Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Advice to HSE:

Potential impact of different serial testing scenarios using rapid antigen detection tests (RADTs) to detect SARS-CoV-2 in meat processing plant workers

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Foreword

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly infectious virus which has caused tens of millions of cases of COVID-19 since its emergence in 2019, with a considerable level of associated mortality. In the context of the ongoing COVID-19 pandemic, SARS-CoV-2 constitutes a significant public health concern due to its high basic reproduction rate, the limited evidence of effective treatment approaches, and the constrained supply of vaccines in the early stages of population-level immunisation programmes.

The National Public Health Emergency Team (NPHET) oversees and provides national direction, guidance, support and expert advice on the development and implementation of strategies to contain COVID-19 in Ireland. Since March 2020, HIQA's COVID-19 Evidence Synthesis Team has provided research evidence to support the work of NPHET and associated groups and inform the development of national public health guidance. The COVID-19 Evidence Synthesis Team, which is drawn from the Health Technology Assessment Directorate in HIQA, conducts evidence synthesis incorporating the scientific literature, international public health recommendations and existing data sources, as appropriate.

From September 2020, as part of the move towards a sustainable response to the public health emergency, HIQA provides evidence-based advice in response to requests from NPHET and the Health Service Executive (HSE). The advice provided is informed by research evidence developed by HIQA's COVID-19 Evidence Synthesis Team and with expert input from HIQA's COVID-19 Expert Advisory Group (EAG). Topics for consideration are outlined and prioritised by NPHET. This process helps to ensure rapid access to the best available evidence relevant to the SARS-CoV-2 outbreak to inform decision-making at each stage of the pandemic.

The purpose of this report is to outline the advice provided to the HSE by HIQA regarding the potential impact of different serial testing scenarios using rapid antigen detection tests (RADTs) to detect SARS-CoV-2 in meat processing plant workers. The advice reflects the findings of a modelling exercise and the input of the HIQA COVID-19 EAG.

HIQA would like to thank its COVID-19 Evidence Synthesis Team, the members of the COVID-19 EAG and all who contributed to the preparation of this report.

Dr Máirín Ryan

Deputy CEO & Director of Health Technology Assessment

Health Information and Quality Authority

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Particular thanks are due to the COVID-19 Expert Advisory Group (EAG) and the individuals within the organisations listed above who provided advice and information.

Membership of the Expert Advisory Group involves review of evidence synthesis documents and contribution to a discussion which informs the advice developed by HIQA's COVID-19 Evidence Synthesis Team and which is provided from HIQA to NPHET and or the HSE.

Not all members of the Expert Advisory Group and Evidence Synthesis Team are involved in the response to each research question. The findings set out in the advice represent the interpretation by HIQA of the available evidence and do not necessarily reflect the opinion of all members of the Expert Advisory Group.

The membership of the EAG was as follows:

Prof Karina Butler	Consultant Paediatrician and Infectious Diseases Specialist, Children's Health Ireland & Chair of the National Immunisation Advisory Committee
Dr Jeff Connell	Assistant Director, UCD National Virus Reference Laboratory, University College Dublin
Dr Eibhlín Connolly	Deputy Chief Medical Officer, Department of Health
Prof Máire Connolly	Specialist Public Health Adviser, Department of Health & Professor of Global Health and Development, National University of Ireland, Galway
Prof Martin Cormican	Consultant Microbiologist & National Clinical Lead, HSE Antimicrobial Resistance and Infection Control Team
Ms Sinead Creagh	Laboratory Manager, Cork University Hospital & Academy of Clinical Science and Laboratory Medicine
Dr Ellen Crushell*	Consultant Paediatrician, Dean, Faculty of Paediatrics, Royal College of Physicians of Ireland &

	Co-Clinical Lead, Paediatric/Neonatology National Clinical Programme
Dr John Cuddihy	Specialist in Public Health Medicine & Interim Director, HSE- Health Protection Surveillance Centre (HPSC)
Dr Cillian de Gascun	Consultant Virologist & Director of the National Virus Reference Laboratory, University College Dublin
Dr Lorraine Doherty	National Clinical Director Health Protection, HSE-Health Protection Surveillance Centre (HPSC)
Ms Josephine Galway	National Director of Nursing, Infection Prevention Control and Antimicrobial Resistance, AMRIC Division, HSE- Health Protection Surveillance Centre (HPSC)
Dr James Gilroy	Medical Officer, Health Products Regulatory Authority
Dr Vida Hamilton	Consultant Anaesthetist & National Clinical Advisor and Group Lead, Acute Hospital Operations Division, HSE
Dr David Hanlon	General Practitioner & National Clinical Advisor and Group Lead, Primary Care/Clinical Strategy and Programmes, HSE
Dr Patricia Harrington	Deputy Director, Health Technology Assessment, HIQA
Dr Muiris Houston*	Specialist in Occupational Medicine, Clinical Strategist – Pandemic, Workplace Health & Wellbeing, HSE
Dr Derval Igoe	Specialist in Public Health Medicine, HSE- Health Protection Surveillance Centre (HPSC)
Prof Mary Keogan	Consultant Immunologist, Beaumont Hospital & Clinical Lead , National Clinical Programme for Pathology, HSE
Dr Siobhán Kennelly	Consultant Geriatrician & National Clinical & Advisory Group Lead, Older Persons, HSE
Ms Sarah Lennon	Executive Director, SAGE Advocacy
Mr Andrew Lynch	Business Manager, Office of the National Clinical Advisor and Group Lead - Mental Health, HSE

Dr Gerry McCarthy *	Consultant in Emergency Medicine, Cork University Hospital & Clinical Lead, National Clinical Programme for Emergency Medicine, HSE
Prof Paddy Mallon*	Consultant in Infectious Diseases, St Vincent's University Hospital & National Clinical Programme for Infectious Diseases, HSE
Prof Cara Martin^	Assistant Professor in Molecular Pathology and Tumour Biology at the Department of Histopathology, Trinity College Dublin HSE ADT Validation Scientific Lead
Prof Simon More^	Professor of Veterinary Epidemiology and Risk Analysis, UCD School of Veterinary Medicine, University College Dublin
Dr Eavan Muldoon*	Consultant in Infectious Diseases, Mater Misericordiae University Hospital, National Clinical Lead for CIT and OPAT programmes & National Clinical Programme for Infectious Diseases, HSE
Dr Deirdre Mulholland	Interim Clinical Lead Health Protection, Knowledge, Evidence and Quality Improvement, HSE- Health Protection Surveillance Centre (HPSC)
Dr Desmond Murphy	Consultant Respiratory Physician & Clinical Lead, National Clinical Programme for Respiratory Medicine, HSE
Dr John Murphy*	Consultant Paediatrician & Co-Clinical Lead, Paediatric/Neonatology National Clinical Programme, HSE
Dr Sarah M. O'Brien	Specialist in Public Health Medicine, Office of National Clinical Advisor & Group Lead (NCAGL) for Chronic Disease
Dr Gerard O'Connor*	Consultant in Emergency Medicine, Mater Misericordiae University Hospital & National Clinical Programme for Emergency Medicine, HSE
Ms Michelle O'Neill	Deputy Director, Health Technology Assessment, HIQA

Dr Margaret B. O'Sullivan	Specialist in Public Health Medicine, Department of Public Health, HSE South & Chair, National Zoonoses Committee
Dr Michael Power	Consultant Intensivist, Beaumont Hospital & Clinical Lead, National Clinical Programme for Critical Care, HSE
Dr Máirín Ryan (Chair)	Director of Health Technology Assessment & Deputy Chief Executive Officer, HIQA
Dr Dónal Sammin^	Director of Laboratories with the Department of Agriculture, Food and the Marine
Dr Lynda Sisson*	Consultant in Occupational Medicine, Dean of Faculty of Occupational Medicine, RCPI & National Clinical Lead for Workplace Health and Well Being, HSE
Prof Susan Smith	General Practitioner & Professor of Primary Care Medicine, Royal College of Surgeons in Ireland
Dr Patrick Stapleton	Consultant Microbiologist, UL Hospitals Group, Limerick & Irish Society of Clinical Microbiologists
Dr Conor Teljeur	Chief Scientist, Health Technology Assessment, HIQA

* Alternate nominee for programme and or association
^ Ad hoc member of EAG for this topic

Members of HIQA's COVID-19 Evidence Synthesis Team:

Susan Ahern, Natasha Broderick, Paula Byrne, Karen Cardwell, Paul Carty, Barbara Clyne, Laura Comber, Christopher Fawsitt, Patricia Harrington, Karen Jordan, Kirsty O'Brien, Eamon O'Murchu, Michelle O'Neill, Sinead O'Neill, Máirín Ryan, Debra Spillane, Susan Spillane, Conor Teljeur, Barrie Tyner, Kieran Walsh.

Conflicts of Interest

Professor Mallon highlighted at the EAG meeting that his institution, University College Dublin, has received funding from Abbott Diagnostics for research into COVID-19 diagnostic antibody testing. Professor Mallon is the lead author on an open-access peer-reviewed publication based on this research (published March 26th 2021; https://doi.org/10.1093/ofid/ofab122).

This potential perceived conflict of interest was noted at the meeting prior to any discussion of the evidence summary or of the associated advice.

No other potential conflicts of interest were declared by members of the Expert Advisory Group.

Advice to the HSE

The purpose of this report is to provide advice to the HSE on the following policy question:

"What is the impact on transmission risk and resource requirements of different approaches to serial testing using rapid antigen detection tests (RADTs) in meat processing plants?"

The response to the policy question is informed by an evidence synthesis considering two elements:

1. a modelling exercise to estimate the impact on transmission risk and resource requirements of different approaches to serial testing using RADTs in meat processing plants. The considered scenarios were expressed in terms of the following key outcomes, the estimated:
    a. expected number of cases
    b. total number of infectious person-days in circulation
    c. total number of staff days in self-isolation or restriction of movement.
    d. number of cases detected (true positives) and number of false positives
    e. number of RADTs conducted and number of RT-PCR tests conducted
    f. resource requirements in terms of support staff to manage or supervise testing
    g. overall cost of testing processes.

2. input from the COVID-19 Expert Advisory Group (EAG).

The key points of this evidence synthesis, which informed HIQA's advice, are as follows:

- Meat processing plants have been associated with a considerable number of outbreaks of SARS-CoV-2 nationally and internationally. A recent analysis completed by HIQA (published 31 March 2021, with data up to 27 February 2021) noted that outbreaks in meat processing plants in Ireland were associated with 2,796 cases of COVID-19, representing a crude relative risk for infection in meat processing plant workers of 3.22 (95% CI 3.11 to 3.34) compared to the general population.

- The reasoning behind the elevated risk within these settings is likely multifactorial and context specific. As with other high risk settings, environmental factors such as reduced ability to social distance, cold air, limited ventilation and loud work spaces have been noted to potentially

facilitate the transmission of the virus. Beyond environmental factors, elements such as shared accommodation, low wages, access to support payments, and the high number of migrant workers within the industry have been highlighted as potential additional contributing factors.

- Extensive measures have been adopted by meat processing plants in an attempt to mitigate the potential for outbreaks in these settings with specific infection prevention and control (IPC) guidance provided by the Health Protection Surveillance Centre (HPSC) and the rollout of serial testing programmes by the HSE in plants with more than 50 employees.

- In line with the national and international guidance, these serial testing programmes use the gold standard test, a laboratory-based real time reverse transcription polymerase chain reaction (RT-PCR) test using oropharyngeal/ nasopharyngeal specimens collected by a healthcare professional, for the detection of SARS-CoV-2.

- When considering operational factors such as practicality, scalability, cost, and timeliness, RADTs may be a valuable addition to the suite of measures used to mitigate transmission risk. However, these operational benefits come at a cost of sensitivity as the tests typically have lower performance compared with RT-PCR. RADTs tend to have better detection capability in instances of higher viral load, typically performing well in those with Ct values less than or equal to 25.

- A minimum performance criteria of ≥80% sensitivity and ≥97% specificity have been set by the World Health Organization (WHO) and European Centres for Disease Prevention and Control (ECDC), with the ECDC highlighting a target closer to ≥90% sensitivity and ≥97% specificity, especially in low prevalence environments. The ECDC recommends that member states perform independent, setting-specific validation before implementing RADT-based testing.

- A validation study of an RADT has been completed in the context of meat processing plant workers engaged in serial testing in Ireland. The validation study compared an RADT based on mid-turbinate nasal swabs obtained by supervised self-sampling and processed on site by trained professionals with the current standard of laboratory RT-PCR based on healthcare provider-taken combined nasopharyngeal/ oropharyngeal swabs.

Modelling potential impact of RADT-based testing scenarios

- This analysis, in the form of a modelling exercise, aimed to assess the potential impact of different serial testing scenarios using RADTs in meat processing plants in Ireland both in addition to, and as an alternative to, the current standard of practice (that is, monthly RT-PCR serial testing). The outcomes of interest from the model included estimates of the expected number of cases, potential infectious person-days in a plant, total number of staff days in self-isolation or restriction of movement, total number of cases detected (true positives) and associated number of false positives, number of tests conducted (both RADT and confirmatory RT-PCR), number of staff required to conduct testing, and cost of testing processes.

- Parameter estimates for the model were gathered from recent literature, previous HIQA evidence summaries, and Irish data sources (including contact tracing and RADT validation study results). A hypothetical cohort of 250 workers within a meat processing plant was simulated. For the RADT-based scenarios, the model assumed the implementation of supervised self-swabbing with a mid-turbinate nasal swab. It was assumed that this sample is provided to an individual who has undergone competency-based training for onsite-processing and reporting. It was further assumed that all positive RADTs would have confirmatory RT-PCR.

- A strategy of continued monthly RT-PCR testing with addition of serial RADT-based testing (that is a combination strategy) does not appear to add substantive benefit over a strategy based on serial-RADT-based testing (with confirmatory RT-PCR for positive results) alone.

- Of the RADT-based serial testing scenarios assessed (varied frequency from once a month to five times weekly without monthly RT-PCR), on balance, the use of RADT at a frequency of once or twice weekly appears to offer the largest benefits in terms of a potentially increased detection of cases, reduction in infectious person-days circulating, and a substantially reduced overall cost relative to the current practice of monthly RT-PCR testing. Fortnightly RADT-based testing may offer comparable rates of detection, and infectious-person days circulating, at a reduced cost compared to current practice.

- The estimates presented within this analysis highlight that increases in the frequency of RADT-based testing are associated with increases in the detection of cases and reductions in potential infectious person-days in circulation. However, increases in the frequency of testing are associated with increases in overall cost, test processing staff requirements, and worker time spent in self-isolation or restriction of movements. Of note while the total cost

was estimated to be lower for a number of the RADT-based scenarios, the full time equivalent staffing requirements for the implementation of testing processes on site was higher for RADT-based scenarios compared to current practice.

- There are important factors not accounted for within this analysis that should be considered within decision-making overall. These include the: acceptability of any change in testing to all relevant stakeholders, potential impact on productivity, training and availability of persons to implement RADT-based regimens, operational and logistical implementation of such testing regimens, in addition to requirements for clarity around operational oversight, clinical governance and quality assurance.

- There are a number of important assumptions and limitations with this analysis which should be considered when interpreting the estimates presented within this report including: uncertainty around a number of key parameters, the context and historical nature of the data utilised, the heterogeneity of meat processing plants, the impact of vaccination roll out and the potential effect of variants of concern. The use of confirmatory RT-PCR test for positive RADT results is an important assumption. In the absence of this assumption, a growing number of false positive tests are observed with increasing frequency of RADT-based testing, resulting in a greater number of days for the worker and close contacts unnecessarily spent in self-isolation and or restriction of movements. Such factors may negatively impact on engagement with such testing programmes. The analyses presented here have made no assumptions regarding on whom the cost of serial testing should fall.

- Given the specificity of the parameter data to meat processing plants, these estimates cannot be applied to other settings. The potential impact of such testing in other settings would need to be supported by validation work and epidemiological surveillance specific to the setting of interest.

COVID-19 Expert Advisory Group

A meeting of the COVID-19 Expert Advisory Group (EAG) was convened to assess the policy question in light of the above key findings and considerations. Input received from the Irish Business and Employers Confederation (IBEC) was presented to the EAG. Considerations identified by IBEC included the use of a risk-based approach to RADT testing in meat processing plants, the inclusion of RADT as part of a suite of mitigation measures and the logistical, operational, and reporting requirements involved in the implementation of such testing regimens. A

presentation on the validation of antigen detection testing in meat processing plants coordinated by the HSE RADT working group was also delivered by Professor Cara Martin for contextual information. Based on the evidence presented, the EAG raised the following points for consideration:

- Air circulation and occupancy levels in certain areas of certain plants present an elevated risk for SARS-CoV-2 transmission. Meat processing plants are not uniform, with differences in activities and products contributing to differences in operational environments and occupancy levels. In addition, individual meat plants are compartmentalised for reasons of animal welfare and food hygiene. In Ireland and internationally, there is significant evidence of within-plant clustering, with large clusters of cases occurring in meat cutting rooms. It was highlighted that there are long-standing EU legislative requirements for the industry to maintain an ambient temperature of ≤12˚C in the meat-cutting rooms. The industry operational norm has therefore been to recirculate chilled air, minimising the number of air changes per hour to achieve this temperature requirement. Recognising that recirculation of air may contribute to super-spreading events by facilitating airborne spread of SARS-CoV-2, the industry has acted to mitigate transmission risk by increasing the number of air changes per hour. However, this will not be possible with the existing air-conditioning infrastructure in the warmer summer months.

- Re-evaluation of environmental requirements, for example ambient air temperatures, would require approval by international regulatory bodies and trading partners. Significant capital investment is required to facilitate upgrading of air handling units and retrofitting of meat processing plants. However, these changes will not be in place until summer 2022 as multisite validations will be required to demonstrate their efficacy in reducing the risk of transmission of human respiratory viruses without compromising food safety. Therefore, additional measures are required to reduce the imminent risk of increased transmission during the warmer summer months.

- Acceptability of RADT-based serial testing to all relevant stakeholders is a crucial consideration. Given the differences within and between meat processing plants, such acceptability is unlikely to be consistent across the sector. In particular, concerns were raised about income protection and security for certain meat processing plant employees. It was noted that issues have previously been highlighted in relation to sick pay within the sector by the Migrants Rights Centre Ireland and trade union representatives for meat

processing plant employees.[1,2] Uncertainty over income may create disincentives for engagement with voluntary serial testing, given the requirement to stay away from work in the context of self-isolation for the individual case, and restriction of movements for close contacts.

- The positive predictive value of RADT testing is impacted by the incidence of COVID-19; with a higher rate of false positives when incidence is low. This highlights the requirement for RT-PCR confirmation of positive antigen tests in the context of serial testing. If there are high numbers of false positives, there may be challenges to the ongoing acceptability of RADT-based testing given requirements for self-isolation and restriction of movement, while awaiting reconciliation with confirmatory RT-PCR tests. This will be increasingly true with lower community incidence and increasing vaccination coverage.

- Serial testing is only one of a suite of measures that can be used to reduce the risk of transmission in a facility. That suite of measures must take into account the need to facilitate the adherence of infected individuals to requirements for self-isolation as a means to reduce the introduction of SARS-CoV-2 into the workplace. When infectious individuals present in the workplace, testing is not a solution to overcome the inherent risk of transmission.

- The current strategy of monthly RT-PCR based serial testing appears to be relatively inefficient compared with more frequent RADT-based testing. RT-PCR testing is associated with longer test turnaround time and more invasive sample collection. While the use of RADT-based serial testing may offer a means to overcome these shortcomings, an effective testing programme is dependent on acceptability, uptake and adherence to testing schedules.

- The uptake of RADT-based testing by workers during the HSE-based validation studies was noted to be very high, with good acceptability of mid-turbinate nasal swabs compared with combined oropharyngeal nasopharyngeal swabs currently used in RT-PCR-based testing. However, it was noted that there have been challenges with the roll-out of RADT-based serial testing which has been offered to the meat-processing plants currently engaged in the HSE run RT-PCR-based serial testing programme. All aspects

[1] House of the Oireachtas. Special Committee on Covid-19 Response debate - Thursday, 13 Aug 2020: Covid-19 The Situation in Meat Processing Plants 2020. https://www.oireachtas.ie/en/debates/debate/special_committee_on_covid-19_response/2020-08-13/3/.
[2] House of the Oireachtas. Special Committee on Covid-19 Response debate - Friday, 10 Jul 2020. https://www.oireachtas.ie/en/debates/debate/special_committee_on_covid-19_response/2020-07-10/3/ .

of RT-PCR-based testing are managed by the HSE Test and Trace programme with sampling undertaken by the National Ambulance Service. In contrast, in the roll-out of RADT-based testing, there is a requirement for the meat processing plants to manage the sampling, testing and reporting processes themselves as well as maintaining quality standards in testing. This has posed logistical and operational challenges at the level of the plant, compounding other commercial challenges the sector is experiencing due to both Brexit and COVID-19. Furthermore, there are concerns that complacency or fatigue may be a factor secondary to the relatively low level of case detection in recent testing rounds. The communication of nuances relating to test accuracy, duration of infectiousness, and frequency of testing is challenging. It was noted that the Department of Agriculture, Food and the Marine (DAFM) has had ongoing engagement with meat processing plants in an effort to improve uptake and communicate the importance of testing frequency.

- In light of the issues encountered in the roll-out of serial RADT-based testing in meat processing plants, a transitional implementation should be considered alongside the current strategy of monthly RT-PCR testing. Maintaining monthly RT-PCR would ensure continued case detection while any issues with the adoption of RADT-based testing are identified and addressed. This approach would also allow evaluation of RADT-based serial testing in real world environments before considering a change in the overall serial testing strategy.

- A risk-based approach may have merit whereby frequency of testing is dictated by plant level factors including the presence of work areas in which there is a combination of high occupancy and relatively poorer ventilation, such as in boning halls, and or disease factors such as community incidence. Furthermore, a standard outbreak management approach could be considered whereby a certain number of positive RADTs within a plant triggers the use of RT-PCR sweep testing.

- If RADTs are to be used as part of the serial testing programme, there is a need for a national plan in relation to quality control, RADT batch acceptance and batch verification. These processes are not currently standardised; standardisation would be important should such testing regimens be implemented. Furthermore, standardisation of training and competency-based assessment for the conduct of such testing would be required; in particular given that the accuracy of RADT-based testing is highly dependent on test processing times.

- Informed consent and confidentiality with the implementation of serial testing regimens were highlighted as important issues. The DAFM has developed and agreed guidelines with the HSE and the industry. It was emphasised that all testing is voluntary and is on the basis of informed consent. To facilitate same, consent forms have been written in plain language and translated into 12 of the most common languages identified in the plants. Processes to maintain worker confidentiality have also been implemented. It was acknowledged that it was essential that these ethical obligations continue to be protected for workers.

- Given the extent of the measures required to mitigate transmission risk in meat processing plants and the potential for outbreaks in these settings to seed outbreaks in the community, it was suggested that reconsideration could be given to prioritising vaccination of meat plant workers.

- It should be emphasised that the findings of this evidence synthesis are specific to meat processing plants as they constitute a higher risk environment. The results should not be considered generalisable to other settings or populations. The model parameters used are specific to this population and therefore cannot be used to directly inform other potential testing regimens outside of this setting. Context-specific issues would need to be considered and evaluated if adopting RADT-based testing in other settings.

Advice

Arising from the findings above, HIQA's advice to the HSE is as follows:

- Case detection rates are generally improved by increased test frequency. RADT-based serial testing provides the opportunity to increase testing frequency of workers in meat processing plants, thereby improving efficiency compared with the current strategy of once monthly RT-PCR.
- Overall, the estimates suggest that RADT-based testing of supervised self-collected samples once or twice a week with RT-PCR confirmation of positive results may be a viable alternative to the current approach of once monthly RT-PCR serial testing of workers in meat processing plants. Relative to monthly RT-PCR serial testing, these scenarios:
    - detect more true positive cases
    - reduce the number of false positives
    - have little impact on the number of days in self-isolation or restriction of movements
    - substantially decrease the overall cost of serial testing
    - are associated with an increase in staff requirements for testing
    - are more efficient (that is, similar effectiveness and lower cost) than strategies that use a combination of continued monthly RT-PCR serial testing in addition to RADT-based testing.
- Any changes to the current strategy would need to take into account the:
    - acceptability to all relevant stakeholders
    - potential impact on productivity, training and availability of persons to implement RADT-based regimens
    - operational and logistical implementation of such testing regimens
    - operational oversight
    - clinical governance and quality assurance
    - batch acceptance
    - training and competency-based assessments for those conducting testing
    - ethical considerations such as informed consent and confidentiality
    - disincentives for participation and engagement with testing processes
    - the potential for a risk-based approach to serial testing in the event of substantial logistical challenges in employer-based implementation.

- In the absence of confirmatory RT-PCR testing for positive RADT results, a growing number of false positive tests are observed with increasing frequency of RADT-based testing. False positives lead to days spent unnecessarily in self-isolation and or restriction of movements for workers and close contacts which may undermine confidence and engagement in serial testing.
- Changes to the current testing strategy should be supported by assessments of acceptability, uptake and adherence to testing schedules. Consideration should be given to a stepwise transition to frequent RADT-based serial testing, with the switch from monthly RT-PCR conditional on successful deployment of RADT-based testing within a plant.
- Given the specificity of the parameter data to meat processing plants, these estimates cannot be applied to other settings. The potential impact of such testing in other settings would need to be supported by validation work and epidemiological surveillance specific to the setting of interest.

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie