Annex A: COVID-19 testing

This note is designed to address outstanding questions on COVID-19 testing with answers provided thematically.

Overview of progress

The fight against coronavirus is one of the greatest public health challenges that we have faced as a nation and our National Testing Programme has tackled it head on. Our achievements on testing have provided a strong foundation from which to launch the NHS Test and Trace service across England, to help identify, contain and control COVID-19, reducing its spread and saving lives.

In January, at the very beginning of the outbreak, Public Health England (PHE) published the protocol for a diagnostic test for COVID-19. They worked with the NHS to rapidly develop what we now refer to as Pillar 1 of the testing programme, which to this day supports the most acutely ill in hospitals, outbreak investigations (including in care homes) and NHS staff working on the frontline.

Since March we have scaled-up our testing capacity from around 2000 tests per day to over 318,000 tests across all Pillars as of 19 July. We set ourselves challenging targets and worked tirelessly to meet them. As a result, all symptomatic people across the whole of the UK can access a test.

In that same time we have also worked with a range of partners to establish a diagnostic network spanning the whole of the UK from scratch.

As of 23 July, this network now spans 73 Regional Testing Sites, 15 walk-through Local Testing Sites, 22 Satellite Testing Sites and 236 Mobile Testing Units across the UK.

Since the publication of our testing strategy in April, we have worked with PHE, the Office for National Statistics (ONS), Biobank, universities and other partners to establish a number of studies to learn more about the incidence and spread of the virus in England. These studies will help us to develop our current and future understanding of the virus.

We are now planning for the next phase of testing, ensuring our programme is as effective as possible in containing the virus, and building resilience for the long-term, especially ahead of winter.

Last week the Prime Minister announced that we are planning to increase our testing capacity to half a million tests a day by the end of October. This will ensure that we are able to meet demand for testing throughout the winter period and allow targeted use of asymptomatic testing to detect more new cases for instance as part of our response to local outbreaks.

Steps we are taking to support staff testing in the NHS

In the early days of dealing with this pandemic, we rightly took the decision that patients and other vulnerable groups must come first. For them a test can mean the difference between life and death, by helping to inform clinicians and ensuring they receive the best possible care. On the 27th of March we announced that frontline NHS staff were the first group we would be expanding to, followed shortly after by those working in social care, as these groups provide care to the most vulnerable members of our society.

We are continuing to test all symptomatic staff as a priority. Further guidance has been provided to NHS organisations regarding utilising testing capacity. Increased lab capacity now enables testing of all non-elective inpatients at point of admission, the introduction of pre-admission testing of all elective patients, and testing prior to discharge to a care setting.

The Chief Medical Officer's (CMO) view is that additional NHS testing capacity should be used for testing non-symptomatic staff (in addition to all patients and symptomatic staff) working in situations where there is an untoward incident or outbreak or high prevalence. He also advises that regular asymptomatic staff testing is best done through enrolling some staff in surveillance studies – such as the PHE-led SIREN study where the primary objective is to monitor whether prior infection detected by antibodies prevents future infection. The SIREN study will also be able to give estimates of prevalence of both acute infection (measured by PCR) and past infection (measured by antibodies) in healthcare workers.

This risk-based, dynamic approach to focus intensive testing in high prevalence areas is essential as when prevalence is very low, the risk of misleading results is higher, and this can undermine the value of testing. We of course keep all clinical advice under review.

Evidence regarding the effectiveness of self swabbing vs swabs administered by a clinician

My officials and I were clear that self swabbing was a process we would only undertake if we truly believed it was safe and effective to do so. International peer reviewed evidence, and real-world assessments from the Department's testing programme has shown that swab tests taken by non-clinically trained individuals are just as effective as those taken by clinicians.

The timings associated with our current testing process

For tests conducted under the Pillar 1 and Pillar 2 testing routes, the Department now publishes weekly statistics on the turnaround time of tests as part of the Test and Trace Statistics publication each Thursday.

Pillar 1 turnaround time is defined by laboratories as the time interval between the specimens received in the laboratory reception to the time of reports dispatched with verification. The data is reported as tests completed within 24hrs and tests completed exceeding 24hrs.

For Pillar 2 this data covers the end to end process of swab taken to results delivered and details the proportion of test results returned to those awaiting them within 24, 48 and 72 hours. Pillar 2 testing can be carried out through several different routes, which include 1) regional test sites; 2) mobile testing units; 3) satellite test centres; and 4) home test kits. The time taken to receive a test result after taking a test has improved across all routes since the launch of the NHS Test and Trace programme on 28 May.

We continue to work closely with the Office for Statistics Regulation and the ONS to ensure statistics are good quality, statistics will necessarily develop in response to needs.

Seeking asistance with Home Testing Kits

More than 1 million home-tests have been despatched since this testing channel rollout began in April. Where, in a small number of instances, process errors have been highlighted

to us that mean that the testing kit cannot be returned, we have taken urgent action to implement robust mitigations to the testing process.

For these, and all other issues people experience whilst interacting with the National Testing Programme, we encourage people to call our dedicated call centres on 119 (in England and Wales) and 0300 303 2713 (in Scotland and Northern Ireland.)

Testing data

We know that in order to manage our response to this pandemic we need to understand where the virus is and how prevalent it is. We also know that decision makers in Local Government need access to timely and accurate data to keep people safe.

PHE has developed a data-sharing agreement with local authorities and has been providing local Directors of Public Health with record level (postcode) testing data since late June. PHE and Directors of Public Health work closely with other local partners in the management of local outbreaks.

We have also provided testing data through NHS Digital's Contain Dashboard. This and other information is provided through a Data Sharing Agreement. This grants the Local Authority data controllership, so it is within their gift to determine how and with who they share it, ensuring compliance with the appropriate guidance.

A public version of this dashboard is available at https://digital.nhs.uk/dashboards/progression

We have also provided data for the public on Coronavirus cases in the UK on Gov.uk, available here: https://www.gov.uk/guidance/coronavirus-covid-19-information-for-the-public and the NHS Test and Trace service on a weekly basis as part of a transparency data set release available here: https://www.gov.uk/government/collections/nhs-test-and-trace-statistics-england-weekly-reports. This is updated weekly and includes a range of statistics from across the programme.

The Office for Statistics Regulationwrote on 15 July saying that they have reviewed the Test and Trace weekly statistics publication against several key aspects of the Code of Practice for Statistics and "regards them as consistent with the Code's pillars of Trustworthiness, Quality and Value."

With regard to private testing operations, under the Health Protection (Notification) Regulations 2010 it is a legal requirement to report cases of COVID-19, or any other notifiable disease, to PHE and any laboratory found not to be adherent to this practice maybe subject to fines. All laboratories, be they public or private, have this statutory duty.

Data on all cases reported to PHE is held in PHE's Second Generation Surveillance System (SGSS). Data from SGSS is fed into the NHS Track and Trace system and is part of the information shared with local authorities on cases in their area.

The Department does not collect data on the number of people or the exact reasons a person might require to be tested more than once. There are a number of clinically valid reasons for retesting a person, for example, a healthcare worker may recieve their second, third or fourth test since the start of the pandemic as a response to the presenetation of COVID-19 like symptoms or regular testing. Or a patient who was tested when their symptoms were mild and tested negative, but has since deteriorated. Clinicians are able to exercise their discretion in order to ascertain the most effective treatment for their patients

and includes retesting a person where appropriate.

Steps we are taking to ensure testing is not just available but accessible for all groups

We are working closely with other government departments and Local Government to maximise our reach and encourage as wide a range of people as possible to access testing.

Everyone with symptoms of COVID-19 is eligible for a test, but we know that certain groups or individuals may find access more difficult, be less likely to want to access a test, or feel unable to self-isolate. This could be for a combination of reasons, from capability through to personal circumstance.

We are working on a number of policies to address these barriers. These include the following:

- The NHS 119 call centre uses the Language Line (an interpreter service) and staff are trained to manage language barriers, including through use of this service. We have also put in place translation services at testing sites.
- We have opened 15 local 'walk-in' test centres [through England] to make it easier for people without cars to get a test. This includes four sites across Leicestershire to support with the local lockdown and help reduce the infection rate.
- We have sign language interpreters at regional tests sites to support access to testing for deaf service users.
- We have introduced and continue to scale home testing services, as well as our satellite testing capacity (which provides an additional means of providing tests to vulnerable groups with access issues such as care home residents).
- We are working with the Royal National Institute for the Blind to understand how we can improve testing services for the visually impaired.

More broadly, policy decisions to implement the test and trace system have also been informed by equality assessments. In line with our legal duties, we are continuing to do this as Test and Trace is rolled out.

Testing to support a return to education

The government will ensure that it is as easy as possible to get a test through a wide range of routes that are locally accessible, fast and convenient. We will release more details on new testing avenues as and when they become available and will work with the Department for Education and schools so they understand what the quickest and easiest way is to get a test.

By the autumn term, all schools will be provided with a small number of home testing kits that they can give directly to parents/carers collecting a child who has developed symptoms at school, or staff who have developed symptoms at school, where they think providing one will significantly increase the likelihood of them getting tested. Advice will be provided alongside these kits.

Testing for antibodies

On 21 May the Government announced plans for a national roll-out of antibody testing in the NHS and care sector. Since the end of May, lab-based antibody tests have been available to

all NHS staff that want one. For care staff, antibody testing will be rolled out in a phased way across regions in England. All NHS and care staff in England are being offered an antibody test, with patients and care residents eligible at their clinician's request. Any expansion of this programme will be announced at the appropriate time.

The Department is also working with the Medicines and Healthcare products Regulatory Agency to ensure the public is aware of unregulated or unverified antibody tests.

The CMO discourages in the strongest terms organisations from buying their own unvalidated antibody tests. Antibody tests are currently only allowed to be sold for professional use. There are no CE-marked or validated self-tests for home use, and it is illegal to supply such products. Professor John Newton has warned that unapproved tests could be misleading, by providing inaccurate or inconsistent results, potentially putting those tested and those around them at risk.

Testing innovations

Saliva based testing is a promising solution that could increase testing capacity and accessibility in the future. Work on national validation and service evaluation is ongoing.

The Department has established a trial of 14,000 people in Southampton to assess this method of testing. The test has already been shown to be highly promising and the pilot is undertaking further validation against polymerase chain reaction (PCR) nasal swabs, with a view to wider use if successful. More information can be found in this press release: https://www.gov.uk/government/news/new-saliva-test-for-coronavirus-piloted-in-southampton.

International evidence and work done to share best practice

With regards to our approach to international best practice and collaboration, we are keen to learn from examples of best practice.

One of my Noble Lords highlighted an example of an "open-testing" policy in one part of the United States, whereby testing was substantially increased and the symptom requirements for individuals to be tested was removed.

Based on the latest clinical and scientific advice and our understanding of the prevalence of the virus of the UK, we have judged that a risk-based approach whereby focusing on asymptomatic testing in high prevalence areas is more useful than mass asymptomatic testing in areas of low prevalence.

Our targets and ensuring we can use our ramped-up capacity most effectively

Testing numbers may fluctuate on a day to day basis, with many factors influencing how many tests are done, and available capacity, on any given day. Current testing capacity across all pillars currently stands at 318,829 as at 19 July 2020 - this includes PCR and antibody tests.

Testing is a vital part of the UK's response to COVID-19 and we have now made testing available to all symptomatic people across the UK. We continue to prioritise available capacity where it can be most effective and any further alterations to eligibility criteria will be assessed on their merits.

Beyond testing of anyone with symptoms, we target available capacity where it is most likely to identify further cases and prevent further transmission. While our priorities will evolve in line with the evidence of who and where is at risk, our current asymptomatic testing priorities include:

- testing widely around outbreaks;
- introducing testing of all staff in adult care homes weekly, residents every 28 days, alongside targeted testing of the wider social care community;
- testing staff in hospitals where there is any indication of increased prevalence or risk;
- undertaking targeted testing of groups and occupations who may be at higher risk;
- undertaking extensive testing for research studies, to help monitor changes in prevalence of COVID-19.

Partnerships to deliver testing

Government has established a multitude of partnerships with industry, academia, local government and others to deliver its testing programme - from companies supplying testing kits and supplies to logistics and processing partnerships.

Our testing programme absolutely could not be delivered without these partnerships and where contracts with commercial partners have been finalised the Department is publishing contract award notices in order to detail them for the public.

Contracts are placed in line with DHSC terms and conditions which include clauses for contract management to ensure that supplier performance and the delivery of value for money can be properly assessed throughout the lifetime of the contract.

As a result of our partnerships, we have been able to rapidly expand our testing capacity and expand coronavirus testing eligibility to all symptomatic people across the whole of the UK.

Supply and specifics of our testing supplies

We cannot provide information on the exact per unit price of the tests we are using as this is commercially sensitive and could, if disclosed, make subsequent negotiations more difficult and mean we are forced to pay more in future.

On the rate of false positive and false negative results, it is worth noting that false-positive (and true-negative) results are more likely to occur when disease prevalence is low, which is generally at the beginning and end of a pandemic or a spike in infection rate. False-negative (and true-positive) results are more likely to occur when disease prevalence is high, which is typically at the height of a pandemic or spike in infection.

Assay performance characteristics, disease prevalence, sampling error, sampling sites and the natural history of an infection all influence the reliability of a result.

The PCR tests we are using are very accurate. Where the primer sequence (which is identical to a part of the virus' genetic code) is detected then the virus is present, if it is not detected that could be because the virus is absent, or the sampling of the individual was not undertaken appropriately. This is not directly related to the sensitivity of the assay and does not imply that the test is substandard.

The analytical sensitivity is therefore 100%.

On materials needed for the process of testing for COVID-19, there is a clear and unprecedented demand for testing supplies and companies, including UK manufacturers,

are ramping up their capacity as quickly as possible. We are working closely with industry to obtain maximum possible supplies for the UK and with the scientific community to explore innovative new options for test kits. In the meantime, we have an assured supply of chemical reagents, swabs and other materials necessary to conduct and process our current demands for testing.

Testing within adult social care

Peers have understandably raised the issue of testing in social care and I have a number of areas I feel it is worth updating you on, which I hope will answer your questions whilst also providing a more general overview.

Testing in adult social care

The organisation responsible for testing differs depending on whether there is a suspected or actual outbreak, or the testing is part of routine 'whole care home' testing.

Where there is a suspected or actual outbreak PHE's Health Protection Teams are responsible for initiating testing of all staff and residents and confirming the presence of positive cases and a wider outbreak.

The process for testing of all care home residents and staff without symptoms, where there is no outbreak, is the responsibility of the Department of Health and Social Care. This process was facilitated by the introduction of the 'whole care home portal' on 11 May. This portal makes it easier for care homes to arrange deliveries of coronavirus test kits. We have now offered whole home testing to all care homes for adults.

To ensure clarity for care home operators we are continually engaging with sector representatives through written communications and regular meetings. We are continuing to listen to the sector about the importance of testing in other types of adult social care settings. I would like to take this opportunity to explain the recent announcements and our plans for testing different adult social care settings.

Care Homes

On 3 July, we announced the next stages in our testing strategy for adult social care. This includes regular retesting for care homes and enhanced outbreak testing for care homes. Over the coming weeks retesting will be rolled out to care homes for over 65s and those with dementia who have registered to receive retesting. We will then expand retesting to the remaining adult care homes. Staff will be tested for coronavirus weekly, while residents will receive a test every 28 days. This retesting helps to prevent and control outbreaks in care homes and means steps can be taken to reduce the spread of the virus, and is in addition to intensive rapid testing in any care home facing an outbreak, or at increased risk of an outbreak. This approach is based on advice from SAGE and PHE in addition to evidence from the initial round of whole home testing and the results from our Vivaldi surveillance survey.

Extra Care and Supported Living

On 16 July we wrote to Directors of Public Health to ask them to help us determine which supported living and extra care settings in their areas should be able to access an initial round of testing for staff and residents. As with care homes, we will use the data from the initial testing rounds to inform our retesting approach. If supported living settings have a suspected outbreak, they should report to PHE Health Protection Teams (HPT). HPTs will then undertake an initial risk assessment, provide advice on outbreak management and decide what testing is needed.

Domiciliary Care

Asymptomatic testing for domiciliary care workers will be guided by the results from the PHE prevalence study into domiciliary care. This study found that the prevalence amongst care workers was similar to the general population. We are in the process of reviewing the implications for testing in domiciliary care. In addition to the adult social care testing strategy, work is underway to support and enable Directors of Public Health to direct some testing locally. This may include further testing resource within adult social care.

Surveillance Study

We have launched the second phase of the Vivaldi study, which will offer regular swab and antibody testing to staff and residents from over 100 care homes to give detailed picture of coronavirus infection in care homes in England and enable care homes to respond quickly to outbreaks. Results from the first phase of the Vivaldi study can be found here : https://www.gov.uk/government/statistics/vivaldi-1-coronavirus-covid-19-care-homes-study-report