

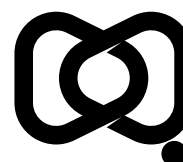


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Nationwide survey of testing practices for respiratory viruses in Australia in the post COVID-19 pandemic era

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Abstract

Background

In the wake of the coronavirus disease 2019 (COVID-19) pandemic, there have been dramatic changes in the testing protocols for respiratory illness. Laboratory identification of respiratory pathogens causing clinical symptoms has become more important in the post-COVID-19 era, both for epidemiological and clinical reasons. This is particularly the case for respiratory syncytial virus (RSV) where a number of preventatives are at the point of clinical translation. The laboratory diagnosis is one of the critical elements in understanding the disease burden of respiratory pathogens and the effectiveness of preventatives. The aims of this study were to understand current laboratory testing and reporting practices across Australia.

Methods

We undertook a cross-sectional survey of Australian NATA (National Association of Testing Authorities) accredited laboratories to collect data on patterns of laboratory testing, the methods used and their reporting processes. The survey asked participants to report on testing of respiratory samples for 2022 as well as current respiratory multiplex testing in 2023.

Outcomes

In total, 45 out of 193 eligible laboratories (23%) completed the online survey. The majority of laboratories were from Victoria and New South Wales (31% and 27%, respectively) and most were hospital-based clinical diagnostic laboratories. Overall, 40% of responding laboratories (18/44) reported that > 80% of all tests in the molecular laboratory in 2023 were respiratory multiplex. Influenza viruses, RSV and SARS-CoV-2 were tested most frequently on respiratory multiplex PCR panels. RSV typing (RSV A or RSV B) was included in under a quarter of panels (9/43; 21%), compared to almost two-thirds for influenza typing (influenza A or influenza B: 29/44; 66%). There was considerable variability in testing platforms used, with thirty-seven laboratories using 87 different platforms (18 unique platforms). GeneXpert® (Cepheid) was the most commonly used platform; with a higher concentration of this instrument in laboratories from the eastern states (New South Wales, Queensland, Victoria). Forty percent of laboratories reported changes to respiratory testing procedures/panels in 2023 compared to the previous year. Laboratories were most likely to report results directly to the referring doctor (96–100%) followed by notifying their jurisdictional Department of Health.

Keywords: Laboratory; respiratory virus; multiplex; respiratory syncytial virus (RSV); influenza; reporting; testing

Introduction

Respiratory syncytial virus (RSV) is the leading cause of hospitalisation in infants. Globally, one study estimated that, in 2015, a total of 33.1 million RSV-related hospital admissions occurred in children < 5 years of age annually.¹ Approximately 45% of RSV infections are in children younger than 6 months of age, placing considerable burden on healthcare services each year.^{2,3} A number of preventatives for RSV have recently been approved by the Australian Government Therapeutic Goods Administration, including a long-acting monoclonal antibody for infants, and maternal and elderly vaccines, with others in various stages of development,^{4–6} including live-attenuated/vector vaccines and mRNA vaccines.⁷ RSV has two subtypes, RSV A and RSV B. As we move into the era of RSV preventatives, knowledge of the circulating subtypes and their potential to change from season to season will be critical in evaluating the effectiveness of preventatives. For example, a clinical trial of a monoclonal antibody to RSV (suptavumab) showed protection against hospitalisation or lower respiratory tract infection with RSV A, but no protection against RSV B because of a newly acquired mutation in the circulating RSV B viruses.⁸

In 2021, laboratory-confirmed RSV became nationally notifiable in Australia,⁹ a measure which will aid tracking the incidence of RSV in the Australian population and will inform a comprehensive understanding of patterns of RSV infections, evolution and spread. These national data sets, through the NNDSS (National Notifiable Disease Surveillance System), will lead to a better understanding of the burden and epidemiology of RSV disease. However, a true national picture was delayed as each jurisdiction implemented surveillance (and preventatives) at different timepoints and robust annual figures were not available until the 2023 calendar year.¹⁰

Laboratory identification of the respiratory pathogens, particularly viruses, causing clinical symptoms has become more important in the post-coronavirus disease 2019 (COVID-19) era, both for epidemiological reasons and for clinical treatments, as antiviral drugs are available for influenza and COVID-19. In contrast, management for RSV is generally limited to supportive care. The availability of RSV-specific information enables health authorities to better deal with and anticipate disease outbreaks using mitigating strategies such as patient isolation and cohorting, and informs authorities on the success of vaccination programs.

Diagnosis of respiratory infections was traditionally performed by direct immunofluorescence on nasopharyngeal aspirates.¹¹ However, more recently, polymerase chain reaction (PCR) has replaced most of the original methods for detecting respiratory viruses, with a variety of platforms and tests being utilised.

Reference laboratories also play an important role, providing high level services, including supporting surveillance and outbreak investigations, reference testing and research. Reference laboratories are able to handle a wider variety of tests than the general diagnostic laboratories, with reference laboratories having specialist assays that are infrequently used in standard laboratories, as well as access to next generation sequencing.

Prior to the COVID-19 pandemic, there was considerable variation in testing practices, both nationally and by population age groups.^{12,13} In the wake of the COVID-19 pandemic, there have also been dramatic changes in the testing protocols for respiratory illness; during the pandemic's period of heightened public health measures (2020–2022), detection of SARS-CoV-2 was prioritised over all other respiratory pathogens, with testing for only this single virus in people presenting with respiratory symptoms. This led to a recommendation by the Victorian Department of Health, in June 2022,¹⁴ for clinicians to request a respiratory virus PCR panel (which commonly included influenza virus and RSV in addition to SARS-CoV-2) on patients presenting with respiratory symptoms, particularly in people at increased risk of severe illness. More recently, there has been a reduction in PCR testing for SARS-CoV-2 in Australia relative to the degree of PCR testing performed during the COVID-19 pandemic. Compared to the waves of the pandemic when the seven-day average PCR testing for SARS-CoV-2 was > 150,000 samples (peaking at a seven-day average of 290,000 samples in December 2021), since 2023 the seven-day average for PCR testing for SARS-CoV-2 has remained substantially lower (< 2,000 tests per day).¹⁵ From 1 January 2023, under the National COVID-19 Health Management Plan,¹⁶ obtaining a Medicare-funded PCR test required a referral from a medical practitioner, and there was no public health requirement for low-risk individuals to seek PCR testing. These changes resulted in a reduction in the number of people tested for SARS-CoV-2 and the opportunity to monitor people for other respiratory pathogen infections.

There has also been an increased use of rapid antigen tests (RATs) designed for home testing; these tests now cover not only SARS-CoV-2 but influenza and RSV as well, replacing the need for PCR testing in many situations.

With these shifts in testing practices, it is important to determine if state recommendations are being translated into routine clinical investigations, and what this impact has been on the testing landscape for respiratory infections. Additionally, it is useful to know: whether multiplex testing is being reserved for particular populations; how laboratories are approaching respiratory sample testing; what platforms are used; what pathogens are being detected; and how laboratories are reporting their results.

The reporting processes and pathways expected of laboratories are similar across jurisdictions. State and territory health departments collect information under their public health legislation, with laboratories, rather than individual clinicians, required to report laboratory confirmed notifiable results for influenza and RSV to jurisdictional health departments. Clinicians can report probable cases or in instances where they suspect someone has died. State and territory health departments then report de-identified notifications data to the NNDSS that collects data on more than 70 diseases that are nationally notifiable in Australia including pertussis, COVID-19, RSV and influenza.⁹

The laboratory diagnosis of RSV and other respiratory infections is the starting point for treatment selection and for understanding the disease burden of RSV and other respiratory pathogens in the community. The aims of this study were therefore to understand laboratory testing and reporting practices across Australia. The primary objectives of the 'Navigator' study were:

1. to determine laboratory testing and reporting practices for RSV (primarily) and other respiratory pathogens (secondarily) in private, public and hospital and outpatient-based pathology laboratories across Australia;
2. to describe variation by provider type (public or private pathology services) and jurisdiction across Australia; and
3. to understand laboratories' reporting structures for respiratory viruses including RSV and influenza.

Methods

This study was a cross-sectional survey reported in consideration of the STROBE recommendations.¹⁷

Participants and recruitment

National Association of Testing Authorities (NATA) accredited laboratories, listed on the NATA website as being ISO 15189 accredited at the time of the survey (mid-2023), were eligible; accredited laboratories were sent an invitation via email or post to participate in the survey. A list of all laboratories located across Australia, either hospital-based (public) or private (community-based), was compiled through the researchers' networks and the NATA website. There were no exclusions. Laboratory managers, supervisors or other nominated individuals were invited to complete the survey.

There were two approaches to sending the study invitation to laboratories. Firstly, an email was sent by the study team to the listed contact person on the NATA website. A maximum of three (3) email reminders were sent. For laboratories who did not respond to the email invitation, a hard copy 'study invitation pack' was mailed. The study invitation pack was addressed to the 'Laboratory Manager' as listed on the NATA website and included a cover letter, Information Statement, survey and return prepaid envelope. The study was approved by the Royal Children's Hospital Human Research Ethics Committee (HREC #92541).

Data collection

The survey collected data on patterns of laboratory respiratory testing, methods and platforms used, reporting processes and demographic information for the laboratory for 2022 as well as current respiratory multiplex testing in 2023. A copy of the survey questions is provided in Appendix A. Specifically for the reporting of results for RSV, influenza, human metapneumovirus (HMPV) and SARS-CoV-2 testing, we asked: 'What is the lab reporting process for [virus X]?' with options: directly to referring Dr; patient; notified to Department of Health; or other.

Each laboratory was invited to complete one survey. To avoid multiple submissions, each laboratory was asked to enter their NATA accreditation number. However, in order to maintain anonymity, the number was not linked to survey responses. Participants could access the survey from a public survey internet link or via the hard copy study invitation pack.

The survey could be completed in multiple sittings. However, once submitted, responses could not be accessed or corrected, as survey data were completed anonymously. Participants could provide their contact details (separate to survey responses) to be entered into a draw to win one of three \$100 digital Coles gift cards. Participants completed the survey between June 2023 and December 2023. Consent to participate in the survey was implied via survey completion.

Data analysis

Data were analysed using standard descriptive statistics. Categorical data were presented as medians and their interquartile range (IQR) due to non-parametric distribution. All statistical analyses were performed using statistical software Stata IC 16.0. Respondents' open text field responses were categorised, where appropriate, with respondent text included verbatim in tables or text.

Results

Study population

From 204 laboratories identified as potentially eligible to participate, 11 could not be contacted (emails undeliverable ($n = 9$) or hard copy invitations were returned to sender ($n = 2$)). From the remaining 193 laboratories, 45 completed the survey (37 online; 8 hard copy), a response rate of 23%. Laboratories with missing data were included in the dataset; denominators clearly indicated when incomplete data were received.

Description of study sample

Most participating laboratories were from Victoria and New South Wales, comprising 31% and 27%, respectively, of participating laboratories (Figure 1). While the profile of participating laboratories was broadly similar to the full set of laboratories listed on NATA, there was under-representation from Queensland and no participation from laboratories in South Australia. Most survey participants were hospital-based clinical diagnostic laboratories, which also reflected the funding position (Table 1). Respondents, participating on behalf of laboratories, were predominantly clinical microbiologists or laboratory managers (each 37%).

Figure 1: Map showing locations of participating laboratories, by jurisdiction,^a Australia



^a Navy and dark green dots denote clusters with number of laboratories included in the cluster, orange markers indicate individual laboratories.

Table 1: Characteristics of survey respondents (N = 45), Australia,^a 2023

Category	Characteristic	Level	Participating laboratories		Eligible laboratories ^b	
			n	%	n	%
Laboratories	Jurisdiction	Australian Capital Territory	2	4	2	1.0
		New South Wales	12	27	61	29.9
		Northern Territory	1	2	1	0.5
		Queensland	8	18	60	29.4
		South Australia	0	0	17	8.3
		Tasmania	3	7	6	2.9
		Victoria	14	31	39	19.1
		Western Australia	5	11	18	8.8
	Funding position	Private	11	24	—	—
		Public	34	76	—	—
	Main clientele	Community	10	22	—	—
		Hospital – adult	5	11	—	—
		Hospital – paediatric	1	2	—	—
		Hospital – adult and paediatric	26	58	—	—
		Hospital and community	2	4	—	—
		Other ^c	1	2	—	—
Respondents	Respondent's role ^d	Clinical microbiologist	16	37	—	—
		Laboratory manager	16	37	—	—
		Senior virology / molecular scientist	10	23	—	—
		Senior microbiologist / molecular scientist	1	2	—	—
	Length of time in professional role	< 5 years	11	24	—	—
		5–10 years	9	20	—	—
		> 10 years	25	56	—	—

a Participants with missing data were included in the dataset; incomplete data are indicated throughout the text.

b Laboratories listed as per NATA website for ISO 15189 and RSV at the time of the survey.

c listed as Public Health.

d n = 2 did not provide response.

Respiratory multiplex PCR testing in 2023

Overall, 40% of respondents (18/44) reported that the majority (> 80%) of all tests in the molecular laboratory in 2023 were respiratory multiplex PCR. Of the laboratories reporting specific pathogens included on a respiratory multiplex panel in 2023 (n = 44), all reported influenza virus, RSV and SARS-CoV-2 (Table 2). Parainfluenza, human metapneumovirus, human adenovirus and human rhinovirus were included in over half (24/44; 57%), while enterovirus, seasonal coronaviruses and human parechovirus were included to a much lesser extent. *Bordetella pertussis* was the most included bacterial pathogen.

Typing for RSV was less likely to be included than influenza typing on the multiplex panels. Of panels including influenza, almost two-thirds included typing (influenza A or influenza B) (29/44; 66%), while fewer than a quarter (N = 9/43; 21%) included RSV typing (RSV A or RSV B). Of note, some laboratories had missing data for typing (influenza n = 1; RSV n = 2). Of the laboratories undertaking multiplex testing in 2023, almost all (N = 43/44; 98%) used real-time PCR for respiratory multiplex assay; a smaller proportion (6/44; 14%) used a BioFire® FilmArray platform (BioMerieux) in addition or alone. This was an increase in the use of real-time PCR compared to 2022, when 92% (36/39) used real-time PCR.

Table 2: Pathogens included on respiratory multiplex in 2023, by participating laboratories (N = 44), Australia

Respiratory pathogen	n	%
Influenza	44	100
RSV	44	100
SARS-CoV-2	44	100
Parainfluenza	24	54
Human metapneumovirus	24	54
Human adenovirus	24	54
Human rhinovirus	24	54
Enterovirus	15	34
Bacterial ^a	13	30
Seasonal coronaviruses	6	14
Parechovirus	4	9
Other ^b	2	5

a Bacterial pathogens included: *Bordetella pertussis*; *Bordetella holmesii*; *Bordetella parapertussis*; *Mycoplasma pneumoniae*; *Chlamydophila pneumoniae*; *Legionella pneumoniae*.

b Other pathogens included: MERS-CoV.

Table 3: Viruses sent to reference laboratories, by participating laboratories (N = 32), Australia, 2023

Pathogen	n	%
Influenza	14	44
RSV	3	9
Parainfluenza	5	16
SARS-CoV-2	14	44
None	10	31
Other	5	16

Viruses submitted to reference laboratories

In total, 32 laboratories responded to this question, with 69% of respondents (22/32) reporting that virus samples were sent to a reference laboratory (Table 3). Of viruses tested, influenza and SARS-CoV-2 were most likely to be sent to a reference laboratory.

Molecular based platforms used for respiratory testing

The majority of labs (38/44; 86%) reported the number of molecular based platforms for respiratory testing at their laboratory. Of these, one (1) provided no further data, while another four (4) reported a higher number of platforms used than data provided. The number of platforms in each laboratory was in the range 1–5, with a median of 3 platforms (laboratories using one platform n = 9; two platforms n = 12; three platforms n = 7; four platforms n = 6; five platforms n = 3). Of the 37 laboratories, five laboratories reported the name of the assay used rather than the platform name (for 1 or more platform); these included manufacturers (Seegene n = 4; in-house n = 1; Roche n = 1). This left 87 known instances of 18 specified platforms.

Table 4: Platforms used by laboratories (N = 37), Australia, 2023

Platform name	Manufacturer	Number of laboratories
GeneXpert®	Cepheid	31
Cobas® Liat®	Roche	13
AusDiagnostics ^a	AusDiagnostics	9
BD Max™	Becton Dickinson	6
Panther®	Hologic	6
Cobas® 6800	Roche	5
Alinity M	Abbott	3
CFX96™	Seegene	3
Lightcycler® 480	Roche	2
BGI Linegene	Beijing Genomics Institute (BGI)	1
BioFire® FilmArray®	bioMerieux	1
CFX96™	Biorad	1
Myra Mic	Bio Molecular Systems (BMS)	1
Liaison® MDV	Diasorin	1
GS1000	Genetic Signatures	1
Seegene Starlet™	Seegene	1
ABI™ 7500	Thermo Fisher	1
ViiA™ 7	Thermo Fisher	1

^a AusDiagnostics platforms included UltraPlex (n = 1), HighPlex (n = 5) and not further specified (n = 3), used by nine separate laboratories.

Table 5: Platforms used by laboratories, by number of platforms in the laboratory, Australia, 2023

Platform (manufacturer)	Number of platforms used by laboratory				
	1	2	3	4	5
GeneXpert® (Cepheid)	✓	✓	✓	✓	✓
Cobas® Liat® (Roche)		✓	✓	✓	✓
Various platforms ^a (AusDiagnostics)	✓		✓	✓	✓
BD Max™ (Becton Dickinson)		✓	✓	✓	
Panther® (Hologic)		✓	✓	✓	✓
Cobas® 6800 (Roche)	✓			✓	✓
Alinity M (Abbott)			✓	✓	
CFX96 (Seegene)	✓		✓		✓
LightCycler® 480 (Roche)			✓		✓
BGI Linegene (Beijing Genomics Institute)				✓	
BioFire® FilmArray® (bioMerieux)					✓
CFX96™ (Biorad)				✓	
Myra Mic (BMS)		✓			
Liaison® MDV (Diasorin)					✓
GS1000 (Genetic Signatures)				✓	
Seegene STARlet™ (Seegene)				✓	
ABI™ 7500 (Thermo Fisher)		✓			
ViiA™ 7 (Thermo Fisher)		✓			
Unknown		✓	✓	✓	✓

a AusDiagnostics platforms included UltraPlex (n = 1), HighPlex (n = 5) and not further specified (n = 3), used by nine separate laboratories.

Of the 87 platforms, where the platform/manufacturer and test details were known, GeneXpert® (Cepheid) was the most frequently used, with most laboratories using this platform (31/37; 83%), followed by Cobas® Liat® (Roche), which was used in 13 laboratories (35%; some used both platforms). Other platforms were used by smaller numbers of laboratories (Table 4). Over half of the laboratories using GeneXpert® (Cepheid) (n = 25) were from the eastern states (New South Wales, Queensland, Victoria); among the eastern states, the highest concentration of participating laboratories using GeneXpert® (Cepheid) was in New South Wales (n = 10), followed by Victoria (n = 9) and Queensland (n = 6). In terms of platform preferences and use, those using fewer platforms in their laboratory (i.e., one or two platforms) preferred the GeneXpert® platform, with 6/9 laboratories using one platform and 11/12 laboratories using two platforms reporting use of the GeneXpert® platform. Those using three or more platforms included greater diversity in the combinations of platforms (Table 5).

Choice of platform for paediatric and adult samples

Four laboratories reported differences in the choice of platform/test for paediatric and adult samples (4/33; 12%). These were all laboratories servicing hospital patients: adult hospital (n = 1) and combined adult/paediatric hospital (n = 3). These differences appear to have been dominated by the need to include RSV and influenza testing for paediatric samples (Table 6). Overall, the strongest influence guiding which test/assay was utilised by laboratories was a combination of processing demand / turnaround time (17/33; 52%), followed by clinician request (11/33; 33%) and lastly laboratory preference/ practice (5/33; 15%).

We asked: What assays did your lab use in 2022? Of the 37 laboratories, 29/37 reported solely using commercial assays and while 8/37 reported using a combination, none reported using in-house only.

Table 6: Approach for paediatric and adult samples, when a difference was reported (N = 4), Australia, 2023

Hospital	Approach for children	Approach for adults
1	Test for RSV + Flu A/B and SARS-CoV-2	Preoperative – SARS-CoV-2 only; others test for all
2	GeneXpert – includes RSV	Cobas Liat
3	GeneXpert – includes RSV	Either analyser, depending on urgency of results
4	GeneXpert – includes RSV	BD Max or Cobas Liat (no RSV)

Seasonal differences & changes from 2022 to 2023

Over half of responding laboratories (18/33; 55%) had seasonal changes to testing patterns. In terms of changes to the previous year, 40% (13/32) reported that they had made changes to their respiratory testing procedures/panels between 2022 and 2023. In general, these changes included the addition or increased use of triplex or multiplex panels, combining/expanding assays to include SARS-CoV-2 and phasing out the use of in-house assay or SARS-CoV-2 only testing. Other laboratories had changed the platforms used for specific patients, for example using one platform to streamline hospital cases and another for rapid hospital cases; and others had 'retired' particular platforms altogether.

Testing and reporting of specific viruses

Routine typing/subtyping of viruses was uncommon: for RSV, influenza and HMPV respectively, routine typing and/or subtyping was undertaken by only 7 (21%), 12 (38%), and 5 (17%) laboratories. Of those that performed typing, only half routinely released these typing results (RSV: 3/7; influenza: 7/12) and to a lesser extent HMPV (1/5). Laboratories were most likely to report results directly to the referring doctor (96–100%) followed by notification of their jurisdictional Department of Health, with RSV (21/32; 65%), influenza (23/32; 74%) and SARS-CoV-2 (21/32; 65%) the most reported viruses. HMPV (11%) was least likely to be reported, noting however that HMPV is not a notifiable disease (Table 7). Smaller numbers across all viruses (RSV, influenza, HPMV, SARS-CoV-2) were reported directly to patients. Several laboratories reported not notifying results to the relevant health department (and thus the NNDSS) for RSV (10/32; 31%), influenza (7/29; 24%) and SARS-CoV-2 (9/29; 31%); however, this may have been due to the person completing the survey not having awareness of the data transfer procedures in place in that laboratory.

RSV testing and reporting

Just over half of laboratories (17/33; 51%) reported always testing for RSV in respiratory samples in 2022. Others only did so if a multiplex test was used (9/33); with a specific clinician request (7/33); or for other reported reasons (5/33), where such other reasons included testing for RSV if the sample was deemed to be clinically indicated (i.e. from someone < 18 years); if using a certain platform; and to fit with workflow and seasonal demands. The number of laboratories reporting that they were routinely testing for RSV in respiratory samples was higher in 2023 (27/32; 84%) than in 2022, with 11/16 laboratories which had not been routinely testing in 2022 now doing so.

Table 7: Testing and reporting of specific viruses (RSV, influenza, HMPV, SARS-CoV-2) by participating laboratories, Australia, 2023

Virus ^a	N ^b	Number of tests performed (at time of survey)				Typing ^f					Lab reporting process ^h								Report results on publicly available website ⁱ	
		Within last 6 months ^c		Within last 12 months ^e		Routinely undertaking typing		Routinely releasing typing results ^g		Proportion of positives typed/subtyped	To doctor		To patient		To Department		Other ⁱ			
		Median	IQR ^d	Median	IQR ^d	n	%	n	%	%	n	%	n	%	n	%	n	%		
RSV	33	5,000	1,850–10,000	9,187	3,384–20,000	7	21	3/7	42	85–100 ^k	32	100	5	15	21	65	2	6	6	20
Influenza	32	6,923	3,170–12,000	10,000	6,000–20,235	12	38	7/12	59	25–100 ^l	30	96	5	16	23	74	2	6	6	20
HMPV	30	400	0–5,000	1,400	0–10,000	5	17	1/5	20	m	18	100	0	0	2	11	1	5	—	—
SARS-CoV-2	32	6,445	2,500–23,202	14,312	5,970–52,650	—	—	—	—	—	31	97	11	34	21	65	1	3	7	24

a RSV: Respiratory syncytial virus; HMPV: human metapneumovirus; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

b Number of participating laboratories.

c Number of laboratories providing responses: RSV (n = 28); influenza (n = 26); HMPV (n = 30); SARS-CoV-2 (n = 27).

d IQR: interquartile range.

e Number of laboratories providing responses: RSV (n = 29); influenza (n = 27); HMPV (n = 31); SARS-CoV-2 (n = 28).

f Typing: RSV (type A or B); influenza A subtype (i.e. H1N1, H3N2); HMPV (sub group testing); SARS-CoV-2 (not asked).

g Proportion calculated is of those routinely releasing typing results.

h Number of laboratories providing responses: RSV (n = 32); influenza (n = 31); HMPV (n = 18); SARS-CoV-2 (n = 32).

i Other: RSV: infection control (n = 1); planning to text (short message service, SMS) to patient (n = 1); influenza: infection control (n = 1); planning to SMS to patient (n = 1); HMPV: planning to SMS to patient (n = 1); SARS-CoV-2: infection control (n = 1).

j Number of laboratories providing responses: RSV (n = 30); influenza (n = 30); HMPV (not asked); SARS-CoV-2 (n = 29).

k Observed range (%); 'season variation' was evident.

l Observed range (%); median proportion of positives typed/subtyped by laboratory was 90%.

m Two of five typing laboratories typed/subtyped all positives (100%); the remaining three typing laboratories did not type/subtype any positives (0%).

Discussion

This study provides a snapshot of laboratory-level respiratory pathogen testing patterns, including multiplex panels, commercial platforms and reporting processes for laboratories in the private and public sector across Australia. We surveyed 45 NATA accredited laboratories, responsible for performing testing for RSV and other respiratory viruses. The survey findings highlight the high degree of variability in testing and reporting practices by laboratories across Australia.

There were 18 different testing platforms used across the surveyed laboratories. In smaller laboratories, such as those using only 1–2 platforms, there was a reliance on smaller lower throughput platforms such as Cepheid GeneXpert, BioFire FilmArray and Cobas Liat. Higher throughput platforms for molecular respiratory testing, such as Cobas 6800/8800 or Panther, were only used in larger laboratories utilising 3 to 5 platforms. However, these were frequently also supplemented with smaller platforms. The differences in the range of platforms used in larger laboratories possibly reflects the need to scale to meet the demands due to the COVID-19 pandemic and the need for rapid and accurate detection of SARS-CoV-2. It was also evident that testing practices were different between jurisdictions. Some jurisdictions—for example, the Australian Capital Territory, the Northern Territory and Tasmania—had more centralised testing and larger throughput platforms were utilised, while other laboratories in decentralised settings were more likely to have smaller throughput platforms (for example New South Wales and Queensland).

The use of smaller throughput platforms provides advantages such as rapid turnaround time, ease of use, portability, and accurate detection of respiratory viruses such as influenza, RSV, and SARS-CoV-2, making them valuable tools for molecular respiratory testing in various healthcare settings. In contrast, the larger throughput platforms were used in centralised clinical and reference laboratories for high-volume molecular respiratory testing. They are equipped with automation, scalability, and a wide range of assay options to meet the demands of comprehensive diagnostic testing. Our study noted a preference for use of commercial multiplex panels relative to in-house. Although our survey did not examine the reasons underpinning laboratory assay selection, commercial multiplex panels are supplied as Australian Register of Therapeutic Goods (ARTG) listed products, offer the ability to detect multiple pathogens from a single specimen and may

provide operational efficiencies compared with multiple individual tests.^{18,19} The extent to which regulatory, operational, economic, or other factors influence assay choice in Australian laboratories warrants further investigation.

While most laboratories are now multiplexing and typing for influenza A/B, a considerable number do not include RSV A/B subtyping. This is possibly driven by the frequent use of GeneXpert, which does not include type for RSV. However, GeneXpert appears to be the preference for testing paediatric samples. Typing and sub-typing for influenza and RSV allows epidemiologists and public health officials to understand the epidemic dynamics of distinct types/sub-types. This in turn enables more robust predictions of epidemic activity during winter, particularly predicting whether epidemic peaks are expected of multiple viruses which can flow on to increased health system pressures. The need for RSV subtyping will be particularly important as we move into the era of RSV preventatives and the need to ensure that both RSV types are effectively covered by both vaccines and monoclonal antibody preventatives. While the level of subtyping varies between countries, for WHO RSV Global Surveillance countries, the current WHO recommendation is, where possible, to subtype all RSV positive samples. In 2024, only two Australian states (Queensland and Western Australia) committed to universal 2024 RSV preventive programs with nirsevimab for all infants,^{20,21} along with New South Wales implementing an RSV preventive program for vulnerable infants.²² In 2025, an Australia-wide RSV infant vaccination program has been introduced, with a national federally funded free maternal RSV vaccination program and an accompanying state-funded free program for the use of nirsevimab for infants whose mothers were not vaccinated or for those infants at increased risk from RSV infections. Accordingly, this information will be important to collect now and into the future to determine the ongoing effectiveness of these cost-intensive programs.

This study's finding, that several laboratories did not report to the relevant health department (and thus the NNDSS) for RSV, influenza and SARS-CoV-2, is concerning. Nonetheless, this finding should be interpreted with some caution, given this was a snapshot of laboratories and the person completing the survey may not have known the systems in place at their facility for automatically uploading of data to state based databases.

However, in all jurisdictions, pathology laboratories are required to report laboratory confirmed notifiable diseases such as influenza, COVID-19 and RSV directly to their respective health department. Like medical clinics, this potentially occurs with software that enables direct, automated reporting to the relevant health department. For example, the Public Health Event Surveillance System (PHESS) in Victoria or Notifiable Conditions Information Management System (NCIMS) in New South Wales can both receive electronic laboratory notifications automatically.

Strength and limitations

The national approach is a key strength of this investigation. It provided a snapshot of testing and laboratory practices from a diverse cross-section of laboratories, including metropolitan/regional, public/private laboratories Australia wide. There were some limitations to this project. The response rate was low (23%) and we did not receive any responses from South Australia. Additional data would have enabled a more comprehensive assessment of testing and laboratory practices, particularly to explore secondary outcomes. Additionally, we asked questions relating to reporting (specifically laboratories reporting results for RSV, influenza and SARS-CoV-2 to relevant health departments). These questions may have been misinterpreted or answered incorrectly and these should be interpreted with caution. We were unable to capture reasons for non-participation. While we cannot be certain all intended recipients received the survey, there may also have been better participation from those with a greater interest in respiratory testing or in other unmeasured ways. This means it is possible that survey participants had higher level of interest in this topic or research than those who did not participate.

Conclusions

This national snapshot of laboratories, performed in the second half of 2023, highlighted diverse testing and reporting practices for respiratory specimens, with 18 unique platforms used across the surveyed laboratories. Smaller laboratories (using only 1–2 platforms) preferred the smaller throughput platforms for molecular respiratory testing, with larger throughput platforms only reported from laboratories using a total of 3–5 platforms. A considerable number of laboratories did not include RSV typing with respiratory multiplex testing and there were discrepancies in the way results were reported. The need for RSV subtyping and accurate data on cases will be paramount as we have now moved into the era of RSV preventatives, which may change the molecular epidemiology of RSV and which requires the careful analysis of RSV that are circulating to ensure the preventatives are effective against both RSV A and RSV B. Influenza A would also benefit from increased subtyping as a way of identifying future spillovers of influenza from birds and animals to humans, thus enhancing our pandemic preparedness.

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Appendix A: 'Navigator' laboratory survey questions

What is your role at the lab?

- ☐ Clinical Microbiologist
- ☐ Laboratory Manager
- ☐ Senior Virology/ Molecular Scientist
- ☐ Virology/ Molecular Scientist
- ☐ Medical Technologist/ Laboratory Technician
- ☐ Infection control practitioner
- ☐ Other

What is the postcode where the laboratory is located?

.

What is your laboratories main clientele?

- ☐ Community
- ☐ Hospital – adult
- ☐ Hospital – paediatric
- ☐ Hospital – adult & paediatric
- ☐ Other

Is your lab private or public?

- ☐ Private
- ☐ Public

How long have you worked in this professional role?

- ☐ < 5 years
- ☐ 5–10 years
- ☐ > 10 years

Including yourself, how many staff members work in the molecular or virology lab (EFT equivalent)?

.

What hours does your Virology/ Molecular Microbiology Laboratory operate?
[Select all that apply]

- ☐ Business hours
 - ☐ Extended weekday hours. . . .
 - ☐ Saturdays
 - ☐ Sundays
 - ☐ Public Holidays
 - ☐ Extended hours all days
-

Respiratory multiplex testing in 2023

What proportion of all tests in the molecular lab 2023 are respiratory multiplex?

- ☐ < 20%
 - ☐ 20–40%
 - ☐ 40–60%
 - ☐ 60–80%
 - ☐ > 80%
-

What respiratory pathogens are included on a multiplex at your lab in 2023?

- ☐ Influenza
 - ☐ Parainfluenza
 - ☐ RSV
 - ☐ Human Metapneumovirus
 - ☐ Human Adenovirus
 - ☐ Human Rhinovirus
 - ☐ Enterovirus
 - ☐ Parechovirus
 - ☐ SARS-CoV-2
 - ☐ Seasonal Coronaviruses
 - ☐ Bacterial
 - ☐ Other
-

Does the multiplex include subtyping for influenza A and B?

- ☐ Yes
 - ☐ No
-

Does the multiplex include subtyping for RSV types A and B?

- ☐ Yes
 - ☐ No
-

What assays does your lab use in 2023 for a respiratory multiplex?

- ☐ Real time PCR
 - ☐ Fluorescent bead microarray
 - ☐ DNA microarray
 - ☐ Antibody microarray
 - ☐ Protein microarray
 - ☐ FilmArray
 - ☐ Other
-

Testing of respiratory samples in your lab in 2022

What type of testing did you perform for the detection of respiratory viruses?

- ☐ Real time PCR
- ☐ Fluorescent bead microarray
- ☐ DNA microarray
- ☐ Antibody microarray
- ☐ Protein microarray
- ☐ FilmArray
- ☐ Other

How many molecular based platforms were used for respiratory testing in your lab during 2022?

.....

How many molecular based platforms were used for respiratory testing in your lab during 2022?

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5+

What assays did your lab use in 2022?

- ☐ In-house developed
- ☐ Commercial
- ☐ Both

Is the choice of platform/test different for paediatric and adult samples?

- ☐ Yes
- ☐ No

What is the testing approach for children?

.....

What is the testing approach for adults?

.....

What guides your practice around what lab test/ assay to use?

- ☐ As requested by clinician
- ☐ Lab preference/ practice
- ☐ Determined by combination demand/ time

Do your testing patterns change from summer to winter? e.g. more multiplex assays are performed in winter vs summer?

- ☐ Yes
- ☐ No

Have you made any changes to your respiratory testing procedures/panels in 2023? [compared to 2022]

- ☐ No changes
- ☐ Added more test viruses/pathogens
- ☐ Reduced test viruses/pathogens
- ☐ Other

Please select which virus samples are sent to a reference laboratory?

- ☐ None
- ☐ Influenza
- ☐ RSV
- ☐ Parainfluenza
- ☐ SARS-CoV-2
- ☐ Other

RSV testing

In 2022...did your lab routinely (always) test for RSV in respiratory samples?

- ☐ Yes
☐ No

When did you test for RSV in 2022

- ☐ Only if a multiplex test is used
☐ Only on a specific clinician request
☐ Other
☐ Never

Are you routinely testing for RSV in 2023?

- ☐ Yes
☐ No

How many tests were undertaken at your lab for RSV?

In the last 6 months:

In the last 12 months:

[Please estimate if unknown]

Do you routinely undertake RSV typing
e.g. determining if it is RSV A or RSV B?

- ☐ Yes
☐ No

Do you routinely release results of RSV typing?

- ☐ Yes
☐ No

What proportion of RSV positive samples get
typed? (RSV-A or RSV-B)

.
(Enter %)

What is the lab reporting process for RSV?

- ☐ Directly to referring Dr
☐ Patient
☐ Notified to Department of Health
☐ Other

Are positive RSV results reported to the
Australian National Notifiable Diseases
Surveillance System?

- ☐ Yes
☐ No

When did you commence reporting to the NNDSS
for RSV? [enter month and year]

.
(Please enter month and year)

Do you report RSV results on a publicly available
website [other than NNDSS]?

- ☐ Yes
☐ No
-

Influenza testing

How many tests were undertaken at your lab for influenza?

In the last 6 months:

In the last 12 months:

[Please estimate if unknown]

Do you routinely subtype influenza A viruses
e.g. H1N1 or H3N2?

☐ Yes
☐ No

Do you routinely release results of subtyping
influenza A positive samples?

☐ Yes
☐ No

What proportion of influenza A positives are
subtyped?

.
(Enter %)

What is the lab reporting process for influenza?

☐ Directly to referring Dr
☐ Patient
☐ Notified to Department of Health
☐ Other

Are positive influenza results reported to the
Australian National Notifiable Diseases
Surveillance System?

☐ Yes
☐ No

When did you commence reporting to the NNDSS
for influenza? [enter month and year]

.
(Please enter month and year)

Do you report influenza results on a publicly
available website [other than NNDSS]?

☐ Yes
☐ No

Human metapneumovirus (HMPV) testing

How many tests/ assays are undertaken at your lab for human metapneumovirus?

In the last 6 months:

In the last 12 months:

Do you routinely undertake human
metapneumovirus subgroup testing?

☐ Yes
☐ No

Do you routinely release results of subgroup testing?

☐ Yes
☐ No

What proportion of human metapneumovirus
testing get typed?

.
(Enter %)

What is the lab reporting process for human
metapneumovirus?

☐ Directly to referring Dr
☐ Patient
☐ Notified to Department of Health
☐ Other (please specify)

SARS-CoV-2 testing

How many tests/ assays are undertaken at your lab for SARS-CoV-2?

In the last 6 months:

In the last 12 months:

What is the lab reporting process for SARS-CoV-2?

- ☐ Directly to referring Dr
 - ☐ Patient
 - ☐ Notified to Department of Health
 - ☐ Other (please specify)
-

Are positive SARS-CoV-2 results reported to the Australian National Notifiable Diseases Surveillance System?

- ☐ Yes
 - ☐ No
-

When did you commence reporting to the NNDSS for SARS-CoV-2? [enter month and year]

.
(Please enter month and year)

Do you report SARS-CoV-2 results on a publicly available website [other than NNDSS]?

- ☐ Yes
- ☐ No

The next section asks about the molecular based platforms used for respiratory testing in your laboratory.

Please answer for the number of platforms your laboratory uses.

For **each** platform used in your laboratory, please list the platform name, manufacturer and number of different tests used on this platform.

For example:

Platform name: GeneXpert

Manufacturer: Cepheid

Number of different tests used on this platform: e.g. 3

Please also tell us about the respiratory tests used on **each** platform. For each respiratory test used please list the test name, viruses detected and number of tests used in 2022.

For example:

Test name: Xpert® Xpress CoV-2/Flu/RSV

Viruses detected: SARS-CoV-2, influenza A/B and RSV

Number of tests used in 2022: 580

Platform One

For the **first** platform used in your laboratory, please list the

Platform name:

Manufacturer:

Number of different tests used on this platform:

Please tell us about the respiratory tests used on this first platform.

For the **first** respiratory test

Test name:

Viruses detected:

Number of tests used in 2022:

For the **second** respiratory test

Test name:

Viruses detected:

Number of tests used in 2022:

For the **third** respiratory kit

Kit name:

Viruses targeted:

Number of tests used in 2022:

For the **fourth** respiratory kit

Kit name:

Viruses targeted:

Number of tests used in 2022:

Platform Two

For the **second** platform used in your laboratory, please list the

Platform name:

Manufacturer:

Number of different tests used on this platform:

Please tell us about the respiratory tests used on this second platform.

For the **first** respiratory test used on this **second** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **second** respiratory test used on this **second** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **third** respiratory kit used on this **second** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

For the **fourth** respiratory kit used on this **second** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

Platform Three

For the **third** platform used in your laboratory, please list the

Platform name:

Manufacturer:

Number of different tests used on this platform:

Please tell us about the respiratory tests used on this third platform.

For the **first** respiratory test used on this **third** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **second** respiratory test used on this **third** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **third** respiratory kit used on this **third** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

For the **fourth** respiratory kit used on this **third** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

Platform Four

For the **fourth** platform used in your laboratory, please list the

Platform name:

Manufacturer:

Number of different tests used on this platform:

Please tell us about the respiratory tests used on this fourth platform.

For the **first** respiratory test used on this **fourth** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **second** respiratory test used on this **fourth** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **third** respiratory kit used on this **fourth** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

For the **fourth** respiratory kit used on this **fourth** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

Platform Five

For the **fifth** platform used in your laboratory, please list the

Platform name:

Manufacturer:

Number of different tests used on this platform:

Please tell us about the respiratory tests used on this fifth platform.

For the **first** respiratory test used on this **fifth** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **second** respiratory test used on this **fifth** platform please list the

Test name:

Viruses targeted:

Number of tests used in 2022:

For the **third** respiratory kit used on this **fifth** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:

For the **fourth** respiratory kit used on this **fifth** platform please list the

Kit name:

Viruses targeted:

Number of tests used in 2022:
