Witness Name: Jon Deeks

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UK COVID-19 INQUIRY

WITNESS STATEMENT OF JON DEEKS

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I, Jon Deeks, will say as follows: -

1 Background

1.1.1 I graduated as a medical statistician in 1989 and have been employed at the Universities of London (1989-94), York (1994-95), Oxford (1995-2006), Sydney (2003-4) and Birmingham (2006- current). I was elected as a Fellow of the Royal Statistical Society in 1990 and received Chartered Statistician status in 2007. I was awarded Senior Investigator status at the National Institute of Health Research (NIHR) in 2010, NIHR Emeritus Senior Investigator status in 2018, and the Fellowship of the Academy of Medical Sciences in 2021.

1.1.2 In my academic career, I have pursued an interest in evaluating diagnostic tests since 1995. I accepted a secondment post as the Senior Research Statistician at the Screening and Test Evaluation Programme at the University of Sydney in 2003 which enabled me to follow my interest and develop my experience and expertise. This was followed by receiving a Department of Health Senior Research Fellowship based at the University of Oxford from 2004-2007. This enabled me to develop a growing portfolio of clinical and

methodological studies evaluating diagnostic tests across multiple disease areas. Since 2006 I have been Professor of Biostatistics at the University of Birmingham and have led a successful research group on test evaluation linked with national and international groups.

1.1.3 The evaluation of a new test first requires initial laboratory evaluations to understand its performance using selected (and sometimes contrived) samples. If laboratory evaluations show that a test could perform appropriately (measuring its analytical performance), a second stage evaluates the test's performance when used by people to whom the test will be applied for a specific role in clinical and real-life settings (measuring its clinical performance). The importance of these stages is described in detail in the RSS Witness Statement and the basis of Recommendations 1, 2 and 3 in the RSS Working Group on Diagnostic Test (WGDT) original report (JJD/01-INQ000114774) and its update (JJD/02-INQ000531106), which I jointly led. Most of the focus of my research has been on studies of this second stage – in terms of their design and delivery, evaluating the methods by which these studies should be done, and systematically reviewing studies to summarise the total evidence that exists on the performance of tests for each role and in each situation to inform evidence-based clinical decision making. I have also been involved in early-stage and laboratory studies through my leadership of the diagnostic themes in the NIHR Birmingham Biomedical Research Centre since 2017.

1.1.4 My expertise in evaluating tests is documented in publications in my CV – currently, this includes 78 primary studies of tests, 67 systematic reviews of tests, and 79 papers, books and chapters developing and explaining the methodology of test evaluation (another 264 publications in my CV cover statistical issues other than test evaluation). Tests that I have evaluated include many in vitro diagnostic tests (e.g., blood tests for tuberculosis), imaging tests (e.g. ultrasound, MRI), and physiological tests (e.g. pulse oximetry measures). I have been involved in studies which have changed diagnostic practice in diagnosing tuberculosis, detecting prostate cancer, ovarian cancer and congenital heart disease in newborns, among other conditions.

1.1.5 I have been involved in conducting systematic reviews of healthcare interventions since 1994 through the Cochrane Collaboration. The Cochrane Collaboration is an international, not-for-profit organisation that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions. Systematic reviews were developed out of a need to ensure that decisions affecting people's lives can be informed by an up-to-date and complete understanding of the relevant research evidence. By systematically assessing primary research studies systematic reviews aim to provide an up-to-date summary of the state of research knowledge on an intervention, diagnostic test, prognostic factor or other health or healthcare technology. Cochrane reviews are widely used in decision-making and guidelines. The Cochrane Collaboration is a key partner with the World Health Organisation (WHO) and provides input on the way research evidence is identified, synthesized, assessed and used by WHO in their international guidelines.

1.1.6 In 2003 I led a team in the Cochrane Collaboration to develop a portfolio of Systematic Reviews of Diagnostic Test Accuracy, which involved: describing and obtaining consensus on the methodology to follow (recently published as a textbook Deeks JJ, Bossuyt PM, Leeflang MM, Takwoingi Y (editors). Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. 1st edition. Chichester (UK): John Wiley & Sons, 2023); developing software to complete the statistical analyses and publication; and following an editorial process that ensures reviews are readable and reliable. The work to deliver this process was the main activity I undertook during my Department of Health Senior Research Fellowship from 2004-2007 with the help of a worldwide network of collaborators. This experience enabled me to lead the Cochrane activity in completing and publishing systematic reviews of Covid-19 tests, as I explain in Section 3.

1.1.7 The WHO Essential Diagnostic List (EDL) is a priority list of medical tests which should be available in all health services in countries supported by WHO and available as an online database (JJD/03-INQ000531107). The EDL provides guidance for individual countries, on which medical tests to use and which not to. The EDL is a companion to the WHO Model List of Essential Medicines which has been maintained since 1977.

1.1.8 I was requested to join a WHO group to create the first WHO EDL in 2018. I was appointed as a member of their Strategic Advisory Group of Experts in vitro diagnostics (SAGE IVD) to advise on matters of global policy and strategy related to IVDs, including advising WHO on the tests to be included in the WHO EDL. WHO SAGE IVD members are appointed to serve a two-year term in their personal capacities, and represent the broad range of disciplines required to advise on the many aspects of in vitro diagnostics and other clinical laboratory-related activities. Members of the SAGE IVD were selected and appointed by the Director-General or by the Assistant Director-General of the Access to Medicines and Health Products Division of WHO. I was one of three UK members of the original SAGE committee in 2018 and was appointed on the basis of my expertise in evaluating tests. I continued to support the EDL as a consultant through to 2020.

1.1.9 Information about the methods used in developing the EDL are explained in Section 2 of my statement as they provide a model that could be used to evaluate new tests as occurred during the Pandemic.

1.1.10 I have had a role as a statistician at the BMJ since 1993 and have been the BMJ Senior Statistical Advisor since 2018. My role ensures that publications at the BMJ are assessed for statistical correctness through a process of statistical peer review and discussion at the weekly Manuscript Meeting. Statistical assessment is delivered by a team of experienced statisticians, which I was leading from 2018 until 2021. The BMJ editors and journalists use my expertise to question statistical issues and concerns that occur in publications and investigations. This role continued during the pandemic.

1.1.11 Given my expertise in test research, the BMJ editors and journalists frequently requested my advice on issues that occurred on test evaluation during the pandemic. This often took the form asking for me to make expert comments in news stories in the BMJ related to test evaluation. I was also requested to speak on five BMJ Talk Evidence podcasts on tests for a medical audience and BMJ blogs, and to author two editorials. These are summarised in Section 5, and listed in an appendix in Section 8.

1.1.12 My role within the Royal Statistical Society (RSS) during the Covid-19 pandemic included membership in the RSS Covid-19 Task Force

(commencing on 24th March 2020) and co-chair of the RSS Working Group of Diagnostic Tests (WGDT) (commencing in June 2020). I was also a member of the RSS and Department of Health and Social Care (DHSC) Panel alongside Professor Sheila Bird. Activities in these roles are covered by the Witness Statement with the RSS which I will not duplicate.

1.1.13 During my career, I have observed and been part of a developing community of experts who have experience in evaluating tests in clinical and real-world settings. The NIHR has largely supported this through funding programmes, such as the NIHR Health Technology Assessment programme (I was a member of the NIHR Health Technology Assessment Theme Board on Diagnostic Tests and Test Technologies from 2009-2010 and served as Deputy Chair of the NIHR Health Technology Assessment Commissioning Board from 2011-2016). The NIHR programme has been a world leader in organising and evaluating tests through its direct linkage to NHS Hospitals, NHS Primary Care, Public Health, and University Clinical Trial Units, who are staffed by experts in trials and study design, trial management, data management, data programming, quality control monitoring, and medical statistics. I held the role of Director of the Birmingham Clinical Trial Unit from 2012 to 2016. In an emergency such as a pandemic, the network of NIHR Clinical Trial Units is well-positioned to be able to deliver high-quality studies competently and at high speed. Some units have expertise in diagnostic tests (JJD/04-INQ000531108). The independent evaluations of the Innova test at the University of Birmingham and the University of Liverpool covered in Section 4 are examples of studies that benefited from support from members of Clinical Trial Units.

1.1.14 NIHR commissioned Diagnostic Evidence Co-operatives in Imperial College London, Oxford, Leeds and Newcastle in 2014 (these were re-named as the NIHR Medtech and In vitro diagnostic Co-operatives in 2017 and subsequently as the NIHR HealthTech Research Centres in 2024). My team at the University of Birmingham had funding from the Diagnostic Evidence Co-operatives, and I acted as chair of the NIHR Diagnostic Evidence Co-operatives methods group (2014-2016) to assist and build expertise and capacity in the NHS to develop new medical technologies and provide evidence on commercially supplied in vitro diagnostic (IVD) tests. I have remained part of the active community in this field but, had no involvement in

the work that the teams did during the pandemic, although I am aware that they had roles in evaluating new tests and attended meetings with Advisory Groups in the DHSC. This involved the Falcon Study, which is mentioned in the Porton Down/University of Oxford evaluation of Innova (see Section 4.2).

1.1.15 Given my expertise in test evaluation, during the pandemic, I took the initiative to communicate and explain findings and claims of the accuracy of diagnostic tests to the public and the media. I took on this role as it quickly became clear that there was confusion, misinformation, and poor understanding of test accuracy and the processes by which new tests need to be evaluated. I had no previous experience in writing and talking with journalists, and I quickly obtained training through the University press office. My activities included talking to medical journalists, writing comments for the Science Media Centre (SMC), and explaining findings, methodology and statistical understanding through Twitter. I gave interviews on national and local radio and television. I briefly summarise activities and themes in Section 5 in my statement, with longer lists in the Appendix in Section 8.

1.1.16 I was appointed by the Medicines and Healthcare products Regulatory Agency (MHRA) as a member of their IVD Expert Advisory Group (MHRA IVD EAG) in March 2021 when this group was first created. I provided expert help on statistical issues with the MHRA in March 2020 - at this point, it was mentioned that they were considering forming an external advisory group, but this did not happen until one year later. I summarise two key documents I was involved in as part of MHRA IVD EAG in Section 6 in my statement.

1.1.17 In Section 7 I conclude my personal observations on the conflicts in the evaluation of tests during the Pandemic. In order for us to move forward in a constructive way to improve our health, wealth and well-being, I propose a Call for International Harmonisation and Standardisation in the Evaluation of Diagnostic Tests.

1.1.18 This statement covers the period from 1st January 2020 to 26th July 2021, and forms a personal statement of my role as a Professor in Biostatistics at the University of Birmingham.

2 WHO Essential Diagnostic List

2.1.1 The first meeting of the WHO SAGE IVD identified and documented the process through which tests would be evaluated before being listed on the EDL (JJD/05-INQ000531109). This is primarily based on the empirical evidence for their performance. The process we identified can be used as a model for evaluating new, or existing tests, in general or emergency use.

2.1.2 The First WHO model list of essential in vitro diagnostics detailed the principle methods for evaluating diagnostic tests, which include:

(a) a systematic summary of evidence with systematic reviews of test accuracy performed with accepted methods;
(b) assessment of the strength and limitations of the evidence, including significant aspects for which evidence is lacking;

(c) and consideration of the generalisability of evidence, particularly to low- and middle-income country settings.

2.1.3 The SAGE IVD emphasises the assessment of the clinical accuracy of a test in the setting in which it would be used. These principles are embedded into Recommendations 2 and 3 from the WGDT Report (JJD/01-INQ000114774) covered in the RSS Witness Statement, and emphasise the importance of clinical or field studies.

2.1.4 The WHO undertakes a Prequalification process of In Vitro Diagnostics before them are approved for use by the WHO, largely undertaken as a laboratory process. This process is similar to the process followed by Public Health England (PHE) during the pandemic, as explained in the DHSC Protocol for Evaluation of Rapid Diagnostic Assays for Specific SARS-CoV-2 antigens (lateral flow tests) (which I abbreviate as "DHSC Protocol for Rapid Tests" in this witness statement) (JJD/06-INQ000474912).

2.1.5 The WHO prequalification stage for in vitro diagnostics involves the assessment of product dossiers, analytical performance evaluations and inspection of manufacturing sites. The performance evaluations are undertaken by a designated Performance Evaluation Laboratory, which ensures that the laboratory adheres to the principles of ISO/IEC 17025 and

ISO 15189. ISO/IEC 17025 is an international standard that sets out the general requirements for the competence, impartiality, and consistent operation of all laboratories (not just test laboratories) ensuring they produce valid and reliable testing and calibration results. ISO 15189 assesses the quality and competence of medical laboratories, ensuring they meet specific requirements for their quality management system, technical competence, and overall compliance with international standards, ultimately aiming to improve patient safety and the reliability of laboratory results.

2.1.6 The prequalification process involves a laboratory assessment of selected samples in an ideal situation to estimate analytical sensitivity, analytical specificity and other characteristics. The process is undertaken in available samples. The WHO regards that their Prequalification process is not sufficient for their inclusion of a test on the EDL, as it is essential to also assess the clinical accuracy of a test in the setting in which it would be used. This principle is embedded into Recommendation 1 from the WGDT Report (JJD/01-INQ000114774) covered in the RSS Witness Statement.

2.1.7 FIND, the Foundation for Innovative Diagnostics (a non-government organisation and WHO Collaborating Centre, which has a mission to support the health of people in low- and middle-income countries through the introduction of new affordable and rapid diagnostics for infectious diseases) undertook independent evaluations of Covid-19 test technologies during the pandemic, many of which were included in our Cochrane reviews. Their protocol for evaluations is available and follows the stages of the WHO prequalification process and the evaluation of the clinical accuracy of a test in LESSONS LEARNEDthe setting in which it would be used (JJD/07-INQ000531110). Below I have included the text from the protocol verbatim as an example of the stages which are covered in their evaluation, through the Lab Evaluation and Clinical Evaluation (the exact technical detail will not be of interest to the inquiry: my purpose of including it is to show the level of detail, and the stages). The FIND protocol and reporting approach provides an exemplar for further test evaluations. They also showed how clinical studies could be completed for multiple tests on an international basis during a pandemic.

"Lab Evaluation: This is a lab-based performance evaluation study of novel Covid-19 Antigen assays to determine comparative sensitivity across multiple tests using contrived samples that are swabs spiked with cultured virus isolate. The master dilution stock used for each dilution series will be tested by RT-PCR and the Ct values will be compared with the index test reactivity. Optionally, off-label swab preparations, i.e. using universal transport media will also be compared. Standard dilution series will be prepared (expressed in TCID50) using cultured virus, and will be used to spike swabs which will then be placed in the proprietary buffer for testing as per manufacturer's instructions. In addition, at least two other, off-label sample types may be analyzed: 1) swabs will be placed directly in UTM and the required volume will be added to each test, according to the instructions for use; 2) swabs will be placed into UTM, then frozen overnight, thawed and then the required volume will be added to each test, according to the manufacturer's instructions for use.

Clinical Evaluation: This is a prospective, multicentre, blinded performance evaluation study of SARS-CoV-2 Ag RDTs. All index test results will be compared to RT-PCR results, are for research use only, and will not be reported for patient care. Individuals suspected to have Covid-19 (as per national or WHO guidelines) presenting at the testing site(s) will be invited to participate. Each participant will have two respiratory swabs collected: one for RT-PCR testing and diagnosis, paired with a second swab to be used on the index RDT. Enrolment will continue until 100 positive samples are obtained for each test (volumes could be combined across sites should multiple sites be evaluating the same test). Alternatively, if swabs placed in UTM are shown to be equivalent in the lab study, then only one swab will be needed per patient to be used across both RT-PCR and index testing."

3 Cochrane Covid-19 Diagnostic Test Accuracy Group (CCDTA)

3.1.1 At the beginning of the Covid-19 pandemic, I instigated and led the publication of a set of Cochrane systematic reviews evaluating the accuracy of diagnostic tests for Covid-19. These reviews were produced by an international team of test evaluation experts (The Cochrane Covid-19 Diagnostic Accuracy Group - CCDTA). We collaborated with stakeholders from the Cochrane Collaboration, the WHO and FIND.

3.1.2 CCDTA was led by 13 test evaluation experts from the Cochrane Collaboration and the Universities of Birmingham, Amsterdam, Utrecht, Leuven and Ottawa, the WHO, FIND, and the Cochrane Infectious Diseases Review Group. The team first met on the 26th of March 2020. To complete the work, we recruited 103 systematic reviewers, statisticians, clinicians, and editors based in 35 research institutes in 15 different countries, spread across 6 continents. The work of each member of the team was funded by their academic institutes.

3.1.3 The first stage of completing a systematic review is to agree on a protocol which details the review question (which is a clinical question describing the test, the participant settings, the target condition or disease of interest, and the role that the test will be used for), and the methods of the primary studies that will be included. The protocol also states the methods that will be used to search for reports of the eligible studies, critically review the evidence, and synthesise the findings. Cochrane protocols and reviews are peer-reviewed to ensure scientific credibility and integrity – we published the CCDTA protocol for our set of reviews within 29 days of our first meeting, including the stages of peer review and editorial process.

3.1.4 The second stage is to identify all available evidence relevant to the review question. Early in the pandemic, several international institutes created open-access databases of Covid-19 studies using feeds from electronic bibliographic databases, as well as preprints of study reports. Preprint archives, such as bioRxiv and medRxiv, became available in 2019 and revolutionised our ability to identify the first reports of every study prior to their peer review and publication, which usually delays the availability of up-to-date evidence. Using regular exports from these international databases, we initially screened every title and abstract of every report. We also accessed available documents from Governments, the WHO and FIND, and matched evidence from studies with the names of all Covid-19 IVD tests that FIND listed. As the global magnitude of studies evaluating Covid-19 increased in an exponential manner, we quickly moved to use artificial intelligence-based text analysis to build review-specific classifiers to narrow the number of studies reports to be screened. This use of machine learning was essential to the process. Even so, by the end of November 2020, we had manually screened over 34,000 study reports.

3.1.5 CCDTA initially focused on studies of antibody tests, and of signs and symptoms to correctly identify Covid-19. By the 27th of April 2020, we had already identified 12,338 study reports to be screened. By the 14th of May, we had ascertained that there were 57 eligible studies of antibody tests and 16 studies of symptoms that met the protocol criteria for inclusion, which we then critically reviewed, tabulated and analysed. Twenty-two days later, the review of antibody tests was finalised, agreed upon by the team, peer-reviewed by independent clinicians and methodologists, edited and published in the Cochrane Library. The total time between closing the search on the 27th of April 2020 through the systematic review, peer review, editorial process and publication was 59 days. Completing and publishing a systematic review normally takes one to three years.

3.1.6 There usually is a frustrating delay between receiving findings of the first studies of an intervention and waiting for a systematic review of all existing data to form health policy. We aimed to complete reviews as fast as possible to enable informed decision-making. Our ability to do this more quickly than normal occurred through recruiting a team of experts who could reallocate their work to the purpose of the pandemic, together with Cochrane being able to prioritise the peer review and publication process. The person-time cost has not been formally calculated and was largely driven by the personal goodwill of the team members, who worked relentlessly through long days and nights. We maintained the momentum of completing and updating reviews throughout the pandemic, recruiting additional reviewers internationally when they became available.

3.1.7 The first five CCDTA reviews covered antibody tests (25th June 2020) (JJD/08-INQ000531111), signs and symptoms (7th July 2020) (JJD/09-INQ000531112), rapid point-of-care antigen and molecular tests (26th August 2020) (JJD/10-INQ000531113), thoracic imaging (30th September 2020) (JJD/11-INQ000531114) and routine laboratory tests (19th September 2020) (JJD/12-INQ000531115). The first three reviews are of the most relevance to the UK (whilst some countries used CT imaging as a diagnostic test in hospitals, the UK never focused on imaging as a routine investigation for Covid-19).

3.1.8 In this witness statement, I demonstrate the importance of systematic reviews in a pandemic situation, to provide an up-to-date and complete understanding of the relevant research evidence. The CCDTA reviews informed many national and international guidelines (such as WHO guidelines) to provide evidence for decision-makers that were highly cited and freely available. However, they did not appear to be considered by DHSC and SAGE.

3.2 Systematic Review of Antibody Tests

3.2.1 The first CCDTA systematic review of antibody tests found 57 studies of 25 commercial tests and numerous in-house tests – which are a small fraction of the 279 tests that FIND had identified as commercially available at the time. (The FDA had temporarily allowed Covid-19 antibody tests to be marketed without regulatory oversight, which led to the market being swamped with many tests without proven accuracy).

3.2.2 The key finding of the review was that antibody tests do not reliably turn positive until 1-2 weeks after infection. Our review was the first study to demonstrate this effect, as by combining data from the many small studies which we identified, we could show the effect of time from infection in subsets of samples from each study. The review considered three different ways in which antibody tests could be used (referred to as use cases).

3.2.3 Use case (a) considered using the test to answer the questions of "Have I got Covid-19?", or "Am I certain that I haven't got Covid-19?" which could allow people to continue with their normal work and take part in social activities. The review showed antibody tests have no role on their own as the primary test to use in the diagnosis of Covid-19 when patients present during the first weeks since onset of symptoms, as their sensitivity was too low.

3.2.4 International and UK Government guidance was in line with this position, but this did not stop manufacturers and distributors from marketing antibody tests for this purpose as a Covid-19 passport for attending events such as sporting activities, including those promoted by well-intended celebrities (JJD/13-INQ000531116). Highlighting this type of promotion of antibody tests was an activity that I undertook through the media, Twitter and MHRA Yellow Card reporting and letters to the MHRA. The process to stop advertising such

use of tests involves the Advertising Standards Authority (ASA) as well as the MHRA. By experience, I found that pointing out these issues through the media was a quicker way of their resolution, and reduce their risk to health, albeit at the risk of personally receiving lawyers' letters from manufacturers and distributors, which the University lawyers helpfully responded to.

3.2.5 Use case (b) showed that antibody tests may have a potential role in those who are RT-PCR-negative or not RT-PCR tested, but Covid-19 is strongly suspected and patients are more than two weeks from the onset of symptoms. This role was of most relevance in low- and middle-income countries where RT-PCR testing was more limited. It showed that antibody tests could be used as part of a diagnostic pathway, but could not provide a timely diagnosis. Rapid antigen tests superseded the potential for using antibody tests for this purpose.

3.2.6 Use case (c) asks the question, "Have I had the disease?" and showed that antibody tests have a role for detecting previous SARS-CoV-2 infection if used at 15 days or more after the onset of symptoms. The primary use of antibody tests is for public health seroprevalence surveys to monitor the pandemic, which was undertaken in several large longitudinal cohort studies.

3.2.7 For use case (c), a second hope early in the pandemic was that if an individual had had Covid-19 they would have acquired immunity and be able to return to work. We were unable to examine evidence of immunity in our review at this time point, as no long-term follow-up studies were yet available. Over time, it became clear that Covid-19 did not produce reliable immunity as people experienced second infections, particularly after genetic changes in the virus, making the consideration of immunity passports unsafe.

3.2.8 Our review included a study funded by the UK Government, which evaluated eight antibody tests (JJD/14-INQ000531117). We had requested early access to any data from these evaluations from the group at the University of Oxford who had undertaken the studies, which they provided. Unlike other studies, the confidentiality agreement that the Government had signed with the manufacturers prevented the names of the 8 tests from being publicly known – the tests were only labelled as A-H. This does not adhere to the principles of Open Science as the knowledge learned cannot be shared.

3.2.9 When our review was published, the SMC hosted a briefing for journalists where two of the authors and one of the editors from Cochrane presented the findings on the 25th of June 2020. We explained the findings and answered questions from journalists (JJD/15-INQ000531118). As the lessons learned from the limited use of antibody tests were clear, we did not prioritise updating this review. The first update was published in November 2022 (JJD/16-INQ000531119).

3.3 Misleading claims of the accuracy of antibody tests

3.3.1 During May 2020 there were many misleading claims of "game changing" antibody tests by politicians and manufacturers. These included claims of 100% accuracy of antibody tests by Roche and Abbott purchased by the Government. As these laboratory studies were being undertaken by Public Health England, I discussed their design and reporting with their experts to ensure that they were statistically appropriate. However, we could not stop the manufacturers from overstating the performance of their tests.

3.3.2 To ensure the public were made aware of the misleading ways in which manufacturers can spin their findings, I experimented using Twitter to provide short summarises of importance statistical issues. My 16th May 2020 "21 ways to spin results from a Covid diagnostic test accuracy" tweets (JJD/17-INQ000475138) were quickly well received, and Twitter became a routine way in which I communicated findings and simple explanations.

3.3.3 On the basis of my Twitter activity, I was also asked to explain misleading claims of test performance for the Roche and Abbott tests by Tim Harford on Radio 4 More or Less on June 10th 2020 (JJD/18-INQ000475135). Our discussion outlined the ways in which the 100% accuracy claims by Roche and Abbott have been created by cherry picking results of very small, selected subsamples, which we could unpick from the evidence provided by Public Health England that I had reviewed.

3.3.4 At this time the Government and senior scientific advisors were proceeding to develop and evaluate a new antibody lateral flow test (the AbC-19 Covid-19 self-test developed by Abingdon Health) in collaboration with the University of Oxford and the UK-Rapid Test Consortium. The initial results of their

evaluation in August claimed that the test was 99.40% accurate. The company only provided limited information of the study from which this claim was made, the study being described as a "secret trial". With help with Sarah Boseley (the then health editor at the Guardian) I found out details of the study design of the "secret trial" which I explained in my Guardian article "Too many corners are being cut in the race to find a Covid-19 antibody test" (JJD/19-INQ000474901). In this case, the study had excluded cases which were most likely to give false negative results, leading to the high claims of accuracy. Subsequent independent studies confirmed that the performance of the test was much lower than the original claim.

3.4 Systematic reviews of rapid point-of-care antigen and molecular tests

3.4.1 The review of the rapid point-of-care antigen and molecular tests was published on 26th August 2020 based on evidence that was available by the 25th May 2020 (JJD/10-INQ000531113). In contrast to the antibody tests, the evidence base at this point was very immature and small.

3.4.2 We found eight evaluations of five different antigen tests, which showed great variability in their sensitivity whilst having high specificity, giving few false positives. Our confidence in the evidence was very limited.

3.4.3 We also evaluated studies of four different rapid molecular tests, which showed a sensitivity of 95% and a specificity of 99%. We noted a large difference in Covid-19 detection between the two most evaluated molecular tests. Our confidence in this evidence was also very limited.

3.4.4 As we were aware of the ongoing development of these tests, we prioritised updating this search and review, immediately rescreening for new studies. This enabled us to provide the evidence requested by the Liverpool team in November 2020 when they were developing their protocol for their study of mass-testing using the Innova assay (4.5). We could have provided this information to DHSC, the University of Oxford and Porton Down if they had asked. As, at this point in time DHSC was deciding on the use of a lateral flow test, it would have seemed important to be aware of all the international

evidence of the performance of the lateral flow tests that could be used in the UK.

3.4.5 The update of the rapid antigen test review was published on the 24th of March 2021, based on searches to the 30th of September, and independent evaluations from national reference laboratories, FIND and the Diagnostics Global Health website to the 16th of November 2020 (JJD/20-INQ000409288). At this time, we found 58 studies of rapid antigen tests, which included studies from the Porton Down/University of Oxford evaluations of the Innova test used by the Government. The analyses, tabulations and explanations cover 400 pages. The development of the evidence base informing the use of rapid antigen tests in the six months between the two versions of our review is notable.

3.4.6 The initial studies of both antibody and antigen tests were 'two-gate' studies, which are at risk of overestimating both sensitivity and specificity, as explained in the WGDT report (JJD/01-INQ000114774) and the RSS Witness Statement. By the update of the review, 29 single-gate studies, which recruited participants before infection status had been ascertained, were available and provided the majority of the evidence. We focused on the results of these studies as they have the highest level of strength of evidence for the accuracy of tests.

3.4.7 We showed that there was substantial variability in the sensitivity of antigen tests by test brand. Only three of the 17 tests evaluated met the WHO's target product profile standards for Covid-19 diagnostics in at least one study ('acceptable' sensitivity ≥ 80% and specificity ≥ 97% which make them suitable as a replacement for laboratory-based RT-PCR). These were: SD Biosensor STANDARD Q, Abbott Panbio and BIONOTE NowCheck.

3.4.8 It is notable that Abbott Panbio, one of the most accurate rapid antigen tests, was one of the four tests assessed by the DHSC in the FALCON study in September 2020 alongside Innova (JJD/21-INQ000528823). Our Cochrane Review update included nine studies evaluating the Abbott Panbio test: three available by the 30th of September 2020, three by the 31st of October 2020, and three by the 14th of November 2020, including independent evaluations by FIND. It is also notable that the DHSC had tabulated the findings on Abbott

Panbio in the FALCON study before commencing the Liverpool study and starting national use of the Innova test. It is also notable that the first acknowledgement that Abbott Panbio had been evaluated by DHSC did not occur until the 30th May 2021 (255 days after the FALCON study commenced), although this report does not make it clear that the evaluation of the Panbio test had been undertaken at the same time as Innova (JJD/21-INQ000528823). Given its high performance and the availability of a robust evidence base it is unclear why the DHSC chose to use the Innova test over Abbott Panbio - if it had been used rather than Innova, it is likely that more infected people would have been detected and more quickly.

3.4.9 We found clear differences in test sensitivity in symptomatic (72.0%, 95% CI 63.7% to 79.0%) and asymptomatic participants (58.1%, 95% CI 40.2% to 74.1%) across tests. This raised concerns about the ability to use these tests in mass screening settings in asymptomatic people, but there was very little evidence in mass screening settings. Our concerns prioritised the importance of the Liverpool study team ensuring that their study included a confirmatory RT- PCR in all participants (Section 4.5.3). There were no studies assessing the accuracy of repeated lateral flow testing or self-testing despite this being part of the use case planned by the Government for mass testing. Very few studies had evaluated the performance of the tests in children. (In our second update of this review published in July 2022 (JJD/22-INQ000531122), we separated results in adults and children, showing that the sensitivity of the tests was on average 10% lower in children than in adults, but data on children was still limited). The importance of testing children should be emphasised in a future pandemic.

3.4.10 All evaluations of Innova were commissioned by the DHSC, other than the University of Birmingham study (Section 4.6). Our review reported the Innova test had an average sensitivity of 47.9% (34.3 to 61.8). This value shows it to be one of the least sensitive tests. This value is lower than that cited in the Porton Down/University of Oxford publications as we included the Porton Down Army study which was not included in the original (JJD/23-INQ000474902), the medRxiv preprint (JJD/24-INQ000531123) and the EClinicalMedicine (JJD/21-INQ000528823) reports. The Chief Investigator of the Porton Down/University of Oxford study provided CCDTA an Excel spreadsheet of the findings of all studies when we requested all data for

inclusion in the systematic review (JJD/25-INQ000531124), and all eligible studies provided were incorporated in the Cochrane review. In a response to our concern that this data was not publicly available (JJD/26-INQ000531125) the editor of the Lancet requested the Chief Investigator to explain the missing data via a letter to the editor of eClinicalMedicine (JJD/27-INQ000531126) which was provided.

3.4.11 The review included an analysis of sensitivity split by RT-PCR Ct value. This showed that most lateral flow tests can easily detect virus with Ct values below 25 (which suggest high viral load) but that there is variability in their ability to detect virus with Ct values above 25. This helps us understand why there are differences in performance between brands – and that only lateral flow tests which can detect virus at lower levels have high sensitivity as required by WHO in their target product profile (the MHRA also introduced a required sensitivity and specificity – see Section 6.1.6). We discuss in the review the lack of empirical evidence of the relationship between infectiousness and the performance of lateral flow antigen tests. What is beyond doubt is that studies which cannot reliably detect infection (whether symptomatic or asymptomatic) at lower viral levels are less sensitive.

3.4.12 The SMC hosted a briefing for journalists about this Cochrane review where three of the authors and one of the editors presented the findings on the 24th March 2021 (JJD/28-INQ000531127). We explained the findings and answered questions to journalists.

3.4.13 Written comments by experts to the SMC (JJD/29-INQ000531128) showed a disagreement between whether the results of the review are useful or whether their importance should be dismissed. Some agreed that the review provides clear evidence of the differences between the sensitivity of different tests, while others argued that the primary studies could only assess whether individuals are infected and not whether they were infectious, and that the use of PCR tests as a reference standard should be abandoned. This is part of the academic narrative that has occurred following the poor results of the Innova test in the Porton Down/Oxford and Liverpool studies. None of the commentators explained how the accuracy of the lateral flow test can be assessed without using a PCR reference standard.

The test accuracy paradigm is based upon assessing the accuracy of a test against a pseudo measure of the "truth" – the reference standard. Whilst there are reference standards to assess infection, there is no reliable reference standard to assess infectiousness. It is important to note that the argument that we should focus on assessing test accuracy to detect infectiousness is unresolvable. It is not possible to obtain direct evidence to check the performance of a lateral flow test when we do not have a reliable reference standard of infectiousness.

4 Evaluation of lateral flow tests for MOONSHOT

4.1 Porton Down and University of Oxford Evaluations

4.1.1 As I have already stated, the evaluation of a new test first requires initial laboratory evaluations to understand their performance using selected (and sometimes contrived) samples. If laboratory evaluations show that a test could perform appropriately, a second stage evaluates the test's performance when used by people in whom the test will be used for a specific role in clinical and real-life settings. The importance of this approach is clear in Recommendations 2 and 3 of the RSS WGDT (JJD/01-INQ000114774) report and follows the methods outlined in Section 2 of my witness statement.

4.1.2 DHSC commissioned PHE Porton Down to establish a Test Development and Evaluation programme in August 2020. They published the DHSC Protocol for Rapid Tests (dated 23rd October 2020) (JJD/06-INQ000474912) for their evaluation method for rapid diagnostic assays for SARS-CoV-2 antigen tests, which outlined three phases, Phase 1, Phase 2 and Phase 3. The process involves only laboratory testing without any field studies and thus can only inform on the analytical (rather than clinical) sensitivity and specificity of the antigen tests. This is a concern as expressed in Recommendation 1 of the RSS WGDT report (JJD/01-INQ000114774). This protocol is in contrast to the FIND protocol shown in Section 2.1.7 which includes both laboratory and clinical and field studies.

4.1.3 Despite the DHSC Protocol for Rapid Tests being restricted to Phase 1-Phase 3 studies, a set of Phase 4 studies was included in both the November 2020 Porton Down/University of Oxford preliminary reports

(JJD/23-INQ000474902, JJD/24-INQ000531123) and the May 2021 EClincialMedicine report (JJD/21-INQ000528823). The design and purpose of these studies are not described or mentioned in the DHSC Protocol for Rapid Tests, and the subsequent reports provide little methodological detail. These studies appear to include only evaluations of the Innova test; there were no Phase 4 stage studies reported for Orient Gene, Deepblue, and Abbott Panbio.

4.1.4 There were eight Phase 4 studies listed in the May 2021 final EClinicalMedicine (JJD/21-INQ000528823) report, two of which were field studies where individuals had RT-PCR testing as well as Innova. These two field studies provide strong evidence of the accuracy of the Innova test: but shows that the sensitivity is poorer than expected from the laboratory studies.

4.1.5 From observing more recent publications from DHSC in 2023 and 2024, I am aware that DHSC undertook further field studies from 2020 to 2021 which were not made public at that time. These studies evaluated Innova and other lateral flow tests. No protocol or catalogue of commissioned studies is publicly available, so it is unclear which studies have been conducted and which are still to be published. In one large field study (JJD/30-INQ000528825), the performance of Innova as a self-test was observed between November 2, 2020, and January 9, 2021, and was found to have slightly poorer sensitivity than the original field study (50%; 95% CI 45.8-55.7). Whilst this analysis was completed in early January 2021, its findings were not reported until April 2024. It would have been helpful for public health professionals and others with similar responsibilities to have been made aware of these findings at this time.

4.1.6 It is unclear where the expertise and experience in designing and delivering Field and clinical studies sat within PHE. There are many experts in studies of this nature including academics funded by NIHR Health Technology Assessment, NIHR Clinical Trial Units, the National Institute for Health and Care Excellence, in the NIHR Medtech and In vitro diagnostic co-operatives and with the National Screening Committee. However, it is unclear what prior experience Porton Down had in delivering Clinical or Field studies. It is noted that the DHSC used Deloitte to assist in these studies, and it is unclear what their expertise was.

4.2 The FALCON Study

4.2.1 The Porton Down and University of Oxford EClinicalMedicine (JJD/21-INQ000528823) report presents results of the Phase 3 FALCON study evaluating four tests: Innova, Orient Gene, Deepblue and Abbott Panbio. The results of all four tests were only reported in the final publication in May 2021; only the Innova results were included in the preliminary reports (JJD/23-INQ000474902, JJD/24-INQ000531123). The Chief Investigator of the FALCON study informed me that they evaluated the four tests simultaneously, with one test being used for each participant. Studies for Orient Gene, Deepblue, and Abbott Panbio are limited to Phase 3 studies; there are no findings available for the Phase 2 studies for these tests, and it is unclear whether they were ever undertaken.

4.2.2 The NIHR FALCON group were asked to evaluate the sensitivity of Innova, Orient Gene, Deepblue and Abbott Panbio in patients attending test-and-trace centres who were found to be positive on PCR. The study commenced testing on the 17th September 2020 and was completed by 23rd October 2020. The patient samples were transferred to Porton Down for testing for all four tests and for a second PCR test. A subset of the patients had a second test undertaken onsite by a Health Care Worker, but this was only done for the Innova test.

4.2.3 The results of the NIHR FALCON study showed that Abbott Panbio and Orient Gene could detect infection more reliably than Innova and Deepblue, particularly in those with viral loads of 10,000–100,000 (equivalent to Ct values of 25-28) and 1000 to 10,000 (equivalent to Ct values of 28-31) (JJD/21-INQ000528823) (Table 4). The sensitivity for Ct values of 25-28 was 73%, 78%, 82% and 89% for Deepblue, Innova, Orient Gene and Abbott Panbio respectively (it is informative to calculate the proportion who get false negative results – the complement which are those who can be harmed – which are 27% for Deepblue, 22% for Innova, 18% for Orient Gene and 11% for Abbott Panbio – which shows that Innova would miss twice as many as Abbott Panbio).

4.2.4 The overall sensitivity values in Table 4 are misleading as the samples from the four tests had different distributions of viral loads, with the Innova samples

on average having higher viral loads than those for the other three groups (for example, percentages with Ct values of ≤25 being 62% for Innova compared to only 47% for Abbott Panbio). It is essential to use a statistical technique known as indirect standardisation to make fair comparisons when there are differences in confounders such as viral load. The eClinicalMedicine paper does not discuss the differences between the four tests, nor use any technique to make fair comparisons between the test groups (JJD/21-INQ000528823).

4.3 Studies of schools

4.3.1 The preliminary Porton Down/University of Oxford report (JJD/23-INQ000474902) reported that Innova was evaluated in four school studies, recruiting 3,987 school children. These studies appear to have been undertaken as implementation studies to assess the feasibility of using lateral flow tests in schools, rather than their accuracy. As there is no description of the study design and method for these studies, and no protocol has ever been available, the methods are very unclear. To evaluate accuracy (i.e. clinical sensitivity and clinical specificity), the studies needed to obtain confirmatory RT-PCR tests on all children as well as the Innova lateral flow test.

4.3.2 These studies report estimates of the specificity of the tests, which could only be obtained if RT-PCR tests were undertaken. If RT-PCR tests were not obtained these results are misleading, which is concerning given that the use of Innova in schools across the country was largely based upon these results. No other study evaluated Innova in school children.

4.3.3 There are four relevant documents available. The original report (Table 1) stated that 3,987 school children had successfully been tested with Innova and that none had received a confirmatory RT-PCR test report (JJD/23-INQ000474902). This indicates that specificity could not have been estimated. The excel spreadsheet sent to CCDTA by the Chief Investigator reported that 3,968 participants had been tested with Innova and that only the 17 children who had received a positive Innova test had also had a RT-PCR confirmation test: 14 of the 17 had been found to be false positives (JJD/25-INQ000531124). Again this indicates that specificity could not have

been estimated, but also that the positive predictive value of the test was poor, with only 18% (3/17) of Innova positives being true positives. Both the pre-print (JJD/24-INQ000531123) and the eClinicalMedicine (JJD/21-INQ000528823) reports state that there were 3,985 school children tested but do not mention anything about RT-PCR tests. They also report specificity values.

4.3.4 The uncertainty in these results matters, as the three published versions are interpreting these results as providing evidence of the specificity of the Innova test in children, and are implying that the accuracy has been evaluated. Without an RT-PCR test being completed, it is not possible to know which of those with negative Innova tests are missed cases (false negatives) and which are true negatives, and the sensitivity and specificity of the test cannot be evaluated.

4.3.5 When the eClinicalMedicine report was published we raised concerns about the misleading nature of these data with Richard Horton, the editor of the Lancet (which has overall editorial responsibility for eClinicalMedicine). He requested us to explain our concerns in a letter to the journal (JJD/26-INQ000531125). The Chief Investigator and one other author responded to our concerns as a letter in eClinicalMedicine (JJD/27-INQ000531126).

4.3.6 The response from the Chief Investigator is ambiguous. First it states that the school studies were designed to assess the feasibility and that they could not assess both positive and negative cases. This indicates that an RT-PCR confirmatory test was not planned.

4.3.7 However, the response then states "We are happy to confirm that all the samples shown in Table 2 had both a negative PCR test and a lateral flow test allowing the false positive rate to be estimated" which implies that an RT-PCR confirmatory test had been done. It is thus unclear whether RT-PCR tests were undertaken, whether they were undertaken in all school children or just in a small number as appeared in the excel spreadsheet (JJD/25-INQ000531124).

4.3.8 There is no audit trail available to confirm who was tested by whom and when. There is no protocol to indicate the intended process. If RT-PCR tests

were done on all, there are no numerical results of RT-PCR, either in terms of CT values (which are reported in all other studies) nor in the numbers of false negatives (which would be expected given the poor sensitivity of Innova in other studies). The findings do not change between the three versions of the document – the first clearly stating that RT-PCR tests had not been undertaken (JJD/23-INQ000474902), the second (JJD/24-INQ000531123) and third (JJD/21-INQ000528823) not mentioning RT-PCR tests at all, whilst the confirmatory letter from the Chief Investigator implies that they had been undertaken (JJD/27-INQ000531126). It is concerning that the national policy of our school children being tested with Innova was based upon such poorly described and potentially misleading reports.

4.3.9 There are other statistical issues in the use of Innova in schools which I contributed to:

(a) As senior members of the RSS, we wrote an Opinion Piece in the BMJ on the 12th of January 2021 concerning the plans for using Innova for schools, noting the substantial concerns about its accuracy by many (JJD/31-INQ000474906). In this article, we pointed out that there was no data on the accuracy of Innova in school children, as explained in Section 4.3. We called for the better evaluation of the test in schools before it was going to be implemented.

(b) In March 2021, many of us wrote articles campaigning and explaining why school children who are Innova test positive need to be checked with RT-PCR due to the increasing risk that they would be false positives as the prevalence of Covid-19 was decreasing (JJD/32-INQ000474903). The importance of monitoring prevalence and changing diagnostic pathways in response is discussed in the RSS Witness Statement. This campaign for the use of routine confirmatory RT-PCR tests led to a change in practice.

(c) In June 2021, with members of Independent SAGE and others, we questioned Gavin Williamson, the Secretary of State for Education through an Opinion Piece in the BMJ, concerning the Daily Contact Testing trial in schools, calling for comprehensive mitigations to protect school children (JJD/33-INQ000474908).

4.4 Press Release of the Porton Down and University of Oxford study of Innova

4.4.1 There were concerns of the press release of the Porton Down and University of Oxford study of Innova, released by both the University of Oxford and the DHSC (JJD/34-INQ000474911), which overstate the performance of the Innova test. I profile these sections:

"The results of the Innova evaluation published today show:

the specificity of the test was recorded as 99.68% – the overall false positive rate was 0.32%, although this was lowered to 0.06% in a lab setting

it has an overall sensitivity of 76.8% for all PCR-positive individuals but detects over 95% of individuals with high viral loads, and minimal difference between the ability of the test to pick up viral antigens in symptomatic and asymptomatic individuals

Sir John Bell, regius professor of medicine at the University of Oxford, said:

The data in this validation report demonstrates that these inexpensive, easy-to-use tests can play a major role in our fight against COVID-19.

They identify those who are likely to spread the disease and when used systematically in mass testing could reduce transmissions by 90%.

They will be detecting disease in large numbers of people who have never previously even received a test."

4.4.2 Alongside my observation that the 76.8% sensitivity value is a select result from the 3B study, ignoring the less favourable but scientifically more credible 58% figure in the phase 4 study, I profile the numerical statements "detects over 95% of individuals with high viral loads" and "mass testing could reduce transmissions by 90%".

4.4.3 The 95% value occurs from the Phase 2 dilution study which was undertaken using spiked samples.

4.4.4 The 90% value occurs from fitting a statistical model of sensitivity to the Phase 3B Falcon study at a CT<25.5 value (calculated as a viral load >100,000 RNA copies/ml). There is no empirical evidence that this CT value in the Falcon study can predict the percentage of transmissions reduced.

4.4.5 In both cases, the use of numerical values appears to have been for headline-grabbing purposes rather than balanced summaries of the evidence and their implications, which may have been misleading to the public. These figures were repeatedly reported in written and oral information from the DHSC and its scientific advisers.

4.5 Liverpool Study

4.5.1 In early November 2020, Liverpool was selected to pilot the use of the Innova test for mass testing. This decision was announced prior to the release of the findings of evaluations of the Innova test by PHE Porton Down and the University of Oxford. Given my awareness that the DHSC Protocol for Rapid Tests (JJD/06-INQ000474912) did not include plans for Field Studies, and that no studies of lateral flow tests in asymptomatic and screening settings had been noted in the world literature at this time (JJD/10-INQ000531113), it was important to encourage the Liverpool team to use a field study design that would evaluate the new test with a RT-PCR reference standard.

4.5.2 I took the initiative to contact researchers I knew at the University of Liverpool and quickly involved communication with Prof Sheila Bird from the RSS WGDT. Over 4th-5th November, we exchanged emails and held a video conference with Profs Buchan, Kenny, and Semple from the University of Liverpool. I attached the email trail recording our discussions (JJD/35-INQ000531130).

4.5.3 In my first email to Prof Kenny I explained the importance of dual testing to provide evidence of the accuracy of the lateral flow test in this setting and pointed out that "the Liverpool pilot provides a fantastic opportunity to run such an evaluation, which will be of clear benefit for the whole country (and world). There are no studies I am aware of that would be evaluating the accuracy of mass screening". The Liverpool team agreed on the importance of validating the test results with a reference standard – in subsequent email

exchanges between Prof Buchan and myself I discussed the need for RT-PCR verification testing and whether it was necessary for only lateral flow positives. I made it clear that we need to validate both positive and negative tests to be able to estimate sensitivity and specificity: I stated you must include verification of the negatives as well as the positives: "that you need them on a large random sample of the test negatives to be able to estimate sensitivity". This aligns with the methodology outlined in the evaluation protocol from FIND. Prof Buchan reported that he would take this requirement to the Scientific and Technical Advisory Cell that day, and subsequently, the Liverpool study followed this design which ensured that it was completed as a Field Study that would provide strong evidence of the performance of the Innova test for mass testing. The study commenced on the 6th of November.

4.5.4 Tight timelines occurred between completing studies, decision-making and commencing pilot implementation for the Moonshot programme, and it is unclear that evidence was used to make decisions throughout the programme. The findings of the Oxford University/Porton Down evaluation were not publicly available until the 11th of November 2020, after the Liverpool study had commenced on the 6th of November. Emails from the Liverpool team to Deeks and Bird showed that the Liverpool team were provided with summary results of the Phase 3B analytical studies from the Oxford University/Porton Down evaluation, but that there was no mention of the findings of the Phase 4 field study, which was later to show poorer clinical sensitivity (58% compared to 78%). Our discussion was based on the selective evidence that had been made available to the Liverpool team. I attach the excel spreadsheet that Prof Buchan shared with us which summarised the findings of the FALCON study, including those of Orient Gene and Abbott Panbio (JJD/36-INQ000531131).

4.5.5 Briefly, the Liverpool study found the Innova test had 40% sensitivity overall, poorer than in the Phase 4 field studies at the Porton Down and University of Oxford (JJD/21-INQ000528823). Analysis by CT values showed that the test only detected 60% of cases with CT values between 18.3 and 24.4 (between 100,000 RNA and 10,000,000), much poorer than in the Phase 3B Falcon study.

4.5.6 Findings of the Liverpool study were first made available on the 30th November 2020 on a web document "Community testing: a guide for local delivery": a policy paper from the Cabinet Office and the DHSC (JJD/37-INQ000475140). The findings are only mentioned in the penultimate paragraph of Annex 2 of this document, which suggests that they may have been hidden and were certainly not highlighted as important. Fuller interim results were reported on 23rd December 2020 from the University of Liverpool (JJD/38-INQ000488599), with a full BMJ paper published on the 7th July 2021 (JJD/39-INQ000231500).

4.6 The Birmingham University Study

4.6.1 The University of Birmingham, on its own initiative, decided to evaluate the accuracy of the Innova test in University students, which is explained in our preprint published on 24th December 2020 (JJD/40-INQ000531133). As part of the national plan to test students for SARS-CoV-2 before the 2020 Christmas break, the DHSC provided the University of Birmingham with Innova LFDs to test 15,000 students. Using a University-owned booking system, a total of 7,189 students were tested between 2nd December and 9th December 2020. Only asymptomatic students were tested: students were refused a test if they had any symptoms of Covid-19 and were referred to a local test site for PCR testing. At this point in time, the University of Birmingham had been commissioned to run a Turnkey Laboratory, funded and accredited by DHSC to increase the capacity of RT-PCR testing as part of Test-and-Trace (active from 21st September 2020 to the 31st March 2021) (JJD/41-INQ000531134). Fuller details of the contract, set-up and usage of the Turnkey Laboratory are described in Professor Alan McNally's witness statement.

4.6.2 Students were provided with a sterile nasopharyngeal swab and under supervision from a trained member of the University testing team, swabbed both tonsils and a single nasal cavity as according to the test instructions. Tests were performed by trained members of the University testing team drawn from postgraduate and final year undergraduate students in the College of Medical and Dental Science in the University, supervised by highly

experienced postdoctoral researchers. In total, a team of 18 test operatives oversaw 36 testing booths, with a student attending a booth every 10 minutes. A further 7 staff acted as results recorders logging the test results via a barcode through a mobile phone device and result recording app, which were both supplied by DHSC. All Innova positive tests were retested by PCR at the Turnkey Laboratory. In addition, on each of the 8 days of testing, a random sample of 90 residual Innova negative tests were selected for confirmatory PCR testing, which constituted a single 96-well plate including positive and negative controls.

4.6.3 Two students were positive on the Innova test who were also positive on PCR. Six of the 718 negative on Innova were positive on PCR, which (following appropriate statistical methods to account for the sampling fraction) shows a sensitivity of 3.2% (95% CI 0.6% to 15.6%). The true prevalence rate in the student population tested was 0.86% (95% CI 0.40% to 1.86%), which at this point was low.

4.6.4 The false negative samples had high Ct values, and therefore above the limit of detection for the Innova LFDs. These may be representative of individuals at the very early or very late stages of infection, who may have a relatively lower titre of SARS-CoV-2 in the swabbed sites at the time the swab was taken. We cannot determine whether the false negatives were likely to be infectious, could become infectious, or had already passed the stage of the infection.

4.6.5 Our ethical approval only allowed us to use anonymised waste samples from student testing, which meant that we were not able to undertake follow-up on the students, which would have allowed us to assess whether the false negatives later showed symptoms of Covid-19.

4.6.6 The lessons learned from the Birmingham study are:

(a) In a pandemic situation, a large study could be undertaken quickly with good logistic planning and willingness (there was no funding for this study).

(b) Field studies, which provide the strongest evidence, can easily be completed in a pandemic setting (few field studies were commissioned by the DHSC).

(c) Evaluating the accuracy of a diagnostic test when a disease has low prevalence is always going to be a challenge in obtaining adequate numbers of those who are diseased to estimate sensitivity. In this case, we were able to use an efficient study design to be able to estimate sensitivity, an approach which could more routinely be used.

(d) With more planning and time it would have been valuable to obtain ethical approval to be able to follow participants after testing. This would allow us to be able to assess whether the missed infections progressed and had negative consequences. It could be possible to set up "sleeping" protocols and ethical approval assessments to be ready for future pandemics (without even specifying the disease and the test) to make this possible.

(e) It would have been reasonably easy to compare the accuracy of two or more tests in this setting by randomising participants to different tests, which would have provided evidence of their comparative accuracy. This would have involved a Clinical Trial Unit to provide a randomisation process. Comparison of alternative tests in a randomised design would have provided the strongest evidence for policy decisions as to what test is most likely to be of benefit to participants.

4.7 Timeline for evaluations on lateral flow tests for Moonshot

4.7.1 During the period August to December 2020 the focus on test evaluation was on the decision and choice of antigen lateral flow tests for use in mass screening, which led to the implementation of the Innova test. Below, I map the timeline of the events and the evidence that became available by date. It is not always clear how and when decisions were made and the evidence which was available at each time point.

26th August 2020 – The Cochrane review of antigen tests was published on evidence available up to the 25th May 2020 (JJD/10-INQ000531113).

31st August 2020 - The SAGE group report on mass testing dated 31st August 2020 (JJD/42-INQ000371699).

8th September 2020 - Information about Moonshot was leaked to the BMJ (JJD/43-INQ000324875, JJD/44-INQ000324874).

17th September 2020 - The FALCON team started to evaluate Innova, Orient Gene, Deepblue, and Abbott Panbio.

21st September 2020 – The University of Birmingham Turnkey Laboratory commenced functioning (JJD/41-INQ000531134).

30th September 2020 – Cochrane updated its search for reports, and at that point had already found three studies of Abbott Panbio publicly available internationally.

14th October 2020 – The three-tier system of restrictions started in England

23rd October 2020 – The FALCON team recruitment of patients was completed.

23rd October 2020 – The DHSC Protocol for Rapid Tests was published on the DHSC website (JJD/06-INQ000474912).

5th November 2020 – The second lockdown was in force.

6th November 2020 – The Liverpool study started recruiting using Innova.

11th November 2020 – The University of Oxford/Porton Down report was released, only stating Innova results (JJD/23-INQ000474902).

19th November 2020 - An email and excel spreadsheet from Oxford was received by the CCDTA team of the results of data summary for Oxford/Porton Down (JJD/25-INQ000531124).

29th November 2020 – The Liverpool study completed recruiting.

30th November 2020 – The results of the Liverpool study mentioned in DHSC Community testing: a guide for local delivery Annex 2 (JJD/37-INQ000475140).

2nd December 2020 – The second lockdown ended.

2nd December 2020 – The University of Birmingham started recruiting using Innova.

9th December 2020 – The University of Birmingham recruitment was completed.

17th December – A SAGE document indicated that they had decided that Ct25 indicated viable transmission (JJD/45-INQ000517329).

23rd December 2020 – The full results of the Liverpool study was posted on the University of Liverpool (JJD/38-INQ000488599).

24th December 2020 – The pre-print of the University Birmingham study was posted (JJD/40-INQ000531133).

6th January 2021 – The third lockdown was in force.

15th January 2021 – The preprint of the University of Oxford/Porton Down report was released, sharing only Innova test results (JJD/24-INQ000531123).

24th March 2021 – The updated Cochrane review of antigen tests was published on the evidence available upto the 15th November 2020 (JJD/20-INQ000409288).

30th May 2021 – The eClinicalMedicine report of the University of Oxford/Porton Down report stating results for all four tests (JJD/21-INQ000528823).

7th July 2021 – A DHSC report states that their comments on interpreting infectiousness is based only on expert opinion (JJD/46-INQ000496195).

14th July 2021 - Correspondence clarifying missing results in the University of Oxford/Porton Down was published (JJD/26-INQ000531125, JJD/27-INQ000531126).

5 Media activity

5.1.1 My Media activity during the pandemic can be grouped under four main headings: (a) "Commercial studies of antibody tests"; (b) "Operation moonshot"; (c) "Evaluation of Innova"; (d) "The Use of Innova in schools". (a) is covered in Section 3.3, (d) is covered in Section 4.3 and are not discussed further.

5.1.2 A list of key interviews, Podcasts, and documents are attached in the Appendix of Section 8. Documents cover comments to the SMC, blogs and editorials at the BMJ, and articles in the press. Interviews cover the BMJ Talk Evidence podcasts, and Radio 4 More or Less (JJD/18-INQ000475135), Radio 4 Inside Science, (JJD/49-INQ000475134) and Radio 4 Newscast (JJD/51-INQ000475136). I do not duplicate letters and statements made by the RSS as these are covered in the RSS Witness Statement. I included an example of my use of Twitter in Section 3.3.2 to explain statistical issues and study findings is in use (JJD/17-INQ000475138).

5.1.3 My principles for contributing to media comments during the Pandemic were to focus on the science and facts, not on the politics or personalities, and only comment on issues in which I had expertise. The University of Birmingham strongly supported the principle of free speech. I received personal support from the University Vice Chancellor, my head of College and the Head of the Institute, who were aware of my media activities. The University recognised my and my team's work by awarding us a "Certificate of Research Achievement and Impact Prize" for our work on "Systematic analysis of the emerging evidence of the effectiveness of diagnostic tests for SARS-CoV-2, and associated public engagement activities". (JJD/52-INQ000475137)

5.1.4 On occasion, the University lawyers took appropriate action when I received harassment on Twitter and websites. I ensured that my written comments were accurate, balanced, and free from unnecessary adjectives and expletives, even when I was frustrated by the inappropriate scientific claims made.

5.1.5 I would like to pay tribute to the professionalism and dedication of the many medical journalists who spent time with me and other experts during the pandemic, discussing and learning about the evaluation of diagnostic tests and understanding the challenging statistical "number theatre" they faced. In nearly all cases, their focus was on ensuring that the facts were accurate and not misleading, and they demonstrated a clear willingness and commitment to correct errors when they were made.

5.2 Operation moonshot

5.2.1 The Government plan of mass testing using antigen lateral flow tests was first publicly mentioned in the BMJ on 8th September 2020, after Government documents had been leaked to the journal. The leak contained a 25 slide PowerPoint "The Moonshot Mobilisation" (authored by The Boston Consulting Group) (JJD/43-INQ000324875) and a 14 page Government document from the Testing and Contact Tracing Policy Division (JJD/44-INQ000324874).

5.2.2 The text document described the PMs ambition to deliver a mass population testing programme before the end of the year, to avoid a second lockdown before a vaccine was available. The expectation was that testing 6 million tests per day would cost over £100 billion to deliver. The document described a "UK mass population testing narrative". The document expressed high ambition to use all technologies that could be used, tabulating six different test technologies, including antigen lateral flow tests. It stated "It will be critical to determine the appropriate uses of these tests based on their sensitivity, specificity, the turnaround times for a result, and the logistical requirements for their deployment and processing." Key characteristics for lateral flow antigen tests were the time to result (10-30 mins) and sensitivity (expected to be 80-100%). It mentioned that new technologies were already being tested.

5.2.3 The document did not explain why mass testing was regarded as the best option, with little consideration of the potential harms. The document did briefly mention potential negative effects of testing and the need for a confirmatory PCR test in parallel for tests with "slightly lower accuracy".

5.2.4 The PowerPoint presentation gave logistic and organisation plans to manage the project and the roles of the staff members.

5.2.5 I was asked with colleagues to write an Editorial for the BMJ based on the Operation Moonshot documents (published on 22nd September 2020) (JJD/47-INQ000475139). At this point, we had no reliable evidence of the performance of lateral flow antigen tests – the plans were entirely based on computer modelling with many optimistic assumptions of their performance. It was essential to explain the lack of an evidence base for the Moonshot plan and concerns about the potential harms that can occur in a screening situation, particularly the risk of false positives.

5.2.6 The SAGE "Multidisciplinary Task and Finish Group on Mass Testing" document was published on the 4th September 2020, and provides a thoughtful consideration of the issues in potentially using mass testing (JJD/42-INQ000371699). Given the media attention to the Moonshot plan, the content of this well-researched document was largely overlooked - I was not aware of it until much later of its publication.

5.2.7 It includes consideration of the implications of both false positives and false negatives from mass testing; the impact of prevalence; the requirements of high rates of testing and self-isolation; the importance of engagement and messaging; and the requirement of taking a system view (noting that the test is only one part of the process). This approach is similar to that used in the National Screening Committee. The document includes scenarios for the use of lower sensitivity tests at a value of 80% – there was no scenarios considered at lower levels of sensitivity such as the 58% from the Innova study.

5.2.8 It also noted that document accuracy estimates were based on "*analytical* rather than *operational* sensitivities and specificities – that they represent ideal circumstances … they should be treated as wholly preliminary until large-scale validations have been performed".

5.3 Evaluation and implementation of Innova

5.3.1 Substantial media activity occurred following the evaluation of Innova from the Porton Down and University of Oxford study, the study at the University of Liverpool, and the study in students at the University of Birmingham. I took part in a SMC expert group briefing on Operation Moonshot on the 16th

November (Deeks, Pollock, Taylor-Phillips, Raffle) to help explain the findings and their meaning and limitations. (JJD/50-INQ000531141)

5.3.2 I with colleagues was asked to explain the results of the Porton Down and University of Oxford study in an Editorial at the BMJ (11th December 2020) and was able to include preliminary findings from the Liverpool study (JJD/48-INQ000474904). The Editorial highlighted the low sensitivity of the Innova test in the these studies, and the misleading descriptions of the accuracy of the studies made by the Government. It explained the risks of not being aware of the pfalse negatives and the potential consequence of false reassurance and delaying isolation if infected.

5.3.3 The editorial concluded: "Whatever decision-making process the UK government used, it ignored key evidence and dismissed expert international advice. The result is a considerable burden on care home staff, universities, NHS staff, public health teams, and schools, with minimal additional safety compared with existing risk mitigation measures. Asymptomatic lateral flow testing is an unhelpful diversion from the important task of vaccination rollout."

5.3.4 The editorial pointed out the problems in the "infectiousness not infection" developing narrative that had become part of the Government messaging. This narrative appeared in the SAGE on December 17th 2020 (JJD/46-INQ000496195) stated the meaning of Ct values of 25 and below as indicating high viral load. In July 7th 2021 a document from DHSC (JJD/46-INQ000496195) reported the classification of whether individuals were infectious or not, stating "expert advice from Public Health England and University of Oxford academics suggests the following broad cut-off points can be used:

(a) People with a viral load above 1,000,000 copies per millilitre: These people are highly likely to be infectious;

(b) people with a viral load between 10,000 and 1,000,000 copies per millilitre: The majority of which will have little infectious virus;

(c) People with a viral load of less than 10,000 copies per millilitre: The majority will have negligible to zero infectious virus".

5.3.5 It is noted that this classification is based on "expert advice" and not empirical evidence, or following an appropriate consensus process. Later statements were made that the Innova test had "a 95% sensitivity for infectious people" which relates to the 25 Ct cutoff and is not based upon evidence of infectiousness. As the DHSC took on responsibility of being the manufacturer of Innova, concern that the DHSC was being misleading as the manufacturer was brought to the attention of the MHRA by the MHRA External Advisory Group on this issue (see Section 6)

5.3.6 I was interviewed on these findings, together with those from the University of Birmingham on local and national radio. National interviews included Radio 4 Inside Science (26th November 2020) (JJD/49-INQ000475134) and Radio 4 Newscast (22nd December 2020). (JJD/51-INQ000475136)

5.3.7 On January 10th 2021 the Government announced that community testing would be expanded across all local authorities in England to test people without symptoms. I was one of many experts requested to comment on this decision by the Science Media Centre (JJD/53-INQ000474909). The comments were polarised between individuals who focused on the potential benefits of testing and those concerned about the potential harms, particularly due to the poor accuracy of Innova.

5.3.8 On January 12th 2021 I wrote a BMJ Blog with Dr Angela Raffle (University of Bristol Population Health Sciences and UK National Screening Programmes) and Dr Mike Gill (Regional Director of Public Health, and former member of UK National Screening Committee) titled "Covid-19: government must urgently rethink lateral flow test roll out" (JJD/54-INQ000474907). We expressed our concerns that mass screening with Innova could risk serious harm and that we called on the government urgently to change course. We pointed out the poor evidence of the test, the misleading information being presented in its performance (particularly in school settings), the harms that can occur with a test with poor sensitivity leading to false reassurance (an issue from the misleading information), and many of the other concerns that were shared with us from many experts in screening, test evaluation and public health.

5.3.9 It is important to put these concerns in the context of:

(1) that three consecutive studies had shown the poor performance of Innova;

(2) that the DHSC was continuing and expanding the Moonshot programme regardless of these findings;

(3) we had just commenced the third lockdown on the 6th January 2021 (the second lockdown from 5th November 2020 to 2nd December 2020 had failed to prevent an increase in cases over Christmas) and that there was a national concern that we needed to make sure that accurate, secure and trusted testing was available after the failure of national testing in the first part of the pandemic.

5.3.10 We were not the only experts to express concerns – with many letters sent to organisations such as the RSS and the discussions at the SMC.

5.3.11 The DHSC and its scientific experts responded to our concerns by writing a letter on the Liverpool University website JJD/55-INQ000488645), which was covered by the media with interviews, including the BBC (JJD/56-INQ000531143) and the BMJ (JJD/57-INQ000474905). The letter and the media coverage did not address our scientific concerns and included an ad hominem attack questioning my expertise in test research, public health and Covid-19.

6 MHRA

6.1.1 My official involvement in the MHRA occurred between March 2021 and July 2021 as a member of the MHRA IVD Expert Advisory Group (MHRA IVD EAG). The MHRA IVD EAG met monthly on a video call and through email exchanges. The agendas and documents were confidential and only made available through a portal during the meeting, so no documents have been retained other than email exchanges.

6.1.2 Much of the discussion at the IVD EAG was around concerns about the DHSC use of the Innova test and the use cases that the DHSC was proposing. Concerns were considered serious; members of the IVD EAG stated that they felt duty-bound to inform the MHRA of their concerns.

6.1.3 Martin Myers (Chair of MHRA IVD EAG) wrote on the 8th of July 2021 to Graham Tunbridge (MHRA Director of Devices) on behalf of the IVD EAG (signed by all members of MHRA IVDEAG who were not on holiday at that time), listing 7 numbered concerns (JJD/58-INQ000531145).

6.1.4 In brief, these cover

(a) the FDA safety notice concerning the Innova test;

(b) conditions of the Emergency Use Authorisation (EUA);

(c) the EUA extension being continued rather than implementing regulatory assessment;

(d) concerns of conflicts in the independence of the DHSC as the manufacturer and the ability of the MHRA to be independent whilst being an executive agency as part of the DHSC;

(e) unjustified claims by the manufacturer (DHSC) that the test detects 95% sensitivity for infectious people.

6.1.5 Graham Tunbridge responded to the concerns in detail. It would be appropriate for the Inquiry to investigate the concerns in detail and obtain expert explanations on these issues. (JJD/59-INQ000531146)

6.1.6 The MHRA IVD EAG advised the MHRA on amending The Medical Devices Regulations 2002 section 38B to state minimal performance requirements for coronavirus test devices which went into place in July 2021. This amendment states that antigen tests (like Innova) need to achieve sensitivity which has a lower limit of the 95% confidence interval above 60% (point 38B). The Innova test does not meet this level. (JJD/60-INQ000531147)

7 A Call for International Harmonisation and Standardisation

7.1.1 The Covid-19 experience has shown that we do not have a consensus on the way in which diagnostic tests must be evaluated. This is a problem as we have a duty to ensure that we choose tests that lead to the best health outcomes and protect patients and the public from causing harm.

7.1.2 To many of us, it is only with irony that we remember that Matt Hancock, UK Secretary of State for Health and Social Care, stated in a press conference on 2nd April 2020 whilst discussing antibody tests, that "That means in three-quarters of cases that test would have given the false comfort of sending someone with coronavirus back on the wards. Approving tests that don't work is dangerous and I will not do it." (JJD/61-INQ000531148). I have little doubt that the scientists on the studies I have discussed were well-intended and believed that their evaluations were appropriate and safe. I, and many others, equally have little doubt that they were wrong in their assessments, and that we were left watching the DHSC asking the nation to use a "bad test".

7.1.3 We have observed a disagreement on the approach in the evaluation of tests. We are not alone in observing such disagreements. This disagreement needs to be resolved for the sake of public health and for our future. But our concern is bigger than that of tests for Covid-19 – it expands to all tests for all conditions, as there is no consensus as to how they all should be evaluated. We cannot even reach a consensus on the technical names of the statistics that we use to measure test performance or the study designs to use.

7.1.4 I believe that the Royal Statistical Society Group on Diagnostic Tests Report can help in forming a list of issues to consider as we explained in our 22 Recommendations. But it is a document written by a small number of experts in a short time period, and will not create consensus on its own. Test evaluation requires a multidisciplinary approach, and stakeholders, including scientists, clinicians, manufacturers, regulators and the public and patients, must be involved.

7.1.5 We do not currently have International Harmonisation and Standardisation in the world of Diagnostic Tests. Whilst the In Vitro Diagnostic Regulation (IVDR) covers relevant areas, its focus is not broad enough to cover the issues which the world of test evaluation needs to address.

7.1.6 Whilst we have models that we can follow – The Council for International Organizations of Medical Sciences (CIOMS) has been active since 1949 with the goal of advancing public health by publishing guidelines on ethics, product development, and safety in medical research, (JJD/62-INQ000531149) and

The International Council for Harmonisation (ICH) has shown that it is possible to obtain consensus and harmonise technical processes in drug evaluation with scientists, regulators and manufacturers at an international level (JJD/63-INQ000474910), these organisations have focused on medicines (drugs and vaccines), with little consideration of medical tests.

7.1.7 A positive outcome of the Covid-19 pandemic could be that we agree to achieve consensus and develop a Standardisation process for the evaluation of tests for the sake of our public health. Achieving this will involve substantial work and goodwill and will have a financial cost, but its long-term and broader benefits could benefit mankind.

8 Appendix: List of documents and interviews

8.1 Opinion and Editorial pieces

8.1.1 Deeks J. Too many corners are being cut in the race to find a Covid-19 antibody test. Guardian 27th August 2020. https://www.theguardian.com/commentisfree/2020/aug/27/covid-19-antibody-test-coronavirus-corners-being-cut (JJD/19-INQ000474901)

8.1.2 Deeks JJ, Brookes AJ, Pollock AM. Operation Moonshot proposals are scientifically unsound. BMJ Editorial. 22th September 2020. https://www.bmj.com/content/370/bmj.m3699 (JJD/47-INQ000475139)

8.1.3 Deeks JJ, Raffle AE. Lateral flow tests cannot rule out SARS- CoV-2 infection. BMJ Editorial 11th December 2020. https://www.bmj.com/content/371/bmj.m4787 (JJD/48-INQ000474904)

8.1.4 Deeks J, Gill M, Bird, S, Richardson S, Ashby D. Covid-19 INNOVA testing in schools: don't just test, evaluate. BMJ Blog. January 12th 2021. https://blogs.bmj.com/bmj/2021/01/12/covid-19-innova-testing-in-schools-dont-just-test-evaluate/ (JJD/31-INQ000474906)

8.1.5 Deeks J, Raffle A, Gill M. Covid-19: government must urgently rethink lateral flow test roll out. BMJ Blog. January 12th 2021.

https://blogs.bmj.com/bmj/2021/01/12/covid-19-government-must-urgently-rethink-lateral-flow-test-roll-out/ (JJD/54-INQ000474907)

8.1.6 Deeks J, Why the school testing regime needs to change. UnHerd 10th March 2021.
https://unherd.com/thepost/why-the-school-testing-regime-needs-to-change/ (JJD/32-INQ000474903)

8.1.7 Gurdasani D, Ziauddeen H, Greenhalgh T, Roberts A, Yates K, Haque Z, Michie S, McKee M, Pagel C, Hyde Z, Bassani DG, West R, Reicher S, Deeks J. .Daily contact testing trials in schools are unethical and extending them to include the delta variant puts everyone at risk. BMJ Blog. June 17th 2021.
https://blogs.bmj.com/bmj/2021/06/17/daily-contact-testing-trials-in-schools-are-unethical-and-extending-them-to-include-the-delta-variant-puts-everyone-at-risk/ (JJD/33-INQ000474908)

8.2 Podcasts

8.2.1 Talk Evidence covid-19 update - lack of testing transparency, how to give good debate. May 4th 2020.
https://podcasts.apple.com/us/podcast/talk-evidence-covid-19-update-lack-testing-transparency/id1513138722?i=1000474442558

8.2.2 Talk Evidence covid-19 update - strategies to end lockdown, more testing. May 22nd 2020.
https://podcasts.apple.com/us/podcast/talk-evidence-covid-19-update-strategies-to-end-lockdown/id1513138722?i=1000475485190

8.2.3 Talk Evidence covid-19 update - dexamethosone, testing, rehabilitation after covid. June 25th 2020.
https://podcasts.apple.com/us/podcast/talk-evidence-covid-19-update-dexamethosone-testing/id1513138722?i=1000479602975

8.2.4 Talk Evidence covid-19 update - antigen testing and developing non drug evidence. Oct 5th 2020.
https://podcasts.apple.com/us/podcast/talk-evidence-covid-19-update-antigen-testing-developing/id1513138722?i=1000493688439

8.2.5 Talk Evidence - Lateral flow tests update, not the best public health approach Jan 16th 2021. https://podcasts.apple.com/us/podcast/talk-evidence-lateral-flow-tests-update-not-best-public/id1513138722?i=1000505525839

8.3 High profile radio and TV features

8.3.1 BBC Radio 4. More or Less. Antibody tests, early lockdown advice and European deaths. June 10th 2020. https://www.bbc.co.uk/sounds/play/m000jw02 (JJD/18-INQ000475135).

8.3.2 BBC Panorama. Belly Mujinga's death: searching for the truth. October 14th 2020. https://www.bbc.co.uk/iplayer/episode/m000nh49/panorama-belly-mujinga-searching-for-the-truth

8.3.3 BBC Radio 4. Inside science. COVID Operation Moonshot; Big Compost Experiment; Gulf of Mexico meteorite and new life. November 26th 2020. https://www.bbc.co.uk/programmes/m000ph4n (JJD/49-INQ000475134).

8.3.4 BBC Newscast. Eels in blankets? How do Covid tests work? December 22nd 2020. https://www.bbc.co.uk/programmes/p0927j62 (JJD/51-INQ000475136)

8.4 Expert Reaction to the Science Media Centre

8.4.1 Expert reaction to PHE laboratory evaluations of Roche and Abbott antibody tests. 19th May 2020. https://www.sciencemediacentre.org/expert-reaction-to-phe-laboratory-evaluations-of-roche-and-abbott-antibody-tests/

8.4.2 Expert reaction to review of antibody tests for SARS-CoV-2. 1st July 2020. https://www.sciencemediacentre.org/expert-reaction-to-review-of-antibody-tests-for-sars-cov-2/

8.4.3 Expert reaction to government buying 1 million home antibody tests for nationwide surveillance. 7th October 2020. https://www.sciencemediacentre.org/expert-reaction-to-government-buying-1-million-home-antibody-tests-for-nationwide-surveillance/

8.4.4 Expert reaction to preliminary report evaluating lateral flow viral antigen detection devices (LFDs). 11th November 2020. https://www.sciencemediacentre.org/expert-reaction-to-preliminary-report-evaluating-lateral-flow-viral-antigen-detection-devices-lfds/

8.4.5 Expert group briefing on 'Operation Moonshot' mass testing/population screening for SARS-Cov-2. 16th November 2020. https://www.sciencemediacentre.org/expert-group-briefing-on-operation-moonshot-mass-testing-population-screening-for-sars-cov-2/

8.4.6 Expert reaction to government announcement that asymptomatic testing is to be rolled out across country starting next week. January 10th 2021. https://www.sciencemediacentre.org/expert-reaction-to-government-announcement-that-asymptomatic-testing-is-to-be-rolled-out-across-country-starting-next-week/

8.4.7 Expert reaction to a preprint looking at viral load and lateral flow devices. January 21st 2021.https://www.sciencemediacentre.org/expert-reaction-to-a-preprint-looking-at-viral-load-and-lateral-flow-devices/

8.4.8 Expert reaction to new analysis on Lateral Flow Device specificity. March 10th 2021. https://www.sciencemediacentre.org/expert-reaction-to-new-analysis-on-lateral-flow-device-specificity/

8.4.9 Expert reaction to statistics for rapid asymptomatic testing in schools in England between 4 March to 10 March 2021. 18th March 2021. https://www.sciencemediacentre.org/expert-reaction-to-statistics-for-rapid-asymptomatic-testing-in-schools-in-england-between-4-march-to-10-march-2021/

8.4.10 Expert reaction to US FDA safety communication on Innova SARS-CoV-2 Antigen Rapid Qualitative Test. 11th June 2021. https://www.sciencemediacentre.org/expert-reaction-to-us-fda-safety-communication-on-innova-sars-cov-2-antigen-rapid-qualitative-test/

8.4.11 Expert reaction to announcement that 60,000 fans will be able to attend the Euro semi-finals. 23rd June 2021.

https://www.sciencemediacentre.org/expert-reaction-to-announcement-that-60000-fans-will-be-able-to-attend-the-euro-semi-finals/

8.4.12 Expert reaction to Events Research Programme Report on Phase 1 findings. 25th June 2021. https://www.sciencemediacentre.org/expert-reaction-to-events-research-programme-report-on-phase-1-findings/

8.4.13 Expert reaction to opinion and data analysis on whether expanding the UK covid-19 case definition would improve the UK's pandemic response. 1st July 2021. https://www.sciencemediacentre.org/expert-reaction-to-opinion-and-data-analysis-on-whether-expanding-the-uk-covid-19-case-definition-would-improve-the-uks-pandemic-response/

8.4.14 Expert reaction to preprint from trial looking at daily testing instead of isolation for contacts of COVID-19 cases in schools and colleges. 23rd July 2021. https://www.sciencemediacentre.org/expert-reaction-to-preprint-from-trial-looking-at-daily-testing-instead-of-isolation-for-contacts-of-covid-19-cases-in-schools-and-colleges/

9 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: 21st March 2025