Title: Public Health Prioritisation of Testing in Current Epidemiological Context

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Organisation: Office of the National Clinical Director Health Protection, HPSC, HSE

Date: 6th January 2021

Action required:
☐ For noting
☐ For discussion
x For decision

Approved for future publication: NO (remove as applicable)

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This paper covers

1. **Prioritisation of PCR in the situation of widespread transmission of COVID-19 in the community and pressures on the testing system.**
2. **An approach to the use of Antigen Diagnostic Testing in the overall approach to managing Pandemic response.**

Context

The level of Covid-19 infection is increasing rapidly in Ireland. The 14-day incidence is now 674 per 100,000, with daily case numbers now in excess of 4,000 cases. Test positivity based on the past seven days is 20%. Hospital and ICU admissions are increasing rapidly, and modelling projections show a deteriorating situation with hospital cases exceeding 1,500-2,500 and ICU cases in excess of 200-400.

Recent days have seen a significant increase in test referrals. Swabbing and laboratory surge capacity has managed to meet the increasing demand. However, should this demand continue as is, or increase, testing capacity may be overwhelmed. Should this situation arise, prioritisation of testing, including symptomatic testing, may be required.

This paper outlines

- An approach for prioritisation of PCR testing should testing capacity be overwhelmed
- The role of Antigen Detection Tests in the current epidemiological context

PCR Testing Capacity

The current maximum daily capacity available for community PCR testing is c. 24,850 tests, allowing for some variations over individual days. This figure excludes current capacity of 4,000 acute hospital laboratory tests focussed on supporting patient care within the acute hospital network.

The daily community capacity of 24,850 includes off-shore testing capacity. This community capacity is focussed on community testing centres, serial testing of nursing homes and the food sector, plus outbreak management. (Appendix B outlines laboratory activity for the period 21st December – 3rd January 2021).

Based on observed volumes and trends over the past months, escalation plans were developed and activated over recent weeks within the community diagnostic laboratories. This surge response included the use of offshore laboratory capacity and enabled the service to respond to the increased demand for testing services across the country. HSE has increased its PCR capacity significantly over recent months. A table outlining the current and planned capacity (in line with the development of the dedicated COVID-19 facility at Backweston) is outlined below.

Table 1. Current and Planned PCR Capacity

Timeline	Community Diagnostic Laboratories Daily Capacity	Acute Hospital Laboratory Daily Capacity	Max. Daily Capacity No. of Laboratory PCR Tests
1st Oct, 2020	16,000	3,500	**19,500**
1st Nov, 2020	19,600	3,900	**23,500**
1st Dec,2020	20,000	3,900	**23,900**
1st Jan, 2021	**24,850**	**4,000**	**28,850**
1st Feb, 2021	26,850	5,000	**31,850**
14th Feb, 2021	28,850	5,000	**33,850**
1st Mar, 2021	31,000	5,000	**36,000**

While ~25,000 daily surge capacity for the community testing component can be achieved, and the HSE is continuing to develop its testing capacity on the Backweston site, the sustainability of an 'end to end' Test and Trace model at this daily activity level, or increased level of daily demand is a concern. On the 31st of December, as a first step, the testing of asymptomatic close contacts was temporarily ceased in order to maintain capacity for the testing of symptomatic suspect cases and those most in need of testing.

Swabbing capacity

The COVID-19 Test and Trace pathway incorporates three distinct components:

1. Referral and Swabbing
2. Laboratory Testing
3. Contact Tracing

In order for the pathway to operate optimally all components must be aligned in terms of volume/capacity. At the level of current demand the limiting step is within the swabbing function. Current community swabbing capacity is c 17,000 samples per day, with an additional 4,000 samples taken within the serial testing facilities, and a further 4,000 samples taken within the acute sector. Swabbing is a resource intensive activity, requiring a minimal skillset.

Increases in outbreak management associated with higher infection rates creates a demand for additional mobile swabbing teams and 'pop-up' swabbing centres placing a substantial strain on the 17,000 per day community sampling capacity. This is particularly relevant when reviewing the potential use of antigen detection tests (ADTs) as these tests also require swabbing.

Approach for Prioritisation of PCR Testing

In the coming days and weeks, should the demand for testing exceed capacity, prioritisation of testing, including among those who are symptomatic, may be required.

Sources of evidence and information consulted in defining priority groups included the World Health Organization[1] and ECDC[2]. The priority groups for testing published by the HSE in April 2020 when testing capacity was limited were also reviewed. A flexible and adaptable approach is required in prioritising testing which must respond to changing epidemiological and logistical situations.

Proposed Priority Groups for PCR Testing:

- Symptomatic healthcare workers.
- Asymptomatic healthcare workers identified as household contacts of a confirmed case[3]
- Symptomatic people who live in the same household as a healthcare worker or a person categorised as High Risk or Very High Risk as per HSE risk categorisation.
- All acute hospital admissions. *Note, consideration may be given to use of antigen detection tests, with PCR confirmation of negative results, in this group.*
- Symptomatic people at risk of developing severe disease. This includes all those categorised as High Risk or Very High Risk, by virtue of their age or medical conditions, according to HSE (appendix A).
- Symptomatic people who work or reside in closed settings or who are members of vulnerable communities – includes residents of long-term care facilities, hospital inpatients, members of the travelling community, ROMA, homeless, residents of direct provision centres, prisons, etc. In an outbreak situation wider testing of asymptomatic people will be determined by Public Health Risk Assessment. *Consideration may be given to use of antigen detection tests, with PCR confirmation of negative results, in this group.*
- Testing of first few cases in a suspected outbreak in setting such as schools, workplaces etc
- People with a history of travel from the United Kingdom or South Africa regardless of symptoms
- Close contacts of confirmed cases with a history of travel from the UK or South Africa

Where schools and childcare continue to operate under government restrictions consideration should be given to testing symptomatic schoolchildren, students and people working in education or childcare

If possible, every effort should be made to maintain serial testing in long term care facilities.

[1] World Health Organisation Critical preparedness, readiness and response actions for Covid-19

[2] ECDC Webpage Laboratory Support

[3] Asymptomatic healthcare workers who are close contacts are prioritised for testing based on a potential need for derogation of asymptomatic close contacts in the context of staffing pressures across **suggestion:** the health services ~~acute hospitals.~~

Role of Antigen Detection Tests

Validation

Field evaluation of Rapid Antigen Detection Tests (RADTs) is underway in Ireland and is nearing completion for some of the 6 RADTs, with final results of verification of performance in symptomatic people for some assays due in the coming days.

- Interim validation results show sensitivity above 80% and specificity >97% in one of the assays **when used in symptomatic patients**.

Results in asymptomatic patients however have shown lower sensitivity, below the minimum performance requirements set by WHO at >=80% sensitivity and >=97% specificity

Logistical and operational constraints

There are however significant operational and logistical challenges in introducing Antigen Detection Tests (ADTs). These include:

- a systematic change to all processes and systems such as referral, scheduling, swabbing, testing, result reporting, contact tracing, and system reporting. Point of care testing and resulting is significantly different to the current model developed with PCR testing.
- establishing appropriate clinical governance over the testing programme and clinical governance from within Microbiology over the test itself
- a need for recruitment, training, and quality management systems for the performance of swabbing and antigen test analysis on site. The human resource requirement is considerable. In one acute hospital where rapid antigen tests were recently deployed in a hospital outbreak as part of a validation exercise, it took 4 scientific staff one full day to test 250 lateral flow antigen tests[4]. They had an additional 2 staff dealing with consent and recording, which are validation specific requirements.
- having a mechanism in place for rapid linkage of positive RADT to the Contact Management Programme for contact tracing and to CIDR for surveillance

While these tests are described as rapid, and simple to perform, they are not designed to be delivered in large numbers. Each test requires approximately 20 minutes to prepare, process and read the result

In many hospitals, rapid PCR turnaround times are available (3-4 hours) and addition of RADT may slow down the testing process.

Use of ADTs

In cases with high viral loads, it is reasonable to assume that RADTs can help reduce further transmission through early detection of highly infectious cases, enabling contact tracing and restriction of movements to start quickly.

In the current situation of very high community prevalence, and in the context of emerging pressures on laboratory capacity for PCR testing, ADTs may have a role in some settings for detection of

[4] RADTs, normally directed against the nucleoprotein of SARS-CoV-2, involving lateral flow assays facilitate fast delivery of results outside of the laboratory setting. They can be read visually, or by the utilisation of a specific reader. However experience in Irish validation studies show they are labour intensive and issues around sensitivity have been raised.

symptomatic cases, particularly in settings where there is swabbing capacity on site, such as in acute hospitals.

Laboratory based antigen detection tests are becoming available. The Diasorin Liaison Antigen test has been successfully evaluated in Cork University Hospital. Using manufacturer's recommended cut-offs, a sensitivity of 85% and specificity of 100% were obtained. However, with optimised cut-offs, a sensitivity of 91% with maintained specificity of 100% can be obtained. The Roche Elecsys Antigen test will be available later this month, and should be validated as soon as possible. Laboratory based antigen tests offer greater scalability, as it is unlikely to be possible to recruit the large number of staff that would be required to perform lateral flow testing to a significant extent. Additionally these tests are more sensitive than RADTs.

For longer term assessment of the role of ADTs, the RADTs steering group recommends that HIQA is asked to model the costs and benefits of the use of RADTs in different settings and contexts, using local Irish validation data wherever possible.

Recommendations for use of RADTs in Ireland

Recommendation 1: Outbreak Response and Control

Who to test:

(a) Test symptomatic persons and their close contacts in PCR confirmed outbreaks
(b) Test symptomatic persons where there is a high suspicion of an outbreak, pending PCR confirmation, if faster presumptive results will inform public health action

In what circumstances:

For symptomatic persons in an outbreak

If symptom onset is <5 days

AND

Test positivity high >=10% among the target population

For close contacts in an outbreak

Time of exposure to a confirmed COVID-19 case is recent: as soon as possible and less than 7 days.

AND

Test positivity high >=10% among the target population

Confirmatory PCR Testing: In all circumstances outlined above any negative RADT result should be confirmed by RT-PCR immediately or, in case of unavailability of RT-PCR, with a subsequent rapid antigen test a few days later (to allow the viral load to increase in those who may have had a previously false negative result).

Threshold for Public Health action: Positive RADT regardless of symptom status

Threshold for notification: Positive RADT

This recommendation requires that a team is readily available to travel quickly on site to support outbreak investigations throughout Ireland. The National Ambulance Service (NAS) has been identified as being in a position to do this, once the operational issues outlined above have been addressed.

Other Potential Use of RADTs

In recent weeks there has been exponential spread of COVID-19 and this may lead to severe pressure on laboratory-based PCR testing, with the potential for it to be overwhelmed. If this circumstance arises, we recommend use of ADT. ADT will be particularly helpful in circumstances where the capacity for swabbing is available on site, such as in the acute hospital setting. In time capacity for swabbing needs to be strengthened which will widen the circumstances in which the use of ADTs can be considered.

Recommendation 2: Symptomatic suspected cases presenting to healthcare and social care settings

- To mitigate the impact of COVID-19 in healthcare and social-care settings, rapid antigen tests can be used for the triage of symptomatic patients or residents at the time of admission and to test symptomatic patients or staff for early detection of cases. Results of testing can guide timely isolation and type of personal protective equipment required. Negative results will require confirmatory PCR testing. A supply of rapid PCR tests has been secured for this purpose in Ireland but antigen tests may have a role in preserving capacity if PCR testing is overwhelmed.

Recommendation 3: Repeat testing of patients and staff when managing and estimating ongoing infectivity in hospital outbreaks

- In hospital outbreaks, ADTs may have a role in early detection of cases in patients and staff, in identification of infectious cases, and also in using repeat antigen testing to guide decisions on when to declare an outbreak closed.

Recommendation 4: For symptomatic patients in community settings when swabbing capacity has increased

- Selected, symptomatic individuals in the community within 5 days of symptom onset. Deployment in this setting would be resource intensive, and will only be possible when clinical governance at Consultant Microbiologist level is available, together with a quality management system, trained testers, and a full operational plan. Recruitment of a significant number of people to perform these tests would be required.

Recommendation 5: Laboratory based antigen tests should be evaluated as a measure to expand testing capacity as they become available.

- The Diasorin Liason assay has been successfully evaluated in Cork University Hospital.
- The Roche Elecsys Antigen assay is expected to be released later in January 2021.

Appendix A

Very High-Risk Groups (Extremely Medically Vulnerable)

- are over 70 years of age - even if you're fit and well
- have had an organ transplant
- are undergoing active chemotherapy for cancer
- are having radical radiotherapy for lung cancer
- have cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
- are having immunotherapy or other continuing antibody treatments for cancer
- are having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
- have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs
- are on dialysis
- have unstable or severe cystic fibrosis. This includes people awaiting a transplant
- severe respiratory conditions including Alpha-1 antitrypsin deficiency, severe asthma, pulmonary fibrosis, lung fibrosis, interstitial lung disease and severe COPD
- have a condition that means you have a very high risk of getting infections (such as SCID, homozygous sickle cell)
- are taking medicine that makes you much more likely to get infections (such as high doses of steroids)
- have a serious heart condition and you're pregnant
- have specific inborn errors of metabolism

High Risk Groups

- are over 60 years of age
- have a learning disability
- have a lung condition that's not severe (such as asthma, COPD, emphysema or bronchitis)
- have heart disease (such as heart failure)
- have high blood pressure (hypertension)
- have diabetes
- have chronic kidney disease
- have liver disease (such as hepatitis)
- have a medical condition that can affect your breathing
- have cancer
- have clinically stable cystic fibrosis
- have a weak immune system (immunosuppressed)

- have cerebrovascular disease
- have a condition affecting your brain or nerves (such as Parkinson's disease, motor neurone disease, multiple sclerosis, or cerebral palsy)
- have a problem with your spleen or have had your spleen removed
- have a condition that means you have a high risk of getting infections (such as HIV, lupus or scleroderma)
- are taking medicine that can affect your immune system (such as low doses of steroids)
- have obesity
- are residents of nursing homes and other long-stay settings
- are in specialist disability care and are over 50 years of age or have an underlying health problem

Appendix B Tests performed and Positivity Rate 21st Dec – 3rd Jan

Date	21-Dec	22-Dec	23-Dec	24-Dec	25-Dec	26-Dec	27-Dec	28-Dec	29-Dec	30-Dec	31-Dec	01-Jan	02-Jan	03-Jan
No. Tests Reported	13,216	20,660	22,884	21,416	11,986	3,530	9,405	13,805	17,484	28,312	27,389	29,846	28,545	20,571
No. Positive Tests	698	1,007	1,269	1,643	1,207	343	1,178	2,007	2,864	4,371	5,621	4,553	6,486	5,199
% Positivity Rate	5%	5%	6%	8%	10%	10%	13%	15%	16%	17%	21%	22%	23%	25%