to their colleagues, to residents and to family members. This would have made it much easier to establish the blood sampling part of the Vivaldi study, because care homes would have required less training to support research delivery and been familiar with research processes.

53. A lot of research that was conducted in the Covid-19 pandemic relied upon, or was augmented by access to population-wide routinely held data. A major barrier to research in care homes is our inability to reliably identify care home residents or staff in these datasets because there is no national 'registry' of care home residents and staff. For example, if you want to know how many people aged >65 years have been admitted to hospital with a urinary tract infection (UTI) this information can be derived fairly easily (albeit imperfectly) using a national database called Hospital Episode Statistics (HES). Yet we cannot reliably estimate the number of care home residents who are admitted to hospital for a UTI, or any other condition, because there we do not have an accurate system to 'flag' or identify residents in HES or other routinely collected data systems. Various approaches have been used based on resident's addresses, but those staying in a care home temporarily, for example for reablement following discharge from hospital, are automatically excluded because their recorded address relates to their permanent home rather than the care home. This really matters when trying to estimate how frequently infections are transmitted from hospital to care homes, for example when a resident is discharged from hospital. During the pandemic, we capitalised on the fact that residents and staff were being regularly tested for Covid-19 to establish a registry of care home staff and residents, because PCR tests were labelled with NHS numbers (identifying individual residents and staff) their care home identifier, and the date of testing. This meant we could infer who was in each care home on a specific day. Now regular testing for Covid-19 has ceased we need a new way to develop and maintain a care home registry. If another pandemic occurred

tomorrow, we would still not be able to reliably measure rates of hospital admissions or A&E attendances in care home residents or staff.

54. As a member of the SAGE Social Care working group we were often reminded that our role was to provide scientific advice, not to consider how to implement policy. I think this undermined the effectiveness of some of our work. Liz Jones from the National Care Forum was an active member of the SAGE SCWG, but there was very little representation of the care providers and /or carers. Greater representation of people with direct experience of working in social care would in my view have been extremely helpful when considering how to implement policy recommendations derived from research.

55. A major focus in Vivaldi was to generate findings that informed policy, however working on policy timescales is a challenge for researchers who are naturally cautious and are used to checking and re-checking their results before publication. I had to step 'outside my comfort zone' to produce findings quickly because I realised it would be futile to generate 'perfect' results six months after they were required. However, it would have been helpful to have discussed this issue explicitly with policymakers, to agree expectations and ensure that everyone understood the risks of over or mis-interpreting research findings. It would be useful if for all policymakers to all have a grounding in statistics, data and the limitations of different types of research studies.

56. Increased clarity about the roles and responsibilities of different types of organisations involved in the pandemic response would support a more effective response to a future pandemic or other public health emergency. For example, when it became clear that data on care homes was inadequate, who was responsible for addressing this? Did responsibility for addressing data access and governance lie with researchers, public health specialists within organisations such as PHE or NHSE, with policymakers, or with other organisations? Many of the data issues that we encountered were systemic issues that to the best of my knowledge affected most of the Covid-19 surveillance studies (e.g. CIS, REACT). In Vivaldi responsibility for addressing these issues lay with the research team.

Recommendations for future pandemic preparedness

57. To respond to future pandemics or other public health threats requires accurate data and the ability to generate research evidence rapidly. Many of the barriers to research that we encountered in the Vivaldi study could be addressed by investment in three areas: care home data infrastructure, partnerships between academia, policymakers and care providers, and research training and capacity building for care home staff. This would deliver high-quality surveillance of infectious diseases in care homes and the research capacity and capability to respond to a future public health threat. These three areas are described in more detail in the following three paragraphs.

58. There is a need for reliable, accurate, individual-level information on who lives and works in a care home. The only organisations which hold this information currently are the care homes themselves, but there are a large number of providers and this information is not shared or held centrally. Therefore we need a mechanism to safely, securely and regularly extract this data from care homes (without creating additional work for care home staff) and for it to be linked to other datasets that are held by the NHS. This would permit monitoring of the burden of infection, and potentially other conditions in residents and staff in 'peacetime'; it would also ensure that we can respond rapidly in the event of a pandemic or other public health emergency. Ideally the data would be linkable in near real-time. This was the approach that was used in the Vivaldi study during the Covid-19 pandemic, capitalising on data infrastructure that had been created in NHS Foundry. Importantly, all the work that we did in Vivaldi was contingent on the Covid-19 testing program. Consequently when testing ceased we lost the ability to monitor infections and related outcomes in residents and staff. Systems such as Capacity Tracker which were developed during the Covid-19 pandemic provide useful care home level data, but this is no substitute for individual level records which are required to monitor the severity of infections, or to assess the effectiveness of new treatments or vaccines. Without new data systems to monitor infections in care homes, we will in my view continue to be poorly prepared for future pandemics.

59. Research is part of the NHS constitution, but there is not a culture of research in social care. In Vivaldi we prioritised building strong partnerships with care providers, but the study was designed without the input of people who live and work in care homes because it had to be established rapidly. Over time, the research team has built strong relationships with residents, families, care home staff and providers, by partnering with organisations that represent these groups (e.g. Care England, the National Care Forum), Community Interest Companies that promote quality in social care (e.g. The

Outstanding Society) and with campaign groups (e.g. Rights for Residents). These partnerships are fundamental to the delivery of high quality, inclusive research in care homes, but it takes time (years) to build these relationships and establish the level of trust that is required to work together effectively. It would be valuable to establish a permanent, funded group of individuals with lived experience of care homes who can represent the views of residents, staff and family members in the event of a future pandemic or other public health emergency. This would reduce the risk that policy decisions have unintended and unforeseen consequences. It would also ensure that care home research studies are only funded if they are feasible and practicable.

60. Research is not part of care workers' roles, so line managers may justifiably be reluctant to release their staff to support research delivery and very few carers have training or experience of research. The National Institute for Health and Care Research (NIHR) Research Delivery network (RDN) provides support to care homes with the goal of increasing their participation in research studies, but these staff are not based within care homes which limits their ability to support study delivery. There is an urgent need to provide research training and capacity building in care homes to create an embedded workforce who can support research delivery and work towards a culture of research in social care. This would ensure that care homes have the skills, expertise, agility and confidence to participate in the types of rapid, complex research studies that may be required as part of the public health response. Research training and capacity building for care home staff could also provide new career pathways for people working in care homes, helping to address sector-wide challenges in recruitment and retention.

61. Finally, there is a need for specific research studies to address gaps that were revealed by the Covid-19 pandemic. For example, there was widespread recognition that measures such as care home closures, visitor restrictions and facemasks could be detrimental to residents, but there was no mechanism to quantify harms from the perspective of residents or family members, which made it difficult to factor these issues into public health decision making. To prepare for future pandemics we need a better understanding of the priorities of residents and families and the trade-offs that they might be willing (or unwilling) to make (e.g. self-isolation) to protect themselves and others. This type of research needs to be conducted in advance of a future pandemic or other threat.

The Vivaldi Social Care project

62. I felt very strongly that we needed to learn from our experiences in Vivaldi. In 2021, I began talking to other academics and representatives from the care sector to explore if there was interest in establishing a new post-pandemic care home study. Its aim was to reduce the impact of the major causes of infection in care homes, such as influenza, Covid-19 and norovirus, which cause outbreaks that have a major, detrimental impact on residents, their families, and care providers. Infections and outbreaks, which are often preventable, also affect the wider health and care system by driving NHS winter pressures and closing care homes so residents cannot be discharged from hospital. I realised that such a study would only work if it was strongly endorsed by, and ideally led by, the care sector. This led to the set-up of a new program of research called 'Vivaldi Social Care' which is a partnership between UCL, the Outstanding Society and Care England. We also work closely with other care sector organisations such as the National Care Forum.

63. Vivaldi Social Care is a 12-month pilot study which is collecting data on residents directly from care homes via residents' digital care records, irrespective of how they are funded, so all residents have the opportunity to be included. This also means we capture data on people who are in care homes temporarily, for example, following discharge from hospital, which is essential to understand how people move between health and care settings. The project was coproduced with the care sector, and has been designed in a way that minimises the workload associated with participation, making it feasible for care homes to take part. The whole project is overseen by residents, their families, care home staff and providers and it is funded by the UKHSA and the NIHR. Further details about the study are available on our website, in our explainer video and in the study protocol [LS2/35 – INQ000544951], [LS2/36 INQ000544952], [LS2/37 – INQ000544953]. The study has two main goals: to demonstrate that it is feasible to collect data on residents from care providers and link it to NHS records, and to demonstrate the value for care providers and policymakers of sharing data by benchmarking rates of infection and hospital admission across care homes.

64. Approximately 700 care homes in England are participating in the project. Data collection began on 27th January 2025, and we anticipate sharing the first set of results in September 2025 (allowing 6 months to accrue sufficient data for meaningful results). Our current focus in the project is to reduce the impact of infections (e.g. flu, norovirus) because we know this is a priority for residents and their families. Longer term, we hope to support a portfolio of research studies on conditions such as dementia,

polypharmacy, mental health and falls prevention. In parallel, we are starting to develop and pilot a program of research training and capacity building for care home staff, which is essential if we want to deliver more complex and impactful research studies, such as clinical trials of new vaccines or future treatments for dementia. We anticipate that investment in training for care home staff will create new career pathways and opportunities. Hopefully it will also incentivise staff members to continue working in the sector. If the project is successful, our ambition is that it would be supported as part of national public health research infrastructure. This would transform our ability to deliver public health research in care homes and ensure we are better prepared for a future pandemic.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: **Personal Data**

Dated: 2nd May 2025