

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

BMJ Open

SARS-CoV-2 swabbing: An efficient and well-accepted method

Journal:	BMJ Open
Manuscript ID	bmjopen-2021-055217
Article Type:	Original research
Date Submitted by the Author:	08-Jul-2021
Complete List of Authors:	Thomas, Hannah; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Mullane, Marianne; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Ang, Sherlynn; Telethon Kids Institute Barrow, Tina; Telethon Kids Institute Leahy, Adele ; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Whelan, Alexandra; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Lombardi, Karen; Telethon Kids Institute; Edith Cowan University Cooper, Matthew; Telethon Kids Institute Stevenson, Paul; Telethon Kids Institute Stevenson, Paul; Telethon Kids Institute Lester, Leanne; University of Western Australia Padley, Andrea; Child and Adolescent Health Service Sprigg, Lynn; Child and Adolescent Health Service Speers, David; University of Western Australia; PathWest Laboratory Medicine Western Australia Merritt, A; PathWest Laboratory Medicine Western Australia Coffin, Juli; Telethon Kids Institute; University of Western Australia Gething, Peter; Telethon Kids Institute; Curtin University Bowen, Asha; Telethon Kids Institute; Curtin University Bowen, Asha; Telethon Kids Institute; Western Australia
Keywords:	COVID-19, Diagnostic microbiology < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES

SCHOLARONE[™] Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our <u>licence</u>.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which <u>Creative Commons</u> licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

reliez on

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

SARS-CoV-2 swabbing: An efficient and well-accepted method

Thomas H M^{1,2}, Mullane M^{1,2}, Ang S¹, Barrow T¹, Leahy A^{1,2}, Whelan A^{1,2}, Lombardi K^{1,3}, Cooper M¹, Stevenson P G¹, Lester L⁴, Padley A⁵, Sprigg L⁵, Speers D J^{4,6}, Merritt A J⁶, Coffin J^{1,4}, Cross D^{1,4}, Gething P^{1,7}, Bowen A C^{1,2,4,5}

¹Telethon Kids Institute, Perth, Western Australia, Australia

² Wesfarmers Centre of Vaccines & Infectious Diseases, Telethon Kids Institute, Perth, Western Australia, Australia

³Edith Cowan University, Perth, Western Australia, Australia

⁴University of Western Australia, Perth, Western Australia, Australia

⁵Child and Adolescent Health Service, Perth, Western Australia, Australia

⁶Pathwest Laboratory Medicine Western Australia, Perth, Western Australia, Australia

⁷Curtin University, Perth, Western Australia, Australia

Corresponding author:

Hannah M Thomas

Hannah.thomas@telethonkids.org.au

+614 31 971 803

Key words:

SARS-CoV-2, swabbing, discomfort, screening, COVID-19

Word count:

2,046

Abstract

Objectives: When the COVID-19 pandemic was declared, Governments responded with lockdown and isolation measures to combat viral spread, including the closure of many schools. More than a year later, widespread screening for SARS-CoV-2 is critical to allow schools and other institutions to remain open. Here we describe the acceptability of a minimally-invasive COVID-19 screening protocol trialled by the Western Australian (WA) Government to mitigate the risks of and boost public confidence in schools remaining open.

Methods: Asymptomatic students and staff in 40 schools were swabbed monthly between June and September 2020. To minimise discomfort, and optimise recruitment and tolerability in unaccompanied children, a combined throat and nasal (OP/Na) swab was chosen over the nasopharyngeal swab commonly used, despite slightly reduced test performance. PCR testing was performed with a two-step diagnostic and independent confirmatory PCR for any diagnostic PCR positives. Concurrent surveys evaluated participant experiences of in-school swabbing.

Results: 13,988 swabs were collected from students and staff. There were zero positive test results for SARS-CoV-2, including no false positives. Participants reported high acceptability: 71% of students reported no or minimal discomfort and most were willing to be re-swabbed (4% refusal rate).

Conclusions: OP/Na swabbing is acceptable and repeatable in schoolchildren as young as 4 years old and may combat noncompliance rates by significantly increasing the acceptability of testing. This kind of minimally-invasive testing will be key to the success of ongoing, voluntary mass screening as society adjusts to a new 'normal' in the face of COVID-19.

Article Summary

Strengths:

- Participation of 40 Western Australian schools, with broad representation across geography, socioeconomic demographics and school type.
- Minimally invasive SARS-CoV-2 swabbing method, likely to enhance rates of active consent and participation in COVID-19 screening.

Limitations:

- Pragmatic, budgetary and logistical considerations limit the sample size of this study.
- School selection was purposeful, not random, to ensure inclusion of a diverse sample. The
 possibility for bias will be addressed at the data analysis stage.

 BMJ Open

Introduction

In late 2019 the SARS-CoV-2 virus emerged, and shortly thereafter, a global pandemic was declared (1). Governments responded with lockdown and isolation measures to combat the spread of COVID-19, including the closure of many schools (2). Quickly, it became clear that building capacity to test for COVID-19 rapidly and accurately would be critical for public safety and confidence in the reopening of schools. Here, we describe the results of the DETECT Schools Study, launched in Western Australia (WA), Australia, to trial a minimally invasive method for asymptomatic SARS-CoV-2 virus screening in primary and secondary schools across the state where children were swabbed unaccompanied by parents or caregivers.

The mandate of the DETECT Schools Study was simple: to screen asymptomatic students and staff swiftly and effectively for SARS-CoV-2 without causing discomfort. This speaks to a broader global need for transformative approaches to SARS-CoV-2 testing, as screening for the new virus becomes a part of daily life. As society grapples with a new 'normal', individuals with respiratory symptoms, those working in high-risk environments and those returning from travel are being swabbed regularly for SARS-CoV-2 in an effort to protect their communities.

At the onset of the COVID-19 pandemic, nasopharyngeal (NP) swabbing for polymerase chain reaction (PCR) detection of SARS-CoV-2 was rapidly adopted globally as the gold standard for COVID-19 diagnosis (3), however the validation of less invasive methods for virus detection is necessary to optimise compliance and increase the reach of mass screening programs moving forwards.

At the time of this study, antigen tests were not yet available. Saliva sample PCR testing had emerged as a practical and non-invasive sampling method for the detection of SARS-CoV-2 in symptomatic (4) and asymptomatic people (5), but there are conflicting studies concerning sensitivity, with some reporting similar detection rates to NP swabbing (6–8) while others indicate low sensitivity (9) and caution against reliance on saliva samples alone for SARS-CoV-2 screening (10). Similarly, oropharyngeal (OP) swabbing is supported by some studies (11) but displays inferior performance to NP

swabbing in others (12). Nasal (Na) swabs offer another minimally invasive alternative with reasonable sensitivity (13,14), which are found to be more sensitive than throat swabs for SARS-CoV-2 detection in children (15) and are suited to high volume screening with a confirmatory NP swab. However, nasal swabs collected late in the disease course are less sensitive than NP samples (16), and modelling suggests that this sampling technique in isolation does not effectively capture patients with a low viral load (17).

Nasal swabbing has previously been found to be more comfortable and only marginally less sensitive than NP sampling for the detection of influenza (18). Pairing a nasal swab with an OP swab offers a minimally invasive method for SARS-CoV-2 detection, with studies indicating specificity equivalent to and sensitivity marginally reduced (~3%) from that of NP swabbing (19–21). This sensitivity is reportedly retained when allowing self-collection (22) or varying the swab type used (23). Harnessing the sensitivity of both sampling techniques may maximise the chances of viral detection while remaining minimally invasive. So, does the use of OP/Na swabbing minimise discomfort enough to justify this small sacrifice in sensitivity? Here we report the use of OP/Na swabbing to rapidly screen for SARS-CoV-2 in a large schoolbased cohort of volunteers, with an aim to optimise comfort and acceptability without losing sensitivity and specificity.

Methods

The state of WA is vast, covering one third the landmass of Australia. The population is concentrated in the capital city of Perth (2.1 million), with the remaining 400,000 people spread across the State's 2.6 million square kilometres. There are 1,131 schools across the state: 818 of these are public (Government) schools, at which a total of 315,148 students were enrolled in 2020 (24).

The study protocol is published (25). Briefly, 40 public schools (28,331 enrolled students and 4,023 employed staff) were purposefully selected by the WA Department of Education for participation in the study, ensuring representative inclusion of education support schools, residential colleges, and regional schools. Students aged 4 – 18 years were eligible, with two-thirds at metropolitan schools and one-third at regional schools from across the state (Figure 1).

Prior to study commencement, written and video study and consent information was distributed by the schools to staff and parents. Staff and parents provided active consent through an online portal supported by the REDCap platform (26). Randomly selected consenting participants (n=150; 90% students, 10% staff) were swabbed at each school in each round unless the school was not large enough to facilitate, in which case as many participants as possible were swabbed. Consented participants could subsequently refuse swabbing or withdraw from the study at any time.

SARS-CoV-2 swabbing of consented students and staff was carried out in the schools over three rounds between June and September 2020. We employed a combined oropharyngeal and nasal flocked swab (OP/Na) (22, 23). During study development, swab comfort was investigated with a group of paediatric volunteers: the CITOSWAB flocked swab (Gaia Science, Singapore) was selected as the preferred swab for OP/Na sampling.

Nurses received training in personal protective equipment (masks, gowns, eyewear and gloves) donning and doffing and swabbing technique before commencing the swabbing study in schools. Using a side-to-side motion, the swab was first swept across the back of the pharynx at least once in each direction, including both tonsils. The same swab was then inserted into one nostril (chosen by the child) along the floor of the nasal cavity parallel to the palate until resistance was encountered, rotated gently five times, withdrawn, and placed in the sheath containing viral transport medium (CITOSWAB, Gaia Science, Singapore). Swabs were transported to the WA public laboratory service provider in Perth, WA, and tested for SARS-CoV-2 using an in-house PCR platform modified from the WHO recommended assay (27) to include an inhibitor control, which detects the pan-sarbecovirus E gene. Validation studies of the PCR were performed early in the pandemic and confirmed a high analytical sensitivity and specificity with appropriate positive and negative controls. Any swab returning an in-house PCR positive result (CT value < 45) was subject to confirmatory testing with the Cepheid Xpert Xpress SARS-CoV-2 assay (BioMerieux, France). In-house and confirmatory PCR detections were reported as positive.

Surveys were administered to a subset of swabbing participants in the two weeks following the first round of swabbing in each school, and again a month after the completion of all swabbing rounds. Surveys asked about participant

experiences of swabbing, including the level of discomfort, concern and disruption associated with in-school testing. Parents were also surveyed about their child's swabbing experience. The surveys were administered during school classes for students and through personal email for staff and parents. Complete survey tools have been published previously (25).

Patient and public involvement

Community involvement and advice was actively sought in the design and preparation of this study. Procedures and resources were reviewed and approved by a National Community Advisory Group for COVID-19 Research, convened by the Telethon Kids Institute and comprising community members from across Australia, including Aboriginal members. The Telethon Kids Institute Kulunga Aboriginal Research Development Unit consulted on study resource development, including culturally-secure and informed consent processes and measures to supporting Aboriginal families.

Ethics approval statement

Ethical approval was obtained from the WA Child and Adolescent Health Service (PRN RGS0000004059) and the WA

Aboriginal Health Ethics Committee (PRN 993).

Results

1,458 school staff members and the parents of 7,386 students engaged with the online consent platform. 7,281 of these students (98.6%) and 1,321 staff (90.6%) consented to be swabbed. Over the three rounds, 13,988 swabs were collected from 5,903 students and 1,036 staff (Table 1).

Table 1. Demographics of school students and staff participating in swabbing.

		Students	Staff
Total participants	9	5,903	1,036
Gender	Female	2,636 (44.7%)	563 (54.3%)
	Male	3,255 (55.1%)	473 (45.7%)
	Other	12 (0.2%)	0 (0%)
Aboriginal and/or	Yes	328 (5.6%)	11 (1.1%)
Torres Strait Islander	No	5,006 (84.8%)	1,022 (98.6%)
	Not identified	569 (9.6%)	3 (0.3%)
Area	Metropolitan	4,479 (75.9%)	812 (78.4%)
	Regional	1,424 (24.1%)	224 (21.6%)

Swabs were collected from across the state, and results provided by text message to all participating families and staff within 72 hours of sample collection. All but one sample returned negative results on the in-house PCR platform, and confirmatory Xpert testing of the in-house PCR detection returned a negative result. As such, none of the 13,988 samples collected were positive for SARS-CoV-2. This was consistent with no cases of local SARS-CoV-2 transmission reported in WA throughout the study period.

5,349 students and 911 staff were randomised to be swabbed more than once across the three rounds. Of these participants, 214 students (4%) and 12 staff (1.3%) declined to be swabbed again (declined on the day or withdrew from the study).

After the first round of swabbing, the majority of student respondents indicated on a five-point scale (none, mild, moderate, painful, very painful) no more than mild discomfort (no discomfort: 19.7%; mild discomfort: 51.0%) (Figure 2A). Most of the remaining students reported moderate discomfort (20.5%), with few indicating that the swabbing was painful (painful: 6.5%; very painful: 2.3%). The majority of staff who had been swabbed also indicated only mild (59.4%) or no (19.6%) discomfort during the procedure.

Most students reported feeling only a little (37.2%) or not at all (47.3%) concerned about participating in testing (Figure 2B). The parents of participating students also reported on their child's levels of concern, with the majority of parents observing little (28.4%) or no (60.8%) concern in their children.

Participating students were also asked whether they had been concerned about swabbing nurses wearing PPE at their school. For the most part, students reported only a little or no concern about this. Primary school students were slightly more likely to be at least moderately concerned (10%) than secondary students (5%).

After three rounds of swabbing, surveys were administered again to an unmatched subset of swabbing participants. Response distributions were comparable to those described for the first survey cycle, with the majority of those surveyed still indicating mild levels of discomfort and concern after ongoing testing.

Discussion

Efficient, accurate SARS-CoV-2 screening will be key to ameliorating the progression of the COVID-19 pandemic. As epidemiological evidence suggests that asymptomatic and pre-symptomatic individuals play a significant role in propagating the transmission of the virus (28–30), in low prevalence settings like WA the screening of asymptomatic populations will continue to be important to prevent a rise in cases. Without the indication of symptoms, this mode of screening requires good will and voluntary participation and must therefore strike a balance between optimising both testing sensitivity and participant comfort. As the discomfort associated with nasopharyngeal SARS-CoV-2 swabbing techniques risks poor adherence to mass screening campaigns (31), alternative approaches will be necessary to cultivate the consistency and reliability of public swabbing adherence necessary moving forwards.

For school-aged children, closing schools to combat the spread of COVID-19 must be balanced against the very real challenges in mental health and inequality likely associated with missing out on the educational and social benefits of school attendance (32,33). Consequently, countries around the world have mobilised to implement mass testing in an effort to support the reopening of schools and other establishments. Refinement of a robust and well-accepted screening mechanism will support the continuation of education; however very little data is available on the acceptability of various swabbing procedures and how this may impact adherence to screening programs.

Through the DETECT Schools Study we have evaluated the acceptability of OP/Na sampling, reported to facilitate SARS-CoV-2 detection with limited or no sacrifice in sensitivity compared to the standard NP procedure (18,34), in a school setting. Sampling was conducted with a flocked nylon swab: while evidence suggests that cotton, synthetic, flocked, and non-flocked swabs all exhibit comparable performance for SARS-CoV-2 detection (35), flocked swabs have previously been shown to deliver a higher yield when swabbing for other respiratory viruses (36).

In a large, representative cohort of school students and staff, our findings indicate that the vast majority of participants experienced minimal or no discomfort during an OP/Na swab. Almost all of those who were asked to participate a

second time agreed, illustrating the high tolerance for repeat procedures which is desirable for optimised respiratory screening programs. Decreased discomfort is also likely to be associated with a reduced possibility of coughing, gagging or sneezing during sampling, in turn decreasing the risk of viral exposure for healthcare staff. While potentially not acceptable in specific settings with vulnerable groups for which sensitivity is paramount, such as entry screening for nursing homes (37), we argue that in schools and other similar settings this small decrease in sensitivity is far outweighed by high rates of consent and compliance which will allow for widespread testing.

Conclusion

Here we report an approach to large-scale asymptomatic swabbing for SARS-CoV-2 leading to high levels of willingness to participate. The sensitivity of this method for the identification of SARS-CoV-2 is supported by other studies. This methodology for screening children was well received by a large cohort and could be utilised to screen for asymptomatic SARS-CoV-2 in other settings, mitigating the requirements for uncomfortable NP sampling and leading to enhanced compliance with programs designed to prevent onwards transmission of SARS-CoV-2.

BMJ Open

Funding

This work was supported by the Western Australian Department of Health [DoH20205875].

Donna Cross' contribution to this paper was supported by a National Health and Medical Research Council Research

Fellowship [GNT 1119339].

Asha Bowen receives an Investigator Award from the National Health and Medical Research Council of Australia

[GNT1175509].

Peter Gething's contribution to this paper was supported by Channel 7 Telethon Trust, Western Australia.

Data availability statement

DETECT Schools Study deidentified participant data is shared with study partners (WA Departments of Health and Education) but is not available to the public. The study protocol is published at https://doi.org/10.3389/fpubh.2021.636921.

Acknowledgements

We would like to acknowledge and thank staff from PathWest, the WA Child and Adolescent Health Service and the WA Country Health Service for their valuable contribution to the DETECT Schools Study. We also thanks all students and staff who participated in swabbing.

Author contributions

Hannah Thomas (HT) coordinated data collection, contributed to data analysis, conducted the literature search,

generated figures and drafted the manuscript.

provided critical revision of drafts.

Sherlynn Ang (SA), Tina Barrow (TB), Adele Leahy (AL), Alex Whelan (AW) coordinated data collection and provided critical revision of drafts. Karen Lombardi (KL) coordinated and provided critical revision of drafts. Matthew Cooper (MC), Paul Stevenson (PS), Leanne Lester (LL) and David Spears (DS) contributed to data analysis and provided critical revision of drafts. Adam Merritt (AM) contributed to design of test workflow, data analysis and provided critical revision of drafts. Andrea Padley (AP) and Lyn Sprigg (LS) contributed to data collection and provided critical revision of drafts. Juli Coffin (JC), Donna Cross (DC), Peter Gething (PG) and Asha Bowen (AB) oversaw conception, design and coordination of the study and provided critical revision of drafts. **Competing interests** Telethon Kids Institute authors report grants from the Western Australian Department of Health during the conduct of this study. Donna Cross and Asha Bowen report grants from the Western Australian Department of Health outside the submitted work. Asha Bowen, Andrea Padley, Lyn Sprigg, David Speers and Adam Merritt are employees of the Western Australian Department of Health. For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

BMJ Open

Marianne Mullane (MM) coordinated the conception and design of the study, coordinated data collection and

BMJ Open

2 3 4	Ref	erences	
5			
6 7 8	1.	Du Toit A. Outbreak of a novel coronavirus. Nat Rev. 2020;18(1):123.	
9 10 11	2.	Viner RM, Russell SJ, Croker H, Packer J, Ward J, Stansfield C, et al. School closure and management practice	S
12 13		during coronavirus outbreaks including COVID-19: a rapid systematic review. Lancet Child Adolesc Heal	
14 15 16		[Internet]. 2020;4(5):397–404. Available from: http://dx.doi.org/10.1016/S2352-4642(20)30095-X	
17 18	3.	World Health Organisation. Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human	
19 20 21		cases: interim guidance. [Internet]. 2020. Available from:	
22 23		https://apps.who.int/iris/bitstream/handle/10665/331329/WHO-COVID-19-laboratory-2020.4-eng.pdf	
24 25 26	4.	Azzi L, Carcano G, Gianfagna F, Grossi P, Gasperina DD, Genoni A, et al. Saliva is a reliable tool to detect SARS	5-
27 28 29		CoV-2. J Infect. 2020 Jul;81(1):e45–50.	
30 31	5.	Yokota I, Shane PY, Okada K, Unoki Y, Yang Y, Inao T, et al. Mass screening of asymptomatic persons for SARS	5-
32 33 34		CoV-2 using saliva. Clin Infect Dis an Off Publ Infect Dis Soc Am. 2020 Sep;	
35 36	6.	Vaz SN, Santana DS de, Netto EM, Pedroso C, Wang W-K, Santos FDA, et al. Saliva is a reliable, non-invasive	
37 38 39		specimen for SARS-CoV-2 detection. Brazilian J Infect Dis an Off Publ Brazilian Soc Infect Dis. 2020 Aug;	
40 41	7.	To KK-W, Tsang OT-Y, Yip CC-Y, Chan K-H, Wu T-C, Chan JM-C, et al. Consistent Detection of 2019 Novel	
42 43 44		Coronavirus in Saliva. Clin Infect Dis an Off Publ Infect Dis Soc Am. 2020 Jul;71(15):841–3.	
45 46	8.	Chen JH-K, Yip CC-Y, Poon RW-S, Chan K-H, Cheng VC-C, Hung IF-N, et al. Evaluating the use of posterior	
47 48 49		oropharyngeal saliva in a point-of-care assay for the detection of SARS-CoV-2. Emerg Microbes Infect. 2020	
50 51		Dec;9(1):1356–9.	
52 53 54	9.	Lin C, Xiang J, Yan M, Li H, Huang S, Shen C. Comparison of throat swabs and sputum specimens for viral	
55 56		nucleic acid detection in 52 cases of novel coronavirus (SARS-Cov-2)-infected pneumonia (COVID-19). Clin	
57 58			14
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

3 4		Chem Lab Med. 2020 Jun;58(7):1089–94.
5 6 7	10.	Riccò M, Ranzieri S, Peruzzi S, Valente M, Marchesi F, Balzarini F, et al. RT-qPCR assays based on saliva rather
, 8 9		than on nasopharyngeal swabs are possible but should be interpreted with caution: results from a systematic
10 11 12		review and meta-analysis. Acta Biomed. 2020 Sep;91(3):e2020025.
13 14	11.	Calame A, Mazza L, Renzoni A, Kaiser L, Schibler M. Sensitivity of nasopharyngeal, oropharyngeal, and nasal
15 16 17		wash specimens for SARS-CoV-2 detection in the setting of sampling device shortage. European Journal of
17 18 19		Clinical Microbiology & Infectious Diseases. 2020. p. 1–5.
20 21 22	12.	Wang X, Tan L, Wang X, Liu W, Lu Y, Cheng L, et al. Comparison of nasopharyngeal and oropharyngeal swabs
22 23 24		for SARS-CoV-2 detection in 353 patients received tests with both specimens simultaneously. Int J Infect Dis
25 26		IJID Off Publ Int Soc Infect Dis. 2020 May;94:107–9.
27 28 29	13.	Tu Y-P, Jennings R, Hart B, Cangelosi GA, Wood RC, Wehber K, et al. Swabs Collected by Patients or Health
30 31		Care Workers for SARS-CoV-2 Testing. Vol. 383, The New England journal of medicine. 2020. p. 494–6.
32 33 34	14.	McCulloch DJ, Kim AE, Wilcox NC, Logue JK, Greninger AL, Englund JA, et al. Comparison of Unsupervised
35 36		Home Self-collected Midnasal Swabs With Clinician-Collected Nasopharyngeal Swabs for Detection of SARS-
37 38 39		CoV-2 Infection. JAMA Netw open. 2020 Jul;3(7):e2016382.
40 41	15.	Palmas G, Moriondo M, Trapani S, Ricci S, Calistri E, Pisano L, et al. Nasal swab as preferred clinical specimen
42 43 44		for COVID-19 testing in children. Pediatr Infect Dis J. 2020;39(9):267–70.
45 46	16.	Pinninti S, Trieu C, Pati SK, Latting M, Cooper J, Seleme MC, et al. Comparing Nasopharyngeal and
47 48 49		Midturbinate Nasal Swab Testing for the Identification of Severe Acute Respiratory Syndrome Coronavirus 2.
50 51		Clin Infect Dis [Internet]. 2020;72(7):1253–5. Available from: https://doi.org/10.1093/cid/ciaa882
52 53 54	17.	Callahan C, Lee R, Lee G, Zulauf KE, Kirby JE, Arnaout R. Nasal-Swab Testing Misses Patients with Low SARS-
55 56		CoV-2 Viral Loads. medRxiv : the preprint server for health sciences. 2020.
57 58		15
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

BMJ Open

2		
3 4	18.	Frazee BW, Rodríguez-Hoces de la Guardia A, Alter H, Chen CG, Fuentes EL, Holzer AK, et al. Accuracy and
5 6		Discomfort of Different Types of Intranasal Specimen Collection Methods for Molecular Influenza Testing in
7 8 9		Emergency Department Patients. Ann Emerg Med. 2018 Apr;71(4):509-517.e1.
10 11	19.	LeBlanc JJ, Heinstein C, MacDonald J, Pettipas J, Hatchette TF, Patriquin G. A combined oropharyngeal/nares
12 13		swab is a suitable alternative to nasopharyngeal swabs for the detection of SARS-CoV-2. J Clin Virol [Internet].
14 15 16		2020;128(May):104442. Available from: https://doi.org/10.1016/j.jcv.2020.104442
17 18 19	20.	Vlek ALM, Wesselius TS, Achterberg R, Thijsen SFT. Combined throat/nasal swab sampling for SARS-CoV-2 is
20 21		equivalent to nasopharyngeal sampling. Eur J Clin Microbiol Infect Dis Off Publ Eur Soc Clin Microbiol. 2020
22 23 24		Jul;1–3.
25 26	21.	Tsang NNY, So HC, Ng KY, Cowling BJ, Leung GM, Ip DKM. Diagnostic performance of different sampling
27 28		approaches for SARS-CoV-2 RT-PCR testing: a systematic review and meta-analysis. Lancet Infect Dis [Internet].
29 30 31		2021 Apr 22; Available from: https://doi.org/10.1016/S1473-3099(21)00146-8
32 33	22.	Wehrhahn MC, Robson J, Brown S, Bursle E, Byrne S, New D, et al. Self-collection: An appropriate alternative
34 35 36		during the SARS-CoV-2 pandemic. J Clin Virol Off Publ Pan Am Soc Clin Virol. 2020 Jul;128:104417.
37 38	23.	Patriquin G, Davis I, Heinstein C, MacDonald J, Hatchette TF, LeBlanc JJ. Exploring alternative swabs for use in
39 40 41		SARS-CoV-2 detection from the oropharynx and anterior nares. J Virol Methods. 2020 Nov;285:113948.
42 43 44	24.	Western Australian Department of Education. Public and non-government schools with full-time students (by
45 46 47		metropolitan, country and combined) - Semester 2, 2020. School Information - Statistical Reports. 2020.
47 48 49	25.	Mullane MJ, Thomas HM, Epstein M, Mandzufas J, Mullan N, Whelan A, et al. DETECT Schools Study Protocol:
50 51		A Prospective Observational Cohort Surveillance Study Investigating the Impact of COVID-19 in Western
52 53		Australian Schools. Front Public Heal [Internet]. 2021;9:16. Available from:
54 55		https://www.frontiersin.org/article/10.3389/fpubh.2021.636921
56 57		
58 59		16
60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

2		
3 4	26.	Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)-A
5 6		metadata-driven methodology and workflow process for providing translational research informatics support.
7 8 9		J Biomed Inform [Internet]. 2009;42(2):377–81. Available from: http://dx.doi.org/10.1016/j.jbi.2008.08.010
10 11	27.	Corman VM, Landt O, Kaiser M, Molenkamp R, Meijer A, Chu DK, et al. Detection of 2019 novel coronavirus
12 13 14		(2019-nCoV) by real-time RT-PCR. Euro Surveill Bull Eur sur les Mal Transm = Eur Commun Dis Bull. 2020
15 16 17		Jan;25(3).
17 18 19	28.	Bai Y, Yao L, Wei T, Tian F, Jin D-Y, Chen L, et al. Presumed Asymptomatic Carrier Transmission of COVID-19.
20 21 22		JAMA. 2020 Apr;323(14):1406–7.
22 23 24	29.	Mizumoto K, Kagaya K, Zarebski A, Chowell G. Estimating the asymptomatic proportion of coronavirus disease
25 26		2019 (COVID-19) cases on board the Diamond Princess cruise ship, Yokohama, Japan, 2020. Euro Surveill Bull
27 28 29		Eur sur les Mal Transm = Eur Commun Dis Bull. 2020 Mar;25(10).
30 31	30.	Moghadas SM, Fitzpatrick MC, Sah P, Pandey A, Shoukat A, Singer BH, et al. The implications of silent
32 33 34		transmission for the control of COVID-19 outbreaks. Proc Natl Acad Sci U S A. 2020 Jul;117(30):17513–5.
35 36 27	31.	Moisset X, Gautier N, Godet T, Parabère S, Pereira B, Meunier E, et al. Nasopharyngeal swab-induced pain for
37 38 39		SARS-CoV-2 screening: A randomised controlled trial of conventional and self-swabbing. Eur J Pain [Internet].
40 41		n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/ejp.1722
42 43 44	32.	Armitage R, Nellums LB. Considering inequalities in the school closure response to COVID-19. Vol. 8, The
45 46		Lancet Global Health. 2020. p. e644.
47 48 49	33.	Lee J. Mental health effects of school closures during COVID-19. Lancet Child Adolesc Heal [Internet]. 2020 Jun
50 51 52		1;4(6):421. Available from: https://doi.org/10.1016/S2352-4642(20)30109-7
53 54	34.	Jamal AJ, Mozafarihashjin M, Coomes E, Anceva-Sami S, Barati S, Crowl G, et al. Sensitivity of midturbinate
55 56		versus nasopharyngeal swabs for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-
57 58		17
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

60

BMJ Open

2 3 4		CoV-2). Infect Control Hosp Epidemiol. 2020 Nov;1–3.
5 6 7	35.	Garnett L, Bello A, Tran KN, Audet J, Leung A, Schiffman Z, et al. Comparison analysis of different swabs and
8 9		transport mediums suitable for SARS-CoV-2 testing following shortages. J Virol Methods. 2020
10 11		Nov;285:113947.
12 13 14	36.	Moore C, Corden S, Sinha J, Jones R. Dry cotton or flocked respiratory swabs as a simple collection technique
15 16 17		for the molecular detection of respiratory viruses using real-time NASBA. J Virol Methods. 2008
17 18 19		Nov;153(2):84–9.
20 21 22	37.	Mina MJ, Andersen KG. COVID-19 testing: One size does not fit all. Science (80-) [Internet].
23 24		2021;371(6525):126–7. Available from: https://science.sciencemag.org/content/371/6525/126
25 26		
27 28		
28 29		
30		
31 32		
33		
34		
35		
36 37		
38		
39		
40 41		
42		
43		
44		
45 46		
40		
48		
49		
50 51		
52		
53		
54		
55 56		
56 57		
58		1
59		

Figure legends

Figure 1. Geographic distribution of schools participating in DETECT Schools Study swabbing.

.erticipating . Figure 2. Distribution of survey responses regarding A) self-reported discomfort (student and staff); B) students' concern about being swabbed (self- and parent-reported); and C) students' concern regarding swabbing staff use of PPE.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

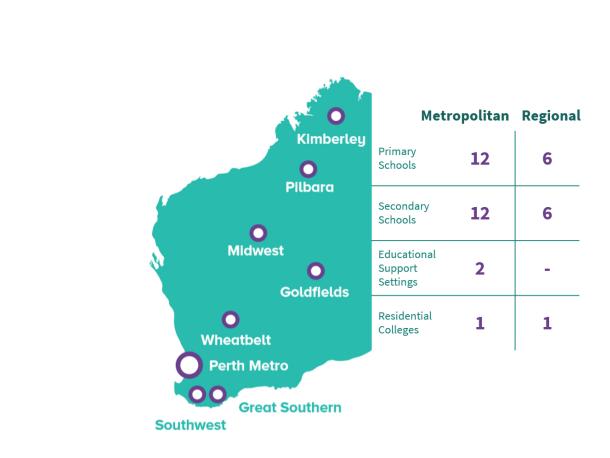
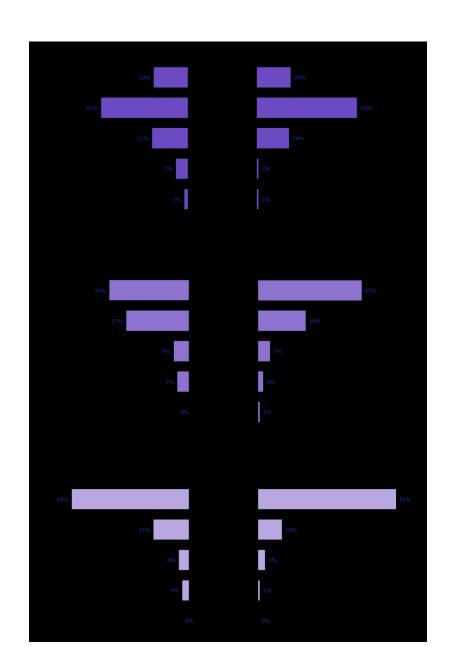


Figure 1. Geographic distribution of schools participating in DETECT Schools Study swabbing.

184x137mm (150 x 150 DPI)

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml



255x384mm (150 x 150 DPI)

STROBE Statement-checklist of items that should be included in reports of observational studies

	Item No	Recommendation		Page
Title and abstract	1	(a) Indicate the study's design with a commonly used	YES	2
		term in the title or the abstract		
		(b) Provide in the abstract an informative and balanced	YES	2
		summary of what was done and what was found		
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the	YES	4
		investigation being reported		
Objectives	3	State specific objectives, including any prespecified	YES	5
		hypotheses		
Methods				
Study design	4	Present key elements of study design early in the paper	YES	5
Setting	5	Describe the setting, locations, and relevant dates,	YES	6
-		including periods of recruitment, exposure, follow-up, and		
		data collection		
Participants	6	(a) Cohort study—Give the eligibility criteria, and the	YES	5-6
-		sources and methods of selection of participants. Describe		
		methods of follow-up		
		Case-control study—Give the eligibility criteria, and the		
		sources and methods of case ascertainment and control		
		selection. Give the rationale for the choice of cases and		
		controls		
		Cross-sectional study—Give the eligibility criteria, and		
		the sources and methods of selection of participants		
		(b) Cohort study—For matched studies, give matching		
		criteria and number of exposed and unexposed		
		Case-control study—For matched studies, give matching		
		criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors,	NA	
		potential confounders, and effect modifiers. Give		
		diagnostic criteria, if applicable		
Data sources/	8*	For each variable of interest, give sources of data and	YES	7
measurement		details of methods of assessment (measurement). Describe		
		comparability of assessment methods if there is more than		
		one group		
Bias	9	Describe any efforts to address potential sources of bias	YES	5
Study size	10	Explain how the study size was arrived at	YES	(explaine
				in
				protocol
Quantitative	11	Explain how quantitative variables were handled in the	YES	(explaine
variables		analyses. If applicable, describe which groupings were		in
		chosen and why		protocol
Statistical methods	12	(a) Describe all statistical methods, including those used	NA	
		to control for confounding	(descriptive)	

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2
3 4
5 6 7
, 8 9
10 11
12 13 14
14 15 16
15 16 17 18 19
20 21
22 23 24
25 26
 19 20 21 22 23 24 25 26 27 28 29 30
31
32 33 34
35
36 37 38 39
40 41
42 43 44
45 46
47 48 49
50 51
52 53
54 55 56
57 58
59 60

		(<i>b</i>) Describe any methods used to examine subgroups and interactions	NA		
		(c) Explain how missing data were addressed	NA		
		(<i>d</i>) Cohort study—If applicable, explain how loss to follow-up was addressed	NA		
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed			
		Cross-sectional study—If applicable, describe analytical			
		methods taking account of sampling strategy			
		(<u>e</u>) Describe any sensitivity analyses			
Results					
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	d	YES	8
		(b) Give reasons for non-participation at each stage		NA	
		(c) Consider use of a flow diagram		- 1	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders		YES	8
		(b) Indicate number of participants with missing data for each variable o interest	f	YES	8
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)		NA	
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures	5	NA	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		NA	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures		NA	
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included		NA	
		(b) Report category boundaries when continuous variables were categorized		NA	
		(<i>c</i>) If relevant, consider translating estimates of relative risk into absolut risk for a meaningful time period	e	NA	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses		NA	
Discussion					
Key results	18	Summarise key results with reference to study objectives		YES	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias		YES	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence		YES	10
Generalisability	21	Discuss the generalisability (external validity) of the study results		YES	11

unexposed groups in cohort and cross-sectional studies. Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (free available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.	*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies. Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background a published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (fra available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	YES	1
		unexposed gr Note: An Exp published exa available on t http://www.au	oups in co planation a mples of he Web si mals.org/	whort and cross-sectional studies. and Elaboration article discusses each checklist item and gives methodologica transparent reporting. The STROBE checklist is best used in conjunction with tes of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Me , and Epidemiology at http://www.epidem.com/). Information on the STROBE e-statement.org.	l backgroun this article edicine at	e (fre

BMJ Open

Acceptability of OP/Na swabbing for SARS-CoV-2: A prospective observational cohort surveillance study in Western Australian schools

Journal:	BMJ Open
Manuscript ID	bmjopen-2021-055217.R1
Article Type:	Original research
Date Submitted by the Author:	06-Oct-2021
Complete List of Authors:	Thomas, Hannah; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Mullane, Marianne; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Ang, Sherlynn; Telethon Kids Institute Barrow, Tina; Telethon Kids Institute Leahy, Adele ; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Whelan, Alexandra; Telethon Kids Institute; Telethon Kids Institute, Wesfarmers Centre of Vaccines & Infectious Diseases Lombardi, Karen; Telethon Kids Institute; Edith Cowan University Cooper, Matthew; Telethon Kids Institute Stevenson, Paul; Telethon Kids Institute Lester, Leanne; University of Western Australia Padley, Andrea; Child and Adolescent Health Service Sprigg, Lynn; Child and Adolescent Health Service Speers, David; University of Western Australia; PathWest Laboratory Medicine Western Australia Merritt, A; PathWest Laboratory Medicine Western Australia Cross, Donna; Telethon Kids Institute; University of Western Australia Gething, Peter; Telethon Kids Institute; Wesfarmers Centre of Vaccines & Infectious Diseases; University of Western Australia
Primary Subject Heading :	Public health
Secondary Subject Heading:	Infectious diseases
Keywords:	COVID-19, Diagnostic microbiology < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES





I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our <u>licence</u>.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which <u>Creative Commons</u> licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

review only

BMJ Open

Acceptability of OP/Na swabbing for SARS-CoV-2: A prospective observational cohort surveillance study in Western Australian schools

Thomas H M^{1,2}, Mullane M^{1,2}, Ang S¹, Barrow T¹, Leahy A^{1,2}, Whelan A^{1,2}, Lombardi K^{1,3}, Cooper M¹, Stevenson P G¹, Lester L⁴, Padley A⁵, Sprigg L⁵, Speers D J^{4,6}, Merritt A J⁶, Coffin J^{1,4}, Cross D^{1,4}, Gething P^{1,7}, Bowen A C^{1,2,4,5}

¹Telethon Kids Institute, Perth, Western Australia, Australia

² Wesfarmers Centre of Vaccines & Infectious Diseases, Telethon Kids Institute, Perth, Western Australia, Australia

³Edith Cowan University, Perth, Western Australia, Australia

⁴University of Western Australia, Perth, Western Australia, Australia

⁵Child and Adolescent Health Service, Perth, Western Australia, Australia

⁶Pathwest Laboratory Medicine Western Australia, Perth, Western Australia, Australia

⁷Curtin University, Perth, Western Australia, Australia

Corresponding author:

Hannah M Thomas

Hannah.thomas@telethonkids.org.au

+614 31 971 803

Key words:

SARS-CoV-2, swabbing, discomfort, screening, COVID-19

Word count:

2,416

Abstract

Objectives: When the COVID-19 pandemic was declared, Governments responded with lockdown and isolation measures to combat viral spread, including the closure of many schools. More than a year later, widespread screening for SARS-CoV-2 is critical to allow schools and other institutions to remain open. Here we describe the acceptability of a minimally-invasive COVID-19 screening protocol trialled by the Western Australian (WA) Government to mitigate the risks of and boost public confidence in schools remaining open. To minimise discomfort, and optimise recruitment and tolerability in unaccompanied children, a combined throat and nasal (OP/Na) swab was chosen over the nasopharyngeal swab commonly used, despite slightly reduced test performance.

Design, setting and participants: Trialling of OP/Na swabbing took place as part of a prospective observational cohort surveillance study in 79 schools across Western Australia. Swabs were collected from 5,903 asymptomatic students and 1,036 asymptomatic staff in 40 schools monthly between June and September 2020.

Outcome measures: PCR testing was performed with a two-step diagnostic and independent confirmatory PCR for any diagnostic PCR positives. Concurrent surveys, collected online through the REDCap platform, evaluated participant experiences of in-school swabbing.

Results: 13,988 swabs were collected from students and staff. There were zero positive test results for SARS-CoV-2, including no false positives. Participants reported high acceptability: 71% of students reported no or minimal discomfort and most were willing to be re-swabbed (4% refusal rate).

Conclusions: OP/Na swabbing is acceptable and repeatable in schoolchildren as young as 4 years old and may combat noncompliance rates by significantly increasing the acceptability of testing. This kind of

minimally-invasive testing will be key to the success of ongoing, voluntary mass screening as society adjusts to a new 'normal' in the face of COVID-19.

Trial registration: Australian New Zealand Clinical Trials Registry - ACTRN12620000922976

Article Summary

Strengths:

- Participation of 40 Western Australian schools, with broad representation across geography, socioeconomic demographics and school type.
- Minimally invasive SARS-CoV-2 swabbing method, likely to enhance rates of active consent and participation in COVID-19 screening.

Limitations:

• The sample size of this study is dictated by pragmatic, budgetary and logistical considerations.

• School selection was purposeful, not random, to ensure inclusion of a diverse sample.

 BMJ Open

Introduction

In late 2019 the SARS-CoV-2 virus emerged, and shortly thereafter, a global pandemic was declared (1). Governments responded with lockdown and isolation measures to combat the spread of COVID-19, including the closure of many schools (2). Quickly, it became clear that building capacity to test for COVID-19 rapidly and accurately would be critical for public safety and confidence in the reopening of schools. Here, we describe the results of the DETECT Schools Study, launched in Western Australia (WA), Australia, to trial a minimally invasive method for asymptomatic SARS-CoV-2 virus screening in primary and secondary schools across the state where children were swabbed unaccompanied by parents or caregivers.

The mandate of the DETECT Schools Study was simple: to screen asymptomatic students and staff swiftly and effectively for SARS-CoV-2 without causing discomfort. This speaks to a broader global need for transformative approaches to SARS-CoV-2 testing, as screening for the new virus becomes a part of daily life. As society grapples with a new 'normal', individuals with respiratory symptoms, those working in high-risk environments and those returning from travel are being swabbed regularly for SARS-CoV-2 in an effort to protect their communities.

At the onset of the COVID-19 pandemic, nasopharyngeal (NP) swabbing for polymerase chain reaction (PCR) detection of SARS-CoV-2 was rapidly adopted globally as the gold standard for COVID-19 diagnosis (3), however the validation of less invasive methods for virus detection is necessary to optimise compliance and increase the reach of mass screening programs moving forwards.

At the time of this study, antigen tests were not yet available. Saliva sample PCR testing had emerged as a practical and non-invasive sampling method for the detection of SARS-CoV-2 in symptomatic (4) and asymptomatic people (5), but there are conflicting studies concerning sensitivity, with some reporting similar detection rates to NP swabbing (6–8) while others indicate low sensitivity (9) and caution against reliance on saliva samples alone for SARS-CoV-2 screening (10). Similarly, oropharyngeal (OP) swabbing is supported by some studies (11) but displays inferior performance to NP

swabbing in others (12). Nasal (Na) swabs offer another minimally invasive alternative with reasonable sensitivity (13,14), which are found to be more sensitive than throat swabs for SARS-CoV-2 detection in children (15) and are suited to high volume screening with a confirmatory NP swab. However, nasal swabs collected late in the disease course are less sensitive than NP samples (16), and modelling suggests that this sampling technique in isolation does not effectively capture patients with a low viral load (17).

Nasal swabbing has previously been found to be more comfortable and only marginally less sensitive than NP sampling for the detection of influenza (18). Pairing a nasal swab with an OP swab offers a minimally invasive method for SARS-CoV-2 detection, with studies indicating specificity equivalent to and sensitivity marginally reduced (~3%) from that of NP swabbing (19–21). This sensitivity is reportedly retained when allowing self-collection (22) or varying the swab type used (23). Harnessing the sensitivity of both sampling techniques may maximise the chances of viral detection while remaining minimally invasive. So, does the use of OP/Na swabbing minimise discomfort enough to justify this small sacrifice in sensitivity? Here we report the use of OP/Na swabbing to rapidly screen for SARS-CoV-2 in a large schoolbased cohort of volunteers, with an aim to optimise comfort and acceptability without losing sensitivity and specificity.

Methods

The state of WA is vast, covering one third the landmass of Australia. The population is concentrated in the capital city of Perth (2.1 million), with the remaining 400,000 people spread across the State's 2.6 million square kilometres. There are 1,131 schools across the state: 818 of these are public (Government) schools, at which a total of 315,148 students were enrolled in 2020 (24).

The study protocol is published (25). Briefly, 40 public schools (28,331 enrolled students and 4,023 employed staff) were purposefully selected by the WA Department of Education for participation in the study, ensuring representative inclusion of education support schools, residential colleges, and regional schools. Students aged 4 – 18 years were eligible, with two-thirds at metropolitan schools and one-third at regional schools from across the state (Figure 1).

Prior to study commencement, written and video study and consent information was distributed by the schools to staff and parents, including study information and consent forms developed in consultation with a consumer advisory group and the Telethon Kids Institute Kulunga Aboriginal Research Development Unit. Staff and parents provided active informed consent through an online portal supported by the REDCap platform (26). Randomly selected consenting participants (n=150; 90% students, 10% staff) were swabbed at each school in each round unless the school was not large enough to facilitate, in which case as many participants as possible were swabbed. Consented participants could subsequently refuse swabbing or withdraw from the study at any time.

SARS-CoV-2 swabbing of consented students and staff was carried out in the schools over three rounds between June and September 2020. We employed a combined oropharyngeal and nasal flocked swab (OP/Na) (22, 23). During study development, swab comfort was investigated with a group of paediatric volunteers: the CITOSWAB flocked swab (Gaia Science, Singapore) was selected as the preferred swab for OP/Na sampling.

Nurses received training in personal protective equipment (masks, gowns, eyewear and gloves) donning and doffing and swabbing technique before commencing the swabbing study in schools. Using a side-to-side motion, the swab was first swept across the back of the pharynx at least once in each direction, including both tonsils. The same swab was then inserted into one nostril (chosen by the child) along the floor of the nasal cavity parallel to the palate until resistance was encountered, rotated gently five times, withdrawn, and placed in the sheath containing viral transport medium (CITOSWAB, Gaia Science, Singapore). Swabs were transported to the WA public laboratory service provider in Perth, WA, and tested for SARS-CoV-2 using an in-house PCR platform modified from the WHO recommended assay (27) to include an inhibitor control, which detects the pan-sarbecovirus E gene. Validation studies of the PCR were performed early in the pandemic and confirmed a high analytical sensitivity and specificity with appropriate positive and negative controls. Any swab returning an in-house PCR positive result (CT value < 45) was subject to confirmatory testing with the Xpert Xpress SARS-CoV-2 assay (Cepheid, California, USA). In-house and confirmatory PCR detections were reported as positive.

Surveys were administered to a subset of swabbing participants in the two weeks following the first round of swabbing in each school, and again a month after the completion of all swabbing rounds. Surveys asked about participant experiences of swabbing, including the level of discomfort, concern and disruption associated with in-school testing. Parents were also surveyed about their child's swabbing experience. The surveys were administered during school classes for students and through personal email for staff and parents. Complete survey tools have been published previously (25).

Patient and public involvement

Community involvement and advice was actively sought in the design and preparation of this study. Procedures and resources were reviewed and approved by a National Community Advisory Group for COVID-19 Research, convened by the Telethon Kids Institute and comprising community members from across Australia, including Aboriginal members. The Telethon Kids Institute Kulunga Aboriginal Research Development Unit consulted on study resource development, including culturally-secure and informed consent processes and measures to supporting Aboriginal families.

Ethics approval statement

Ethical approval was obtained from the WA Child and Adolescent Health Service (PRN RGS0000004059) and the WA Aboriginal Health Ethics Committee (PRN 993).

Results

1,458 school staff members and the parents of 7,386 students engaged with the online consent platform. 7,281 of these students (98.6%) and 1,321 staff (90.6%) consented to be swabbed. Over the three rounds, 13,988 swabs were collected from 5,903 students and 1,036 staff (Table 1).

Table 1. Demographics of school students and staff participating in swabbing.

	6	Students	Staff
Total participants	R	5,903	1,036
Gender	Female	2,636 (44.7%)	563 (54.3%)
	Male	3,255 (55.1%)	473 (45.7%)
	Other	12 (0.2%)	0 (0%)
Aboriginal and/or	Yes	328 (5.6%)	11 (1.1%)
Torres Strait Islander	No	5,006 (84.8%)	1,022 (98.6%)
	Not identified	569 (9.6%)	3 (0.3%)
Area	Metropolitan	4,479 (75.9%)	812 (78.4%)
	Regional	1,424 (24.1%)	224 (21.6%)
Median age (years)		12	48

Swabs were collected from across the state, and results provided by text message to all participating families and staff within 72 hours of sample collection. All but one sample returned negative results on the in-house PCR platform, and confirmatory Xpert testing of the in-house PCR detection returned a negative result. As such, none of the 13,988

samples collected were positive for SARS-CoV-2. This was consistent with no cases of local SARS-CoV-2 transmission reported in WA throughout the study period.

5,349 students and 911 staff were randomised to be swabbed more than once across the three rounds. Of these participants, 214 students (4%) and 12 staff (1.3%) declined to be swabbed again (declined on the day or withdrew from the study).

After the first round of swabbing, the majority of student respondents indicated on a five-point scale (none, mild, moderate, painful, very painful) no more than mild discomfort (no discomfort: 19.7%; mild discomfort: 51.0%) (Figure 2A). Most of the remaining students reported moderate discomfort (20.5%), with few indicating that the swabbing was painful (painful: 6.5%; very painful: 2.3%). The majority of staff who had been swabbed also indicated only mild (59.4%) or no (19.6%) discomfort during the procedure.

Most students reported feeling only a little (37.2%) or not at all (47.3%) concerned about participating in testing (Figure 2B). The parents of participating students also reported on their child's levels of concern, with the majority of parents observing little (28.4%) or no (60.8%) concern in their children.

Participating students were also asked whether they had been concerned about swabbing nurses wearing PPE at their school. For the most part, students reported only a little or no concern about this. Primary school students were slightly more likely to be at least moderately concerned (10%) than secondary students (5%) (Figure 2C).

After three rounds of swabbing, surveys were administered again to an unmatched subset of swabbing participants. Response distributions were comparable to those described for the first survey cycle, with the majority of those surveyed still indicating mild levels of discomfort and concern after ongoing testing.

Discussion

Efficient, accurate SARS-CoV-2 screening will be key to ameliorating the progression of the COVID-19 pandemic. As epidemiological evidence suggests that asymptomatic and pre-symptomatic individuals play a significant role in propagating the transmission of the virus (28–30), in low prevalence settings like WA the screening of asymptomatic populations will continue to be important to prevent a rise in cases. Without the indication of symptoms, this mode of screening requires good will and voluntary participation and must therefore strike a balance between optimising both testing sensitivity and participant comfort. As the discomfort associated with nasopharyngeal SARS-CoV-2 swabbing techniques risks poor adherence to mass screening campaigns (31), alternative approaches will be necessary to cultivate the consistency and reliability of public swabbing adherence necessary moving forwards.

For school-aged children, closing schools to combat the spread of COVID-19 must be balanced against the very real challenges in mental health and inequality likely associated with missing out on the educational and social benefits of school attendance (32,33). Consequently, countries around the world have mobilised to implement mass testing in an effort to support the reopening of schools and other establishments. COVID-19 molecular surveillance will be important moving forwards to ensure the safety of schools and individuals, especially in high prevalence countries in which cases continue to climb. Refinement of a robust and well-accepted screening mechanism is required to support the continuation of education; however very little data has been available on the acceptability of various swabbing procedures and how this may impact adherence to screening programs.

Through the DETECT Schools Study we have evaluated the acceptability of OP/Na sampling, reported to facilitate SARS-CoV-2 detection with limited or no sacrifice in sensitivity compared to the standard NP procedure (18,34), in a school setting. Sampling was conducted with a flocked nylon swab: while evidence suggests that cotton, synthetic, flocked, and non-flocked swabs all exhibit comparable performance for SARS-CoV-2 detection (35), flocked swabs have previously been shown to deliver a higher yield when swabbing for other respiratory viruses (36).

In a large, representative cohort of school students and staff, our findings indicate that the vast majority of participants experienced minimal or no discomfort during an OP/Na swab. Almost all of those who were asked to participate a second time agreed, illustrating the high tolerance for repeat procedures which is desirable for optimised respiratory screening programs. This also suggests that individuals may be open to completing self-collected sampling, which has been shown to deliver adequate sensitivity for SARS-CoV-2 detection (37). Decreased discomfort is also likely to be associated with a reduced possibility of coughing, gagging or sneezing during sampling, in turn decreasing the risk of viral exposure for healthcare staff. While potentially not acceptable in specific settings with vulnerable groups for which sensitivity is paramount, such as entry screening for nursing homes (38), we argue that in schools and other similar settings this small decrease in sensitivity is far outweighed by high rates of consent and compliance which will allow for widespread testing.

This study was part of Western Australia's jurisdictional response to the COVID-19 pandemic in April 2020. At the time of design, the state had been in a complete lockdown for five weeks, and schools were closed. The study was designed and implemented to reassure families and the public that schools could re-open, and to inform the level of risk of transmission in a school setting. However, during this period of time, transmission of SARS-CoV-2 was so well controlled with public health measures that there were no detected community cases of COVID-19 for almost 10 months and as such there were also no confirmed cases in the study. Whilst this could be considered a methodological limitation, we have demonstrated the acceptability and ease of implementing a molecular based swabbing program in a school context with minimal disruption to students or educational outcomes.

Conclusion

Here we report an approach to large-scale asymptomatic swabbing for SARS-CoV-2 leading to high levels of willingness to participate. The sensitivity of this method for the identification of SARS-CoV-2 is supported by other studies. This methodology for screening children was well received by a large cohort and could be utilised to screen for

1 2	
3 4	asymptomatic SARS-CoV-2 in other settings, mitigating the requirements for uncomfortable NP sampling and leading
5 6	to enhanced compliance with programs designed to prevent onwards transmission of SARS-CoV-2.
7 8	
9 10	
11	
12 13	
14 15	
16 17	
18 19	
20 21	
22 23	
24	
25 26	
27 28	
29 30	
31 32	
33 34	
35 36	
37 38	
39 40	
41	
42 43	
44 45	
46 47	
48 49	
50 51	
52 53	
54 55	
56	
57 58	13
59 60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Funding

This work was supported by the Western Australian Department of Health [DoH20205875].

Donna Cross' contribution to this paper was supported by a National Health and Medical Research Council Research

Fellowship [GNT1119339].

Asha Bowen receives an Investigator Award from the National Health and Medical Research Council of Australia

[GNT1175509].

Peter Gething's contribution to this paper was supported by Channel 7 Telethon Trust, Western Australia.

Data availability statement

DETECT Schools Study deidentified participant data is shared with study partners (WA Departments of Health and Education) but is not available to the public. The study protocol is published at https://doi.org/10.3389/fpubh.2021.636921.

Acknowledgements

We would like to acknowledge and thank staff from PathWest, the WA Child and Adolescent Health Service and the WA Country Health Service for their valuable contribution to the DETECT Schools Study. We also thanks all students and staff who participated in swabbing.

Author contributions

Hannah Thomas (HT) coordinated data collection, contributed to data analysis, conducted the literature search,

generated figures and drafted the manuscript.

BMJ Open

Marianne Mullane (MM) coordinated the conception and design of the study, coordinated data collection and

2
3
4
5
6
7 8
o 9
10
11
12
13
13 14 15
15
16 17
17
18
19
20
21
21 22
22 23
23 24
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39 40
40
41
42
43
44
45
46
47
48
49
50
51
52
53
55 54
54 55
56
57
58
59

60

provided critical revision of drafts. Sherlynn Ang (SA), Tina Barrow (TB), Adele Leahy (AL), Alex Whelan (AW) coordinated data collection and provided critical revision of drafts. Karen Lombardi (KL) coordinated and provided critical revision of drafts. Matthew Cooper (MC), Paul Stevenson (PS), Leanne Lester (LL) and David Speers (DS) contributed to data analysis and provided critical revision of drafts. Adam Merritt (AM) contributed to design of test workflow, data analysis and provided critical revision of drafts. Andrea Padley (AP) and Lyn Sprigg (LS) contributed to data collection and provided critical revision of drafts. Juli Coffin (JC), Donna Cross (DC), Peter Gething (PG) and Asha Bowen (AB) oversaw conception, design and coordination of the study and provided critical revision of drafts. **Competing interests** Telethon Kids Institute authors report grants from the Western Australian Department of Health during the conduct of this study. Donna Cross and Asha Bowen report grants from the Western Australian Department of Health outside the submitted work. Asha Bowen, Andrea Padley, Lyn Sprigg, David Speers and Adam Merritt are employees of the Western Australian Department of Health.

References

- 1. Du Toit A. Outbreak of a novel coronavirus. Nat Rev. 2020;18(1):123.
- Viner RM, Russell SJ, Croker H, Packer J, Ward J, Stansfield C, et al. School closure and management practices during coronavirus outbreaks including COVID-19: a rapid systematic review. Lancet Child Adolesc Heal. 2020;4(5):397–404.
- 3. World Health Organisation. Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases: interim guidance. 2020.
- Azzi L, Carcano G, Gianfagna F, Grossi P, Gasperina DD, Genoni A, et al. Saliva is a reliable tool to detect SARSCoV-2. J Infect. 2020 Jul;81(1):e45–50.
- Yokota I, Shane PY, Okada K, Unoki Y, Yang Y, Inao T, et al. Mass screening of asymptomatic persons for SARSCoV-2 using saliva. Clin Infect Dis an Off Publ Infect Dis Soc Am. 2020 Sep;
- Vaz SN, Santana DS de, Netto EM, Pedroso C, Wang W-K, Santos FDA, et al. Saliva is a reliable, non-invasive
 specimen for SARS-CoV-2 detection. Brazilian J Infect Dis an Off Publ Brazilian Soc Infect Dis. 2020 Aug;
- To KK-W, Tsang OT-Y, Yip CC-Y, Chan K-H, Wu T-C, Chan JM-C, et al. Consistent Detection of 2019 Novel
 Coronavirus in Saliva. Clin Infect Dis an Off Publ Infect Dis Soc Am. 2020 Jul;71(15):841–3.
- 8. Chen JH-K, Yip CC-Y, Poon RW-S, Chan K-H, Cheng VC-C, Hung IF-N, et al. Evaluating the use of posterior
 oropharyngeal saliva in a point-of-care assay for the detection of SARS-CoV-2. Emerg Microbes Infect. 2020
 Dec;9(1):1356–9.
- Lin C, Xiang J, Yan M, Li H, Huang S, Shen C. Comparison of throat swabs and sputum specimens for viral
 nucleic acid detection in 52 cases of novel coronavirus (SARS-Cov-2)-infected pneumonia (COVID-19). Clin
 Chem Lab Med. 2020 Jun;58(7):1089–94.

1		
2 3 4	10.	Riccò M, Ranzieri S, Peruzzi S, Valente M, Marchesi F, Balzarini F, et al. RT-qPCR assays based on saliva rather
5 6		than on nasopharyngeal swabs are possible but should be interpreted with caution: results from a systematic
7 8 9		review and meta-analysis. Acta Biomed. 2020 Sep;91(3):e2020025.
10 11 12	11.	Calame A, Mazza L, Renzoni A, Kaiser L, Schibler M. Sensitivity of nasopharyngeal, oropharyngeal, and nasal
13 14		wash specimens for SARS-CoV-2 detection in the setting of sampling device shortage. European Journal of
15 16 17		Clinical Microbiology & Infectious Diseases. 2020. p. 1–5.
18 19	12.	Wang X, Tan L, Wang X, Liu W, Lu Y, Cheng L, et al. Comparison of nasopharyngeal and oropharyngeal swabs
20 21		for SARS-CoV-2 detection in 353 patients received tests with both specimens simultaneously. Int J Infect Dis
22 23 24		IJID Off Publ Int Soc Infect Dis. 2020 May;94:107–9.
25 26	13.	Tu Y-P, Jennings R, Hart B, Cangelosi GA, Wood RC, Wehber K, et al. Swabs Collected by Patients or Health
27 28 29		Care Workers for SARS-CoV-2 Testing. Vol. 383, The New England journal of medicine. 2020. p. 494–6.
30 31	14.	McCulloch DJ, Kim AE, Wilcox NC, Logue JK, Greninger AL, Englund JA, et al. Comparison of Unsupervised
32 33		Home Self-collected Midnasal Swabs With Clinician-Collected Nasopharyngeal Swabs for Detection of SARS-
34 35 36		CoV-2 Infection. JAMA Netw open. 2020 Jul;3(7):e2016382.
37 38 39	15.	Palmas G, Moriondo M, Trapani S, Ricci S, Calistri E, Pisano L, et al. Nasal swab as preferred clinical specimen
40 41 42		for COVID-19 testing in children. Pediatr Infect Dis J. 2020;39(9):267–70.
43 44	16.	Pinninti S, Trieu C, Pati SK, Latting M, Cooper J, Seleme MC, et al. Comparing Nasopharyngeal and
45 46		Midturbinate Nasal Swab Testing for the Identification of Severe Acute Respiratory Syndrome Coronavirus 2.
47 48 49		Clin Infect Dis. 2020;72(7):1253–5.
50 51	17.	Callahan C, Lee R, Lee G, Zulauf KE, Kirby JE, Arnaout R. Nasal-Swab Testing Misses Patients with Low SARS-
52 53 54		CoV-2 Viral Loads. medRxiv : the preprint server for health sciences. 2020.
55 56	18.	Frazee BW, Rodríguez-Hoces de la Guardia A, Alter H, Chen CG, Fuentes EL, Holzer AK, et al. Accuracy and
57 58		17
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

2		
3 4		Discomfort of Different Types of Intranasal Specimen Collection Methods for Molecular Influenza Testing in
5 6		Emergency Department Patients. Ann Emerg Med. 2018 Apr;71(4):509-517.e1.
7 8 9	19.	LeBlanc JJ, Heinstein C, MacDonald J, Pettipas J, Hatchette TF, Patriquin G. A combined oropharyngeal/nares
10 11		swab is a suitable alternative to nasopharyngeal swabs for the detection of SARS-CoV-2. J Clin Virol.
12 13 14		2020;128(May):104442.
15 16 17	20.	Vlek ALM, Wesselius TS, Achterberg R, Thijsen SFT. Combined throat/nasal swab sampling for SARS-CoV-2 is
17 18 19		equivalent to nasopharyngeal sampling. Eur J Clin Microbiol Infect Dis Off Publ Eur Soc Clin Microbiol. 2020
20 21		Jul;1–3.
22 23 24	21.	Tsang NNY, So HC, Ng KY, Cowling BJ, Leung GM, Ip DKM. Diagnostic performance of different sampling
25 26		approaches for SARS-CoV-2 RT-PCR testing: a systematic review and meta-analysis. Lancet Infect Dis. 2021 Apr
27 28 29		22;
30 31	22.	Wehrhahn MC, Robson J, Brown S, Bursle E, Byrne S, New D, et al. Self-collection: An appropriate alternative
32 33 34		during the SARS-CoV-2 pandemic. J Clin Virol Off Publ Pan Am Soc Clin Virol. 2020 Jul;128:104417.
35 36	23.	Patriquin G, Davis I, Heinstein C, MacDonald J, Hatchette TF, LeBlanc JJ. Exploring alternative swabs for use in
37 38 39		SARS-CoV-2 detection from the oropharynx and anterior nares. J Virol Methods. 2020 Nov;285:113948.
40 41 42	24.	Western Australian Department of Education. Public and non-government schools with full-time students (by
42 43 44		metropolitan, country and combined) - Semester 2, 2020. School Information - Statistical Reports. 2020.
45 46 47	25.	Mullane MJ, Thomas HM, Epstein M, Mandzufas J, Mullan N, Whelan A, et al. DETECT Schools Study Protocol:
47 48 49		A Prospective Observational Cohort Surveillance Study Investigating the Impact of COVID-19 in Western
50 51 52		Australian Schools. Front Public Heal. 2021;9:16.
52 53 54	26.	Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)-A
55 56		metadata-driven methodology and workflow process for providing translational research informatics support.
57 58		18
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2		
3 4 5		J Biomed Inform. 2009;42(2):377–81.
6 7	27.	Corman VM, Landt O, Kaiser M, Molenkamp R, Meijer A, Chu DK, et al. Detection of 2019 novel coronavirus
8 9		(2019-nCoV) by real-time RT-PCR. Euro Surveill Bull Eur sur les Mal Transm = Eur Commun Dis Bull. 2020
10 11 12		Jan;25(3).
13 14	28.	Bai Y, Yao L, Wei T, Tian F, Jin D-Y, Chen L, et al. Presumed Asymptomatic Carrier Transmission of COVID-19.
15 16		JAMA. 2020 Apr;323(14):1406–7.
17 18 19	29.	Mizumoto K, Kagaya K, Zarebski A, Chowell G. Estimating the asymptomatic proportion of coronavirus diseas
20 21		2019 (COVID-19) cases on board the Diamond Princess cruise ship, Yokohama, Japan, 2020. Euro Surveill Bu
22 23 24		Eur sur les Mal Transm = Eur Commun Dis Bull. 2020 Mar;25(10).
25 26 27	30.	Moghadas SM, Fitzpatrick MC, Sah P, Pandey A, Shoukat A, Singer BH, et al. The implications of silent
28 29		transmission for the control of COVID-19 outbreaks. Proc Natl Acad Sci U S A. 2020 Jul;117(30):17513–5.
30 31 32	31.	Moisset X, Gautier N, Godet T, Parabère S, Pereira B, Meunier E, et al. Nasopharyngeal swab-induced pain for
33 34 35		SARS-CoV-2 screening: A randomised controlled trial of conventional and self-swabbing. Eur J Pain. n/a(n/a).
36 37	32.	Armitage R, Nellums LB. Considering inequalities in the school closure response to COVID-19. Vol. 8, The
38 39 40		Lancet Global Health. 2020. p. 644.
41 42	33.	Lee J. Mental health effects of school closures during COVID-19. Lancet Child Adolesc Heal. 2020 Jun
43 44 45		1;4(6):421.
46 47	34.	Jamal AJ, Mozafarihashjin M, Coomes E, Anceva-Sami S, Barati S, Crowl G, et al. Sensitivity of midturbinate
48 49 50		versus nasopharyngeal swabs for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-
51 52		CoV-2). Infect Control Hosp Epidemiol. 2020 Nov;1–3.
53 54 55 56	35.	Garnett L, Bello A, Tran KN, Audet J, Leung A, Schiffman Z, et al. Comparison analysis of different swabs and
57 58		
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1		
2 3		transport mediums suitable for SARS-CoV-2 testing following shortages. J Virol Methods. 2020
4 5		transport mediums suitable for SANS COV 2 resting following shortages. 5 who wethous, 2020
6		Nov;285:113947.
7 8		
9	36.	Moore C, Corden S, Sinha J, Jones R. Dry cotton or flocked respiratory swabs as a simple collection technique
10 11 12		for the molecular detection of respiratory viruses using real-time NASBA. J Virol Methods. 2008
12 13 14		Nov;153(2):84–9.
15 16 17	37.	Braz-Silva PH, Mamana AC, Romano CM, Felix AC, de Paula A V, Fereira NE, et al. Performance of at-home self-
17 18 19		collected saliva and nasal-oropharyngeal swabs in the surveillance of COVID-19. J Oral Microbiol. 2020
20 21 22		Dec;13(1):1858.
23 24	38.	Mina MJ, Andersen KG. COVID-19 testing: One size does not fit all. Science (80-). 2021;371(6525):126–7.
25 26		
27 28		
29	Figure	1. Geographic distribution of schools participating in DETECT Schools Study swabbing.
30 31		
32 33		
34 35	-	2. Distribution of survey responses regarding A) self-reported discomfort (student and staff); B) students' concern being swabbed (self- and parent-reported); and C) students' concern regarding swabbing staff use of PPE.
36 37		
38		
39 40		
41 42		
42 43		
44		
45 46		
47		
48		
49 50		
51		
52		
53		
54 55		
56		
57		
58 59		20
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

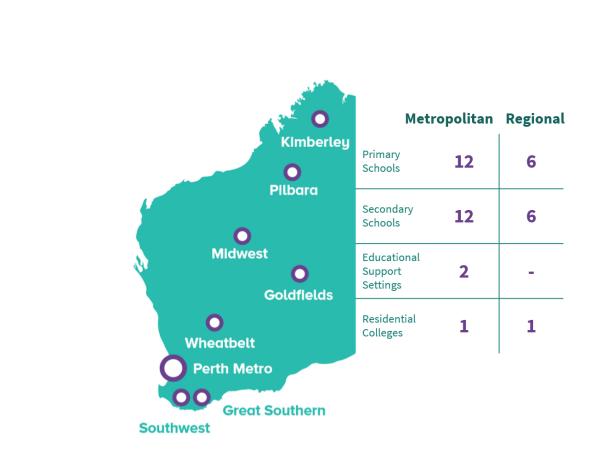
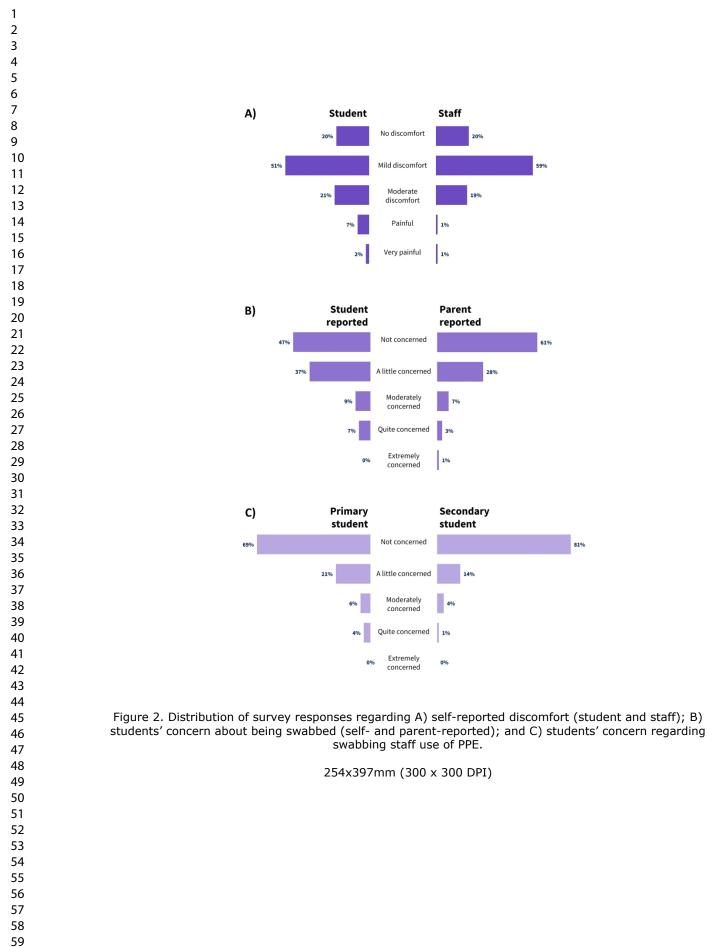


Figure 1. Geographic distribution of schools participating in DETECT Schools Study swabbing.

184x137mm (150 x 150 DPI)

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml



STROBE Statement—checklist of items that should be included in reports of observational studies

	No	Recommendation		Page
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used	YES	2
		term in the title or the abstract		
		(b) Provide in the abstract an informative and balanced	YES	2
		summary of what was done and what was found		
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the	YES	4
		investigation being reported		
Objectives	3	State specific objectives, including any prespecified	YES	5
		hypotheses		
Methods		0		
Study design	4	Present key elements of study design early in the paper	YES	5
Setting	5	Describe the setting, locations, and relevant dates,	YES	6
		including periods of recruitment, exposure, follow-up, and		
		data collection		
Participants	6	(a) Cohort study—Give the eligibility criteria, and the	YES	5-6
		sources and methods of selection of participants. Describe		
		methods of follow-up		
		Case-control study—Give the eligibility criteria, and the		
		sources and methods of case ascertainment and control		
		selection. Give the rationale for the choice of cases and		
		controls		
		Cross-sectional study—Give the eligibility criteria, and		
		the sources and methods of selection of participants		
		(b) Cohort study—For matched studies, give matching		
		criteria and number of exposed and unexposed		
		Case-control study—For matched studies, give matching		
		criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors,	NA	
		potential confounders, and effect modifiers. Give		
		diagnostic criteria, if applicable		
Data sources/	8*	For each variable of interest, give sources of data and	YES	7
measurement		details of methods of assessment (measurement). Describe		
		comparability of assessment methods if there is more than		
		one group		
Bias	9	Describe any efforts to address potential sources of bias	YES	5
Study size	10	Explain how the study size was arrived at	YES	(explaine
				in
				protocol)
Quantitative	11	Explain how quantitative variables were handled in the	YES	(explained
variables		analyses. If applicable, describe which groupings were		in
		chosen and why		protocol)
Statistical methods	12	(a) Describe all statistical methods, including those used	NA	
		to control for confounding	(descriptive)	

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2
3 4
5 6 7
6 7 8 9
10 11
12 13 14
15 16 17
17 18 19
20 21
22 23 24
25 26
20 21 22 23 24 25 26 27 28 29
30 31
32 33 34
35 36 37
37 38 39
40 41 42
42 43 44
45 46 47
48 49
50 51 52
53 54
55 56 57
58 59
60

		(<i>b</i>) Describe any methods used to examine subgroups and interactions	NA		
		(c) Explain how missing data were addressed	NA		
		(<i>d</i>) Cohort study—If applicable, explain how loss to follow-up was addressed	NA		
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed			
		Cross-sectional study—If applicable, describe analytical			
		methods taking account of sampling strategy			
		(\underline{e}) Describe any sensitivity analyses			
Results					
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	d	YES	8
		(b) Give reasons for non-participation at each stage		NA	
		(c) Consider use of a flow diagram			
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders		YES	8
		(b) Indicate number of participants with missing data for each variable o interest	f	YES	8
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)		NA	
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures	S	NA	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		NA	
		Cross-sectional study—Report numbers of outcome events or summary measures		NA	
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included		NA	
		(b) Report category boundaries when continuous variables were categorized		NA	
		(<i>c</i>) If relevant, consider translating estimates of relative risk into absolut risk for a meaningful time period	e	NA	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses		NA	
Discussion					
Key results	18	Summarise key results with reference to study objectives		YES	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias		YES	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence		YES	10
Generalisability	21	Discuss the generalisability (external validity) of the study results		YES	11

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	YES	
*Give information	ation sepa	arately for cases and controls in case-control studies and, if applicable, for exp	osed and	
	-	bhort and cross-sectional studies.		
-		and Elaboration article discusses each checklist item and gives methodological transparent reporting. The STROBE checklist is best used in conjunction with	-	
-	-	ites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Me		(1
		, and Epidemiology at http://www.epidem.com/). Information on the STROBE		is
available at w	ww.strob	e-statement.org.		