Testing Strategy for Wales
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When we published our Testing Strategy on 15 July 2020, we were emerging from lockdown after the first wave of the Covid-19 pandemic. Since that time testing has continued to play a pivotal role in our overall approach to preventing the transmission of Covid-19 across Wales.

Testing on its own does not remove or reduce the extent to which the virus is circulating in our communities. Everyone, irrespective of whether they have had a test recently, must maintain social distancing where possible, practise good hand hygiene and follow the guidelines on the wearing of face coverings in order to keep us all safe.

Testing can play a part in reducing the harms associated with Covid-19 and since the last strategy was published, new testing technologies have demonstrated it is possible to test at far greater scale, frequency and speed than ever before. We need to utilise the best of what these new technologies can offer, in ways which are trusted, safe, and achieve our overarching priorities for testing for Wales. We also need to remain agile in our approach to testing as we learn more about the virus, any new strains and transmissibility.

This update sets out how new testing technology will work alongside our existing testing infrastructure to support our priorities. As we begin 2021 our approach will continue to evolve to meet the challenges we face. Testing will continue to play an important role alongside the vaccine in supporting us to save lives and livelihoods during 2021 and the longer term.
Testing people to identify those who have Covid-19 is one part of our overall programme to control the spread of Covid-19.

Tracing those people who have been in close contact with a person who has tested positive, and providing advice and guidance is critical to stopping the virus spreading through our communities. We use the NHS Covid-19 app, alongside traditional contact tracing staff, to notify people if they come into contact with someone who later tests positive for coronavirus.

It is important that there is a seamless link between testing and tracing. We are therefore working on digital solutions to ensure it is as easy as possible to record the result of any test, so that contact tracing can begin as early as possible, and any contacts of positive cases can be identified and asked to self-isolate.

The integration of genomics data will enable further detailed analysis and provide data to support potential clusters identified via contact tracing. Genomics also provides the capability to examine the import of virus into Wales, a capability that has already been used during the first wave and over the summer of 2020. This capability will be particularly important as global travel is restored as we move into 2021.

Asking people to self-isolate is an important way to break the transmission of the virus but for many people it can mean the loss of income. In October 2020, the Welsh Government made funding available to support people and remove the financial barriers faced by people needing to self-isolate. The self-isolation support scheme is for those on low incomes, who cannot work from home and must self-isolate. It is also for parents and carers on low incomes with children who are self-isolating. A £500 fixed payment is available to eligible people who are asked to self-isolate because they have tested positive for coronavirus or because they have been identified as a close contact by the NHS Wales Test Trace Protect service. The Statutory Sick Pay Enhancement scheme also provides full pay for certain social care workers when they need to take time off due to Covid-19.

Testing and the dynamics of COVID-19 infection

Our understanding of Covid-19 is improving all the time helping us know how to interpret results and determine when testing can be of most benefit. Covid-19 is the disease caused by infection with the SARS-CoV-2 virus. Based on the original virus we know:

- The median incubation period of the virus is 5.1 days, and more than 97% of individuals who develop infection will do so by 14 days after exposure.
- Individuals are maximally infectious around the time of symptom onset. They are deemed infectious for two days prior to symptom onset and for ten days after symptom onset, although infectivity declines significantly after five days.
- The spectrum of symptoms is wide. While a proportion of people have severe infection (particularly the elderly or those with underlying conditions), up to a third of individuals who test positive for the virus have no symptoms at all.
- During the course of a typical illness the amount of virus in upper respiratory samples increases and is maximal around the time of symptom onset, correlating with maximum infectivity. Thereafter the amount of viral protein or RNA declines. Viral RNA may remain detectable for a period of weeks or months after recovery, although this does not represent live infectious virus.

1 https://gov.wales/self-isolation-support-scheme
The virus is continuing to adapt. We use genomics to provide a tool to examine the effect of mutations on diagnostic test performance, and to identify and track mutations that may require further investigation.

We use our understanding of the dynamics of the infection alongside the characteristics and performance of the various tests available to us to inform decisions on how best to use the different tests.

We continue to undertake testing of symptomatic individuals using RT-PCR tests. The availability of rapid test results from new testing methodologies (e.g. Lateral Flow tests) offers the potential to supplement the current testing offer and develop new approaches to testing. Our approach to using any testing technology is informed by the available evidence. We keep our testing approach under review and if evidence changes we consider and revise our approach as necessary.

The major elements for evaluation of test accuracy are diagnostic sensitivity and specificity, which determine the likelihood of false positive or false negative results:

- The likelihood of false positive results is primarily determined by the specificity of the test.
- The likelihood of false negative results is determined by the sensitivity of the test and the prevalence of Covid-19 in the test population.

The performance or accuracy of any given test is not only determined by the test performance but the context in which testing takes place. For example if the testing targets symptomatic individuals this increases the pre-test probability of a positive result and therefore would reduce the proportion, although not the number, of positive results that were false positive results. Also, if the testing protocol adopted involved repeat testing, each round of repeat testing would reduce the numbers of false negative results.

The diagram below illustrates some of the differences between RT-PCR testing and some of the alternative less sensitive testing modalities such as lateral flow tests. It illustrates that when individuals are at their most infectious (most likely to spread the virus) lateral flow tests are likely to be more accurate. This means they are a good test for determining infectivity because when used on people at their most infectious their sensitivity is higher.

We continue to be advised by experts in Public Health Wales and the Testing Technical Advisory Group to ensure the quality and efficacy of testing.
Testing and Genomics, Investigating the Virus

In Wales we have benefited from investment in Pathogen Genomics capacity as part of the Genomics for Precision Medicine strategy, combined with a national network of laboratories across the UK under the umbrella of COG-UK, which provides a capability that is truly world-leading. The volume of data generated within Wales and the wider UK, and its use in real time, is globally leading. The identification of clusters and transmission chains, with the immediate epidemiology, has provided valuable actionable information which has supported our NHS and Health Protection teams in their efforts to control the spread of SARS-CoV-2 in hospitals and our communities. On a national scale genomics analyses have supported the Welsh and UK Governments in policy making.

SARS CoV-2 is an RNA virus and, as with numerous RNA viruses, is prone to changes within its sequence. The dominance of a variant of concern in South East England within a short timescale has yielded a significant increase in cases, resulting in an overall increase in hospitalisations and deaths. The identification and characterisation of this variant was by genomics, and genomics is the only method in existence that is able to unambiguously identify variants of concern or variants that should be investigated. It is inevitable that further variants of concern and interest will emerge, and this requires vigilance which can only be provided via a functioning genomics network throughout the UK. Testing is linked to this network so we can seamlessly test to detect the virus, and undertake sequencing to identify any variations. Testing and genomics will also help with post vaccination surveillance. Working with other UK partners, and across the animal and human health sectors, genomics provides a linkable set of data for addressing research questions, and for horizon scanning.

Testing Capacity and Performance

Demand modelling for the RT-PCR test takes place regularly and accounts for a number of variables, the spread of the disease, the incidence of new cases and transmission rates in the community, the prevalence of symptoms and the emerging evidence on how testing can best be deployed to prevent infection, and increased demand generated by confirmatory testing following positive results from a lateral flow device. It also needs to take account of the behaviours that can drive demand.

Our strategy in July set out the RT-PCR modelling requirement that contact tracing combined with the other testing purposes could potentially require us to need as many as 20,000 tests a day. From this total the contact tracing demand was estimated at 4,500 - 11,000 per day.

Since we published the previous strategy we have seen increasing demand for testing undertaken per week from less than 18,000 (mid July) to a high of just under 127,000 (mid December). We have also within this period managed spikes in demand driven for example by the return of schools in September.

The testing strategy published in July outlined our commitment to build resilience, sustainability and to improve turnaround times in NHS Wales laboratories. In August we announced investment of £32 million to support enhancements and expected potential lab capacity levels have been achieved. Currently, approximately 70% of laboratory capacity to process RT-PCR tests is through the Lighthouse Laboratory (LHL) Network and 30% from NHS Wales laboratory capacity. Wales could now access a total of 37,000 laboratory tests per day if required. Typically turnaround times for individuals attending physical channels receiving results are 80% in one day and 98% within two days; for care homes and closed setting environments over 85% are
currently receiving their results within two days via LHL or NHS Wales laboratories and we continue to work on improving these times.

We have also expanded the range of our testing sampling and infrastructure. Our sampling capacity now includes Local Testing Sites (LTSs) that enable people to access testing on foot giving more local access for people and communities to be tested. We are planning to open further sites early in 2021. We are increasing the capacity of our mobile testing units and will be considering how we also use the new testing technology available to us within our mobile testing approach to support our testing priorities. We will also further explore opportunities to extend our asymptomatic testing capacity including Asymptomatic Testing Sites in communities, places of work, schools and colleges.

We now have an extensive range of facilities across the country – details here https://gov.wales/regional-coronavirus-testing-facilities
Our Priorities

We know that the harm caused by Covid-19 is not limited to the direct harm caused to those who become infected. Harm also arises when the NHS and social care systems are overwhelmed; when other non-Covid related activities are reduced; and as a result of wider societal actions such as lockdown.

Our testing strategy aims to minimise or alleviate these harms wherever possible.

In addition to using testing to diagnose and identify Covid-19 to help with treatment and to support contact tracing, thereby reducing the spread of the disease, we are realising the potential offered by new testing technologies to adopt approaches to testing that enable individuals to continue to receive in person education and to work, and that help to maintain key services when the prevalence of the virus is high. Tests are used across a variety of settings including hospitals, test sites, care homes and mobile testing units. Alongside the vaccination programme, testing will also support the safe return to normal society and economic activity.

We are making use of our world class genomics capability to enhance our testing capability to support diagnostics, enable better management of outbreaks, to detect new variants, and enhance our surveillance of the spread of the virus in our communities across our country. As the prevalence of the virus in our communities changes, our approach to testing and the emphasis needed on each of our priorities will need to respond and adapt.

In line with the overriding guiding principles of the four harms and continuing to keep the seven principles set out by the Royal College of Pathologists very much in mind we have reviewed our testing priorities which remain:

1. To support NHS clinical care – diagnosing those who are infected so that clinical judgments can be made to ensure the best care.

2. To protect our NHS and social care services and individuals who are our most vulnerable.

3. To target outbreaks and enhance community surveillance in order to prevent the spread of the disease amongst the population.

4. To support the education system and the health and well-being of our children and young people and to enable them to realise their potential.

5. To identify contacts of positive cases to prevent them from potentially spreading the infection if they were to become infected and infectious, and to maintain key services.

6. To promote economic, social, cultural and environmental wellbeing and recovery.

Put another way, our strategy is to:

1. Test to diagnose
2. Test to safeguard
3. Test to find
4. Test to maintain
5. Test to enable
1. Test to diagnose

We need to identify patients who are infected/infectious as quickly as possible, particularly those presenting to hospital so that they may benefit from specific treatment for Covid-19. A confirmed diagnosis is also important to reduce uncertainty and the need for further investigations. In this context a highly sensitive and specific test is required. Any test result should be interpreted in the clinical context and further testing directed as necessary.

Our testing strategy moving forward will continue to focus on supporting people receiving care and or being admitted to hospitals. This will include;

- Testing symptomatic patients on admission. The prevalence in this population is currently approximately 25%\(^4\). This test should have high sensitivity so that a minimum of false negative patients enter ‘clean’ areas, and should have a high specificity so that a minimum number of false positive patients are exposed to Covid-19 areas.

- Asymptomatic patients should also be tested on admission. The prevalence in this population is likely to be 1-3%\(^5\). While it is beneficial to have a high sensitivity test, given the lower prevalence in this population the number of false negatives from a lower sensitivity test may be acceptable.

- Any patients who develop symptoms during admission should be tested. This should be a test with high sensitivity and specificity.

- Testing of asymptomatic in-patients five days after admission would aim to identify asymptomatic infected/infectious individuals who may have been incubating infection at the time of admission. The prevalence of infection in this population, having had a negative test on admission and remaining asymptomatic is likely to be very low (~0.25 – 0.5%). While it is beneficial to have a high sensitivity test, given the lower prevalence in this population the number of false negatives from a lower sensitivity test may be acceptable.

- The testing of planned admissions within 72 hours prior to admission can protect patients who would be at increased risk from Covid-19 due to planned procedures (e.g. chemotherapy or surgery), and also support streaming of patients into ‘green’ pathways. The major protective measure is self-isolation for the 7-14 days prior to admission, but testing can provide reassurance. A test with high sensitivity and specificity should be used.

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\(^4\) PHW Lumira DX Ed Study

\(^5\) Initial analysis from the Merthyr pilot indicated a positivity rate of 2.3%.
2. Test to Safeguard

Covid-19 is a challenge in closed settings such as hospitals, care homes and prisons because it can be difficult to control the spread once infection is introduced. The risk of infection being brought into a closed setting is related to the prevalence of infection in the community, therefore greater vigilance is needed when prevalence within the population is higher.

Infected individuals may enter closed settings as symptomatic or asymptomatic residents, visitors, or staff members. The primary measures to control risk of infection are the use of appropriate Infection, Prevention and Control procedures. Testing can provide some additional safeguards but cannot be used as a sole means of control.

Symptomatic staff, wherever they work, should self-isolate and request a test. The test should have high sensitivity to prevent false negative results (e.g. RT-PCR).

Testing of asymptomatic staff working with vulnerable people, especially within closed settings, can potentially identify infected/infectious individuals who might otherwise pose a risk. While it is beneficial to have a high sensitivity test, the number of false negatives from a lower sensitivity test may be acceptable if individuals would not be identified otherwise. Modelling suggests that testing weekly with a high sensitivity test can reduce transmission events by approximately 50%, and testing twice weekly with a lower sensitivity test can also reduce transmission by 50%. For this reason, our asymptomatic testing using lateral flow tests is undertaken at a minimum of twice per week.

In December 2020, the Welsh Government published a detailed control plan for social care to assist social care services and the public in understanding the measures in place to protect the most vulnerable individuals in Wales. This document sets out the testing that should be in place for staff at different levels of prevalence, and how to minimise the risk when allowing visitors and external care staff into the home.

We commenced an ambitious vaccination strategy in December 2020, aiming to protect the most vulnerable first, including all care home residents and staff; frontline health and social care staff; those 70 years of age and over; and clinically extremely vulnerable individuals. Whilst this is incredibly positive, testing must remain in place for the foreseeable future. This is because the evidence is not yet available to determine the whether vaccination reduces the risk of the virus being transmitted to others. As vaccination progresses and we have further information on vaccination effectiveness, we will keep our testing approach under review.

Our approach to testing to safeguard currently involves asymptomatic testing of:

- **NHS staff** - Testing of asymptomatic staff can potentially identify infected/infectious individuals who might otherwise mix within the hospital.

- **Care home staff** - Testing of asymptomatic staff can potentially identify infected/infectious individuals who might otherwise mix within the care home.

- **Supported Living staff** - Testing of asymptomatic staff visiting vulnerable people can potentially identify infected/infectious individuals who might otherwise expose the vulnerable individuals they visit.

- **Special school staff** - Testing of asymptomatic staff working with vulnerable people can potentially identify infected/infectious individuals who might otherwise expose the vulnerable individuals they work with.

- **Domiciliary care staff** - Testing of asymptomatic staff visiting vulnerable people can potentially identify infected/infectious individuals who might otherwise expose the vulnerable individuals they visit.

Staff working in other residential care and support settings – Testing of asymptomatic staff visiting vulnerable people can potentially identify infected/infectious individuals who might otherwise expose vulnerable individuals.

Prisoners – Any prisoners who develop symptoms should be tested. All new arrivals should be tested on admission. This test should have high sensitivity and specificity (e.g. RT-PCR); the impact of false negative results could be significant due to the difficulty in controlling spread.

Care home residents – Any residents who develop symptoms should be tested. Admissions from the community or from hospitals or other closed settings should be tested prior to admission. This test should have high sensitivity and specificity (e.g. RT-PCR); the impact of false negative results could be significant due to the vulnerable nature of the residents and the setting, and therefore these should be minimised.

Visitors:

- Symptomatic individuals who might be visitors should self-isolate and order a test. They should not visit a care home. In this context, the test should have a high sensitivity to prevent false negative results.

- For asymptomatic visitors, the main control measure is reduced social mixing for the 7-14 days prior to visiting. Testing can provide reassurance that a visitor is not infected/infectious at the time of the visit. The test process should ideally have a high sensitivity to prevent false negative results. If the test has a lower sensitivity (e.g. LFD), the process can be rendered more sensitive by repeated testing as above.

- Professional visitors should be tested prior to attending at a care home. If they are part of a regular testing programme (e.g. under the NHS testing programme) they will not need to be tested again prior to entry. If professional visitors are not part of a regular testing programme, they should be tested at the time of the visit. The test should ideally have a high sensitivity to prevent false negative results. If the test has a lower sensitivity (e.g. LFD), the process can be rendered more sensitive by repeated testing as above.

3. Test to Find

Identifying and isolating Covid-19 cases in the community reduces the transmission of infection, supports contact tracing and helps to slow or stop the spread of the disease. Reduced prevalence of infection in the community reduces the number of severe infections, protects vulnerable individuals, protects the NHS, and reduces mortality.

Everyone who thinks they have symptoms of Covid-19 should get a test. We now have a number of channels through which people can access testing including a network of testing centres with more planned for 2021, making testing for Covid-19 more accessible than ever before. Our testing sites include:

- Regional Testing Sites (RTS) – provide drive through facilities
- Local Testing Sites (LTS) – provide walk in facilities
- Mobile Testing Units (MTUs) – can provide flexible facilities to increase accessibility and to focus in areas of need
- Home testing – for people to have tests posted to them to take at home

But given that people may have mild or no symptoms, there are certain contexts in which we need to deploy more active case finding approaches such as those trialled in Merthyr Tydfil and the Lower Cynon valley where whole area testing was undertaken during late November and December 2020.
A detailed evaluation of the approach is on-going but interim findings are guiding our approach for the development of our Community Testing Framework for Wales to support Test to Find. Key guiding principles will include the need for community testing in Wales to be locally led, based on evidence from surveillance and local knowledge, use risk based assessments, integrate with other local testing arrangements, focus on areas of need and have an exit strategy in place.

Active Case finding has also been used very successfully during 2020 to manage outbreaks, typically these have been linked to workplaces. This work has been supported by genomics, which has proved invaluable for distinguishing single-source outbreaks from multiple introductions into workplaces – a capability that we will build on and add to. Testing the entire workforce has identified positive cases that may otherwise have gone undetected which in turn could have contributed to onward and wider community transmission.

Genomics offers capabilities to resolve groups of positive tests into clusters which may represent transmission chains. This provides a powerful capability that we have been using extensively to support outbreak response in Wales to date. This capability, when combined with active examination of the relatedness of new cases, provides an opportunity to rapidly and proactively identify potential clusters of cases, enabling outbreaks to be caught earlier.

Our approach in Merthyr and Lower Cynon involved using lateral flow tests on a scale not seen before in Wales. This followed a pilot that had started in Liverpool aimed at testing the whole city population. The key determinant in identifying infected/infectious individuals and controlling spread of the virus is the coverage of the test population.

The testing in Merthyr and Lower Cynon took place from 21 November to 22 December with over 50,000 tests undertaken. This includes 33,315 lateral flow tests in Merthyr test sites and over 3,000 tests undertaken in schools, 14,304 in Lower Cynon test sites and 1,769 home test PCR kits returned. This represented two thirds of the targeted population and resulted in 1,135 positive cases being identified and self isolated to prevent further transmission.

4. Test to Maintain

Regular testing of staff in the workplace, including in education and childcare settings, increases surveillance to identify asymptomatic cases faster. Testing can support other critical measures (such as social distancing) to help reduce the spread of the virus and maintain services. We have started to pilot regular testing in some workplaces and will further explore opportunities with partners to deliver more workforce testing across the public and private sector.

On average about 10% of contacts develop Covid-19, increasing to closer to 15% with the new variant. Currently, contacts of infected individuals are required to self-isolate for 10 days. While this strategy should effectively remove infected/infectious contacts from mixing and transmitting infection, it has a number of potentially negative impacts:

• It can create workforce pressures in our critical public services
• It can put pressures on key businesses that impact on critical supplies
• And large numbers of children and young people miss out on face to face education

We are exploring whether testing of asymptomatic contacts could allow them to remain in work or education, safely, as an alternative to isolating for 10 days. Daily testing for the 5-7 days from identification as a contact could reduce the risk that a person attends work or education while infected/infectious. It may also provide opportunities for more active case finding. We are currently piloting and evaluating this approach, for example with South Wales Police. If effective, it will mean that the number of people not in work as a result of self-isolating could reduce, meaning key services can be more easily maintained.

Whether this type of daily contact testing can or should be adopted will be dependent on whether the test results can be verified and whether the individuals concerned work with vulnerable people, and whether they work within a closed setting. Daily tests only give a snapshot of infectivity at the time of the test. Risks remain from a contact becoming infectious between tests. Given the risks of exposing vulnerable people to infection in closed settings, this approach should only be used after careful individual risk assessment of the case and environment.

This strategy may therefore be appropriate in some contexts but not those where the repercussions arising from a false negative could be very serious. Pilots will give us more information upon which to base final decisions.

5. Test to enable

As we move forward with the vaccine roll out and towards lower prevalence of the virus, later in 2021, we will look to see how testing can further support a return to normality and meet our sixth testing priority - to promote economic, social, cultural and environmental wellbeing and recovery.

As we move from pandemic to endemic, our approach will evolve and could involve testing to enable people with a negative result or those who demonstrate the required level of antibodies in their system to:

• Attend work and normal daily activity;
• Attend a cultural or sporting event;
• Travel internationally
• Meet friends and family

Further work and approval of the testing approach and process will be required to fully deliver Test to Enable but we need to start preparing for life during and after the roll out of the vaccine to support aspects of returning to normality. Appropriate and effective testing schemes may provide additional safeguards alongside the vaccine.

Alongside testing focused on the vaccine itself, it will be critical to be able to examine vaccine failures, and to identify if there are viral factors or mutations that may explain a vaccine failure. Genomics provides the only system to perform this sort of analysis, and we will put in place systems to ensure that cases from vaccine failures are characterised using genomics. This can then be combined with other surveillance data to enable public health measures to be taken if required, as well as providing valuable data to vaccine producers to allow them to update vaccines as required.
Antibody testing

Natural antibodies are produced by the body in response to an infection and can usually be found in the blood after around 2 weeks following infection. Antibody levels usually drop after recovery and may not be detected by a test after some time has passed following recovery. Vaccine induced antibodies are produced following vaccination. These also take time to develop. We do not yet know whether or how these antibodies decline over time for a vaccinated individual and/or whether vaccinated individual can transmit the virus.

To date antibody testing has been used to measure the seroprevalence of COVID-19 antibodies; that is the level of COVID-19 antibodies present in the blood serum of a population. From June to November 2020 we delivered antibody testing for key priority groups: healthcare workers, social care workers and residents, teachers and pupils in the education hubs. Over 89,000 antibody tests were carried out with 11% having positive results. Welsh Government continues to offer antibody testing to domiciliary care workers. This information has been used to understand prevalence of the disease in different populations and to improve our understanding of the virus and how it affects people.

We are now considering how antibody testing and studies of the Welsh population can help us understand the efficacy of the vaccine in relation to immunity, both for an individual and across the population.

We also need to evaluate this approach in light of the increased transmissibility associated with the new variant.

Next Steps

The plans and actions under each of the priorities will be developed and delivered in partnership with Local Health Boards and other key partners. There is already effective joint working and practice being shared across partners. We will continue to ensure that this intelligence is shared and deliver a team Wales approach to ensure that we can optimise capacity, manage resourcing challenges and reduce complexity in the system.

We will also build in regular review and evaluation processes in key areas to support how we develop the next phase of our testing approach alongside increased vaccination of the population.