Briefing

Enhancing the routine returnee testing regime in MIQFs: introduction of saliva testing on days 6 and 9

Date due to MO:	16 August 2021	**Action required by:**	17 August 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20211810
To:	Hon Chris Hipkins, Minister for COVID-19 Response		
Copy to:	Hon Dr Ayesha Verrall, Associate Minister for Health		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

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Enhancing the routine returnee testing regime in MIQFs: introduction of saliva testing on days 6 and 9

Security level:	IN CONFIDENCE	**Date:**	12 August 2021
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

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Purpose of report

1. This report seeks your agreement to the enhancement of the routine returnee testing regime, through the introduction of additional testing on days 6 and 9, and the use of a saliva sample for PCR testing. This report discloses all relevant information and implications.

Summary

2. The majority of returnees in managed isolation and quarantine facilities (MIQFs) undergo routine nasopharyngeal swabbing on days 0/1, 3 and 12 of their stay. Around 60% of acute cases are identified at day 0/1 and 20% at day 3 testing. Approximately 10% are identified due to non-routine testing between days 3 – 12 (usually due to symptom onset), and around 10% are identified due to routine day 12 testing.

3. Early identification of cases of COVID-19 is an important tool for mitigating the risk of in-MIF transmission, as this will enable transfer to a quarantine facility sooner and decrease the time during which a transmission event can occur. Accordingly, routine testing on around day 6 may identify pre-symptomatic (and asymptomatic) cases earlier in their stay.

4. Furthermore, we currently lack robust data about the average detection rate at different time points between days 3 and 12. Testing on around **days 6 and 9** will enable us to gather detection rate data at two intervals between days 3 – 12, and inform future advice about the options of shorter stays in MIQFs from a public health perspective.

5. Introducing additional nasopharyngeal tests to the routine returnee testing regime is not recommended due to the pressure and risk it will add to the health workforce, as well as the imposition on returnees. Utilising self-administered saliva testing for these additional tests represents an opportunity to design a process that reduces the workload for the health workforce, whilst increasing routine testing frequency among returnees.

6. The key potential risks involved with introducing saliva testing to the returnee testing regime include:

    a. Inadvertently causing a significant increase in the health workforce workload – for example, if extensive staffing resource is required to educate returnees on how to

perform a saliva test, and follow up with returnees that either fail to provide a saliva sample, or provide an inadequate sample;

b. The infection prevention and control (IPC) risks associated with the delivery of saliva testing tubes to returnees, and the collection of samples from returnees. These risks relate to the frequency of staff foot traffic in returnee corridors, the overall frequency of returnee door opening events, and synchronous returnee door opening events between adjacent (or opposite) rooms.

c. Because saliva testing will not be supervised by a healthcare worker for workforce capacity and IPC reasons, there is a risk that returnees provide inadequate samples (e.g. contaminated or insufficient volume of saliva) or procure a sample from another individual (e.g. another person in their bubble).

7. Detailed operational and logistical planning is required to resolve these issues and develop systems and processes that maintain the safety of staff and returnees, ensure the integrity of the testing regime, and minimise the impact of the additional tests to the health workforce.

8. Asia Pacific Healthcare Group (APHG) have been engaged to deliver a nationwide saliva testing programme, and the phased rollout of surveillance testing for border workers is underway. The existing APHG contract terms, conditions and service specifications are sufficient for the provision of surveillance testing for returnees and provides an opportunity for cost saving per test across both groups.

9. We propose a phased implementation approach to introducing saliva testing to the routine returnee testing regime on days 3, 6, and 9, beginning with a proof-of-concept pilot in select location(s) (see paragraphs 35 - 42 and **Appendix 1**). The proof-of-concept pilot will enable us to confirm operational policy considerations, successfully design the operational and logistical processes required to support safe and effective implementation, and assess (and mitigate) the workforce impact prior to full system-wide implementation.

10. Note that the proof-of-concept pilot will enable us to assess the suitability of saliva testing for routine day 3 testing of returnees via collection of paired nasopharyngeal and saliva samples on day 3, prior to a wider system roll-out.

Recommendations

We recommend you:

a) **Note** that from a public health perspective, there is value in increasing routine returnee testing frequency between days 3 – 12 to support early detection of cases, and to inform future decision-making regarding potential shortened lengths of stay in MIQFs. **Yes/No**

b) **Note** that we do not recommend implementing additional nasopharyngeal testing as part of the routine returnee testing regime, as this would have a significant impact on the health workforce, and would likely be a substantial imposition on returnees given the relatively high frequency of nasopharyngeal testing they already undergo. **Yes/No**

c) **Note** that the Ministry's position on saliva testing has evolved over time to reflect our growing confidence in the sensitivity and reliability of saliva testing. **Yes/No**

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d) **Agree** that we introduce routine saliva testing on days 6 and 9 to the returnee testing regime, with a view to replace day 3 nasopharyngeal testing with saliva testing provided we are confident in the suitability of saliva testing for the day 3 test after the proof-of-concept pilot in September 2021. **Yes/No**

e) **Note** that there are risks associated with introducing saliva testing to the returnee testing regime, including inadvertently increasing the health workforce workload, IPC risks associated with the delivery and collection of samples to and from returnees, and the risk of returnees providing inadequate and/or unreliable samples. **Yes/No**

f) **Agree** that the introduction of saliva testing on days 6 and 9 be implemented using a phased approach, first utilising a proof-of-concept pilot in September 2021 to confirm operational policy considerations, successfully design the operational and logistical processes required to support safe and effective implementation, and assess (and mitigate) the workforce impact prior to full system-wide implementation in mid-October 2021. **Yes/No**

But can we speed this up considerably?

g) **Note** that Asia Pacific Healthcare Group have been engaged to deliver a nationwide saliva testing programme which could include surveillance testing for returnees without any need for variation of contract or the requirements to initiate a new procurement process. **Yes/No**

h) **Note** that to facilitate the introduction of saliva testing as a testing modality for returnees, the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 will need to be amended to expand the definition of "medical examination and testing". Subject to your agreement to the proposal, we will provide you with further advice to enable to you to make the amendment by 10 September 2021 in advance of the proposed proof-of-concept pilot. **Yes/No**

Bridget White
Deputy Chief Executive
COVID-19 Health System Response
Date: 13/08/2021

Hon Chris Hipkins
Minister
COVID-19 Response
Date: 17/8/21

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Enhancing the routine returnee testing regime in MIQFs: introduction of saliva testing on days 6 and 9

Background

Current routine returnee testing regime in MIQFs

11. The majority of returnees in MIQFs undergo routine nasopharyngeal swabbing on days 0/1, 3 and 12 of their stay. Returnees from designated 'low risk countries' only undergo routine testing on days 3 and 12.

12. Note that in addition to the routine testing regime, returnees undergo additional 'non-routine' testing if they develop symptoms consistent with COVID-19, if they are identified as close contacts of confirmed (or probable) case, and at the direction of a Medical Officer of Health following a bubble or IPC procedural breach.

13. Note that oropharyngeal (throat) swabbing has slightly reduced sensitivity than nasopharyngeal swabbing, particularly in asymptomatic individuals, and so is currently available to returnees only at the discretion of a Medical Officer of Health.

There is strong public health rationale for introducing additional routine tests between days 3 and 12 for returnees in MIQFs…

As an in-MIQF transmission risk mitigation…

14. Early identification of cases of COVID-19 is an important tool for mitigating the risk of in-MIQF transmission. Excluding bubble close contacts of cases and historical cases:

- Around 60% of acute cases are identified via routine day 0/1 testing;
- Around a further 20% of acute cases are identified via routine day 3 testing;
- Of the remaining 20% of acute cases, around half of these are identified via non-routine testing between days 3 and 12 (e.g. if they become symptomatic); and
- The other half are identified via routine day 12 testing.

15. Even when tested upon onset of symptoms, a returnee is likely to have been infectious for at least 48 hours prior to onset of symptoms. Furthermore, the pre-symptomatic and early symptomatic phases are often associated with the highest viral load and the highest rate of transmission.

16. As a result, routine testing on around day 6 may identify pre-symptomatic (and asymptomatic) cases earlier in their stay, facilitating earlier transfer out of managed isolation settings and into quarantine settings. This is part of a suite mitigations to reduce the risk of in-MIQF transmission, both to other returnees and to MIQF staff.

17. Additionally, early detection of cases will support earlier release for asymptomatic cases, who are required to remain in a MIQF for at least 10 days after their positive test.

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18. We have worked with key stakeholders in recent months – including the Ministry of Business, Innovation and Employment (MBIE), the Medical Officers of Health involved in the MIQ system, and the District Health Board (DHB) leaders for MIQ – to explore the option of adding an additional test to the routine returnee testing schedule at around day 6. From a public health perspective, there was general endorsement of the approach, although noting the likely health workforce impacts of introducing additional nasopharyngeal testing, and the additional imposition on returnees.

… And to support the 'Reconnecting Aotearoa New Zealand' work programme

19. Because the current routine returnee testing regime includes an extended gap in routine testing between days 3 and 12, we currently lack robust data about the average detection rate at different time points between days 3 and 12.

20. The 'Reconnecting Aotearoa New Zealand' work programme is considering the possibility of shorter stays in MIQ for different groups of returnees, based on their risk profile. However, without data about detection rates in the latter part of returnees' 14 day stay, there is limited ability to make evidence-informed decisions about whether shorter stays in MIQFs are safe from a public health perspective.

21. Accordingly, introducing routine testing on **days 6 and 9** will enable us to gather detection rate data at two intervals between days 3 – 12, and inform future advice about the options of shorter stays in MIQFs from a public health perspective.

Utilising saliva testing within the routine returnee testing regime provides an opportunity to reduce impact on the health workforce and minimise the imposition of additional testing on returnees

22. As detailed in previous advice, the MIQF health workforce is under significant strain. Within the context of returnee testing and as a result of cohorting, returnee testing workload pressures are particularly acute when testing days align for different groups of returnees within the facility (e.g. when routine day 0/1 and day 3 tests align across the cohort).

23. With the addition of routine day 6 (and 9) testing, there could be overlaps in day 3 and 6, and day 6 and 9, testing – exacerbating the workforce challenges associated with peaks in returnee testing workloads. As a result, the introduction of additional routine nasopharyngeal swabbing for returnees would not be sustainable nor feasible within the context of the current MIQF health workforce capacity constraints.

24. Additionally, the introduction of an additional nasopharyngeal swab into the routine returnee testing regime represents a further imposition on returnees. Most returnees undergo at least three nasopharyngeal swabs during their stay in a MIQF, in addition to pre-departure testing. As a result, requiring further nasopharyngeal swabbing may result in an increase in test-refusal for the additional test(s), and may have Bill of Rights Act (BORA) implications which would need to be worked through further.

25. As detailed in HR20211563 *"Updated position on testing for COVID-19 using saliva as a sample"*, the Ministry's position on the use of saliva testing in some surveillance testing circumstances has evolved in response to our increased confidence in the sensitivity and reliability of the saliva testing modality. Current evidence suggests there may be a slight

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decrease in the sensitivity of self-performed saliva PCR compared to nasopharyngeal PCR.

26. In HR20211563, we confirmed that we are confident there are surveillance situations where saliva testing may be acceptable instead of nasopharyngeal swabs, including where frequent saliva testing of border workers can potentially identify cases earlier, before chains of transmission are generated. In line with this advice, frequent saliva testing of returnees may support early identification of cases.

27. Because saliva tests are self-administered, utilising saliva testing to implement additional routine testing on days 6 and 9 is an opportunity to increase the testing frequency of returnees – as both an in-MIQF transmission risk mitigation, and to support the Reconnecting Aotearoa New Zealand work programme – while limiting the impact on the health workforce.

28. Note that we do not recommend that the health workforce supervise returnee saliva testing due to capacity constraints, as well as the IPC risk to staff associated with face-to-face contact with returnees for extended periods.

29. Saliva testing is not suitable for all routine returnee tests. At a minimum, we will retain nasopharyngeal testing as the required and default testing modality for day 0/1 and day 12 testing. Because of the public health significance of these tests – day 0/1 testing because it detects around 60% of our acute cases, and day 12 testing because it is the final test prior to departure into the community – it is important that these tests are undertaken in a supervised manner using the gold standard nasopharyngeal swabbing modality. We will explore the suitability of saliva testing for routine day 3 testing (see paragraphs 35 - 42 below).

30. This "mixed modality testing schedule" should be viewed as a sequence of tests which combine the gold standard (but more invasive) nasopharyngeal tests with frequent, less invasive self-administered saliva tests.

31. This sequence combines high initial detection rates and assurance of lack of infection prior to leaving the MIF via nasopharyngeal swabbing on days 0/1 and 12, with rapid detection of infectious cases within managed isolation via day 3, 6, and 9 saliva testing. This is considered to be a strong option for identification of all positive cases of COVID-19 within MIFs, and timely transfer to quarantine.

32. Note that in line with previous clinical advice, nasopharyngeal swabbing will continue to be utilised for diagnostic/investigatory testing e.g. for symptomatic returnees, close contacts, and as directed by a Medical Officer of Health following a high-risk bubble or IPC procedural breach.

Risks associated with introducing saliva testing to the routine returnee testing regime

33. Key risks associated with introducing saliva testing to the routine returnee testing regime are as follows:

    a. There may be unintended impacts on the health workforce that inadvertently increase their workload – for example, if extensive staffing resource is required to educate returnees on how to perform a saliva test, and follow up with returnees that either fail to provide a saliva sample, or provide an inadequate sample.

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b. IPC risks associated with the delivery of saliva testing tubes to returnees, and the collection of samples from returnees. Specifically, to reduce the risk of aerosol transmission within MIQFs, there is ongoing work underway across the MIQ system to:

   i. reduce the frequency of 'foot traffic' of both staff and returnees in returnee zones,

   ii. reduce the overall frequency of returnee door opening events, and

   iii. prevent synchronous returnee door opening events between adjacent (or opposite) rooms.

c. Detailed operational and logistical planning is required to ensure that the processes established to deliver and collect saliva sample tubes adhere to these principles and do not increase transmission risk to returnees or staff.

d. Because saliva testing is self-administered and will not be supervised by a healthcare worker, there is a risk that returnees provide inadequate samples (e.g. contaminated or insufficient volume of saliva) or procure a sample from another individual (e.g. another person in their bubble).

e. Utilising two different testing modalities (nasopharyngeal swabbing and saliva testing) within the routine returnee testing regime is likely to raise questions among returnees regarding why saliva testing is not suitable for other tests in their testing regime. This will be mitigated via the returnee communications plan, however, there may be residual risk of returnees refusing to undergo nasopharyngeal swabbing at key points (day 0/1 and 12 tests) and requesting saliva testing.

34. A plan to resolve these issues and develop systems and processes that maintain the safety of staff and returnees, ensure the integrity of the testing regime, and minimise the impact of the additional tests to the health workforce is provided below.

We propose a phased approach to the implementation of routine returnee saliva testing

35. The wider work programme is supported by six work packages (refer to **Appendix 1** for further detail):

a. **Work package 1:** pilot design and measurement

b. **Work package 2:** operational policy and legal considerations (e.g. confirming policy for testing of young children, managing refusals of day 6/9 testing)

c. **Work package 3:** operational logistics

d. **Work package 4:** returnee communications

e. **Work package 5:** stakeholder engagement

f. **Work package 6:** internal (MIQF staff) communications

36. A phased approach to implementation, led by a proof-of-concept pilot at select locations (work package 1), will enable us to confirm operational policy considerations and successfully design the operational and logistical processes (work packages 2 – 4) required to support safe and effective implementation. Specifically, the pilot will enable us to:

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a. Continue nasopharyngeal swabbing on day 3 per current protocols while the practicality and efficacy of self-performed saliva samples on day 3 is assessed. This will support our decision-making about whether replacing day 3 nasopharyngeal swabbing with saliva testing is appropriate;

b. Evaluate the workforce impact (both for the health and non-health MIQ workforce) of the additional saliva tests, and refine our processes to ensure there is no additional burden on the health workforce – with the aim to ultimately reduce their workload;

c. Assess returnee experience and ensure that our collateral, communications, and processes are clear and easily understood by returnees;

d. Evaluate whether the enhanced returnee testing regime supports earlier identification of cases. Note that assuming the current proportion of positive cases in the returnees remains constant at approximately 5 per thousand (10 per week), it would be difficult to directly compare the efficacy of the detection rate between self-performed saliva samples and healthcare worker performed nasopharyngeal swabs. Current evidence suggests there may be a slight decrease in the sensitivity of self-performed saliva PCR compared to nasopharyngeal PCR. However, to identify anything other than a large difference in sensitivity would require the trial to be run for many months.

37. The proposed enhanced routine testing regime for the proof-of-concept pilot is as follows:

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Modality	NP		NP & S			S			S			NP		
NP = nasopharyngeal; S = saliva														

38. Provided we have confidence in the suitability of saliva testing on day 3 following the paired nasopharyngeal and saliva testing during the proof-of-concept pilot, we intend to move towards a day 3 saliva test for the wider roll-out of the enhanced testing regime:

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Modality	NP		S			S			S			NP		
NP = nasopharyngeal; S = saliva														

39. Ultimately, this is expected to reduce the swabbing workload for health workforce, improve returnee experience by decreasing the number of nasopharyngeal swabs required, whilst supporting early detection rate of cases between days 3 and 12 and contributing to the ongoing Reconnecting Aotearoa New Zealand work programme.

40. We are progressing with planning for this pilot, including confirming the location(s) and timing of the pilot, and co-designing the operational and logistical processes with the DHBs.

41. We are planning to incorporate a trial of a remote healthcare workforce to this programme of work, to provide educational support to returnees regarding the saliva

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testing process during remote daily health checks. This is anticipated to reduce the impact of the additional saliva testing on the on-site health workforce.

42. We intend to commence this pilot by 14 September 2021 and continue it for at least 2 cohort cycles. Following a rapid 'lessons learned' evaluation of the pilot and a refinement of policies and processes, we intend to commence national implementation of the enhanced testing regime for new cohorts arriving from mid-October 2021.

There is the potential that the risks identified in providing saliva testing to returnees cannot be sufficiently mitigated

43. A key objective of the proof-of-concept pilot is to ensure that saliva testing can be introduced into the routine returnee testing regime in a safe and effective way, which minimises the impact on the workforce. If the risks identified in paragraph 33 cannot be sufficiently mitigated, we may need to:

    a. Revert to nasopharyngeal swabbing for routine day 6 testing; and

    b. Cease the requirement for routine day 9 testing.

44. Note that further work to assess the BORA implications for introducing additional nasopharyngeal swabbing to the routine returnee testing programme – over and above the current day 0/1, 3 and 12 testing regime – would be required, as indicated in paragraph 24.

Contracting and funding implications

45. APHG have been engaged to deliver a nationwide saliva testing programme. The phased rollout of surveillance testing for border workers is underway and includes those who are employed within the MIQFs. This provides an opportunity to leverage the existing operational and logistics processes already in place.

46. The existing APHG contract terms, conditions and service specifications are sufficient for the provision of surveillance testing for returnees without any variation to the existing contract or the requirement to initiate a new procurement process.

47. The existing APHG contract pricing structure for the anticipated testing volumes for returnees, when combined within the border workers surveillance testing, provides an opportunity for cost saving per test across both groups.

Legal implications

48. Introducing saliva testing to the routine returnee testing regime will require a change to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 (the Order). Currently, under clause 9 of the Order, returnees are required to undergo medical examination and testing for COVID-19 *"at any time throughout their period of isolation or quarantine, as directed by a medical officer of health or a health protection officer."*

49. Under the Order, medical examination and testing is defined as one or more of:

    a. taking temperatures;

    b. seeking and obtaining information about symptoms;

    c. carrying out chest auscultation;

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d. taking nose swabs or mouth swabs (or both).

50. A new direction from a Medical Officer of Health directing the new testing *frequency* will be sufficient to direct returnees to undergo testing on days 6 and 9, in addition to the current testing requirements on days 0/1, 3 and 12.

51. However, the Order will need to be amended to provide for saliva testing as a defined *testing method*. We expect to update the Order by 10 September 2021 to enable the proof-of-concept pilot to proceed as planned.

Equity

52. Whilst a shift towards the use of non-invasive testing methods for parts of the routine returnee testing regime is expected to be beneficial for returnees and well-received, there may be language and health literacy-based inequities in returnees' experiences of saliva testing in an MIQ environment. This is likely to be a new testing method for many returnees, and because it is self-administered, some returnees may find it challenging to understand and adhere to the required processes.

53. To address this challenge, a range of collateral and resources will be provided to returnees to explain the saliva testing process – including picture-based, video-based, and translated materials. Additionally, where returnees require an interpreter for their daily health checks, explanation of the saliva testing process will be included in the health check process as described in paragraph 41.

Next steps

54. Subject to your agreement, we will progress with the phased implementation plan as detailed in this briefing and in **Appendix 1**.

55. We will keep you informed of our progress in our regular weekly reporting, and will provide you with a further update on the outcome of the pilot and confirm our plans for the wider system-wide roll out in early October 2021.

ENDS.

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Appendix 1: high-level phased implementation plan

Phased implementation of more frequent returnee testing

What we need to do and why?
Introduce additional returnee testing to further reduce risk of in-MIF transmission and to provide data to inform future decision making on reduced length of stay.

Proposed approach
Phased implementation with initial pilot to test operational processes and workforce impact

Assumed testing regime
Initial implementation for pilot: Day 0/1 (N) Day 3 (N&S) Day 6 (S) Day 9 (S) Day 12 (N)
Intended final roll out: Day 0/1 (N) Day 3 (S) Day 6 (S) Day 9 (S) Day 12 (N)

Work package 1 – pilot design and measurement
- Determine appropriate length of pilot(s) and location
- Determine pilot design objectives including measurement of:
  - ✓ Paired day 3 sampling efficacy
  - ✓ Workforce impact (health and others) – with intent to reduce current burden on health workforce
  - ✓ Returnee experience
  - ✓ Earlier identification of cases

LEAD: MOH
Design due: 20 August 2021
Implement from: 14 September 2021

Work package 2 – Ops policy/ legal questions
- Confirm mechanism for legally enabling testing direction
- Approach to children or other exemptions from testing
- Approach for refusals (for each test day and type)
- Confirm flexibility in testing dates if required operationally i.e. day 5/6 rather than 6
- Implications of unviable samples
- Update Operations Framework

LEAD: MOH
DUE: 27 August 2021
Finalise post pilot.

Work package 3 – Operational logistics
- Labelling processes, drop off and collection from returnees
- Collection from MIQF
- Managing returnee queries
- Roles and responsibilities
- IPC measures
- Integration with Border System
- Integration with existing health checks process (and opportunity to enhance)
- Funding implications

LEAD: MOH
DUE: 10 September 2021
Finalise post pilot

Work package 4 – returnee communications
- Providing information to returnees on the requirements and why
- Enabling returnees to understand what they need to do for saliva testing
- Support for external communications and responding to queries
- Support for returnee surveys to assess experience

LEAD: MBIE
DUE: 14 September
Finalise post pilot

Work package 5 – stakeholder engagement
- PHUs – working through with them implications and resolve any policy questions
- MBIE RIQCC – ensure operations well integrated
- DHBs – leading implementation on the ground

Work package 6 – internal communications to MIQF workers
- Information on the new requirements and rationale
- Information on the process and role of non-healthcare workers in supporting the process (TBD)s

First deliverable: Briefing for Minister on high level approach for implementation due 16 August
Second deliverable: Detailed implementation plan due 20 August 2021 along with risk register

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