

MSAC Application 1712

Out-of-laboratory sleep studies in the diagnosis and management of sleep disordered breathing in children & adolescents

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):
Corporation name: Australasian Sleep Association
ABN: 51 138 032 014
Business trading name: Australasian Sleep Association

Primary contact name: REDACTED

Alternative contact numbers
Business: **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers
Business: **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

2. (a) Are you a consultant acting on behalf of an Applicant?

- Yes
 No

(b) If yes, what is the Applicant's name

N/A

3. (a) Are you a lobbyist acting on behalf of an Applicant?

- Yes
 No

(b) If yes, are you listed on the Register of Lobbyists?

N/A

(c) Have you engaged a consultant on your behalf?

- Yes
 No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

4. Application title

Out-of-laboratory sleep studies in the diagnosis and management of sleep disordered breathing in children and adolescents.

5. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Sleep disordered breathing [SDB] is common in children, with obstructive sleep apnoea [OSA] the most prevalent. Predisposing conditions include enlarged adenoids and tonsils, obesity, reduced neuromotor tone and abnormalities of airway shape or size. Primary treatment includes adenotonsillectomy then CPAP for residual disease.

Untreated SDB in children leads to increased health care costs and negative outcomes including poor growth, cognition, behaviour and a predisposition to cardiovascular events as adults.

Diagnosis is confirmed by polysomnography. The small number of accredited paediatric sleep laboratories (currently with lengthy waiting lists) limits access to services. Children living substantial distances from a laboratory often experience delays in diagnosis, or are referred for adenotonsillectomy without prior polysomnography to confirm OSA.

Provision of timely and accurate diagnosis of SDB through home sleep studies will:

- Significantly reduce national waiting lists with lower cost than laboratory studies
- Improve diagnostic capability in children with low tolerance for laboratory conditions
- Improve monitoring of children on respiratory support therapy
- Improve access to diagnosis and treatment for children living distant from accredited laboratories
- Reduce unnecessary surgery for children without accurate diagnosis.

6. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The proposed medical services are overnight investigation of sleep [8+ hours] outside of a sleep laboratory:

1) Full polysomnography for children [3-12 years] and adolescents [12-18 years]: Level 2 study – a minimum of 7 channels including EEG, EOG, Chin EMG, ECG or heart rate, airflow, respiratory effort and oxygen saturation. After clinical assessment, addition of transcutaneous carbon dioxide monitoring should always be considered.

2) Cardiorespiratory study for children and adolescents [3 -18 years]: Level 3 study – a minimum of 4 channels including ECG or heart rate, airflow, respiratory effort and oxygen saturation. EEG, EOG and EMG are not included. After clinical assessment, addition of transcutaneous carbon dioxide monitoring should always be considered.

3) Overnight oximetry monitoring to screen for OSA in children [1-12] living > 50 km from an accredited paediatric sleep laboratory: Level 4 study. After clinical assessment, addition of transcutaneous carbon dioxide monitoring should always be considered.

7. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service: n/a

N/A

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

Four new item numbers are being requested for children and adolescents from 1-18 years.

i & ii) item numbers for full polysomnography in an out-of-sleep-laboratory setting (level 2 studies); one for 3-12 years and a second for 12-18 years [similar to present in-laboratory item numbers 12210 and 12213]

iii) an item number for cardiorespiratory monitoring (level 3 studies) for

- review of respiratory support (CPAP or BiPAP) in an out-of-sleep-laboratory setting for children 3-18 years
- as an alternative diagnostic study for those with suspected OSA where the child is unable to tolerate the full setup for level 1 or 2 studies; child does not tolerate EEG and EMG head leads but requires assessment for significant obstructive breathing as per clinical assessment.

iv) an item number for overnight oximetry for determination of moderate -severe OSA for children that reside >50 km from an accredited paediatric sleep laboratory aged 1-12 years.

A new item which also seeks to allow access to the MBS for a specific health practitioner group

- i) For children aged 1-12 years item numbers will be only for clinicians qualified in paediatric sleep medicine by the Royal Australasian College of Physicians [RACP] and are on the clinician list with a paediatric sleep laboratory accredited by the ASA/NATA Sleep Disorders Service Accreditation Program.
- ii) For children/adolescents aged 12 -18 years the full PSG item number will be used by clinicians qualified in either paediatric or adult sleep medicine by RACP and are on the clinician list with a paediatric or adult sleep laboratory accredited by the ASA/NATA Sleep Disorders Service Accreditation Program for this age group.

A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)

At present paediatric [0-12 years] and adolescent [12-18 years] sleep studies can only be performed in a sleep laboratory.

The new item numbers are being sought for sleep study investigations at home:

- i) for 3-12- and 12-18-years age groups to be set up by a professional who is listed in the technical staff with an accredited sleep laboratory, monitored by a parent with access via video and/or digital link to a paediatric sleep professional or an accredited sleep laboratory. The lower age limit is to increase safety and acquisition of data for very young patients where the wires connecting to the monitoring equipment may pose a hazard or are easily dislodged.
- ii) for children living more than 50 kms from an accredited paediatric sleep laboratory, for whom access to an accredited paediatric sleep laboratory is difficult, allowing diagnostic and treatment care to occur closer to the child's residence and/or prevent unnecessary surgical intervention.
- iii) in a child/family centred environment, whether for diagnosis or to monitor respiratory support (where national guidelines recommend review every 6-12 months.)[1]

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
 No

(g) If yes, please advise:

N/A

8. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

9. For investigative services, advise the specific purpose of performing the service:

- To be used as a screening tool in asymptomatic populations
- Assists in establishing a diagnosis in symptomatic patients
- Provides information about prognosis
- Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

10. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No

11. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

- Yes
- No

(b) If yes, please list the relevant PBS item code(s):

N/A

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

N/A

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

N/A

12. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

N/A

(b) If yes, please provide the following information (where relevant):

N/A

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

N/A

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

N/A

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A

13. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables:

- i. Nasal prongs and/or thermistor for detection of airflow
- ii. Net to assist with head leads staying attached
- iii. Contact gel under EEG,EMG and EOG leads, or single use leads

Multi-use consumables:

- i. EEG, EMG and ECG leads,
- ii. Respiration bands [chest and abdominal]
- iii. Oxygen saturation and carbon dioxide specific probes
- iv. Thermistor

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

14. (a) If the proposed medical service involves use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer, or any other type of therapeutic good, please provide details

Multiple home sleep monitoring devices have been validated for use in paediatrics internationally.

No manufacturers are sponsoring this application.

Equipment and consumables listed under 14 (b) of this application

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III
 AIMD
 N/A

15. (a) If not listed on the ARTG, is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

16. If the therapeutic good is not ARTG listed, is the therapeutic good in the process of being considered by TGA?

Yes

We have listed some of the current devices, but as technological advances in this field are frequent, we anticipate new, and suitable devices becoming available.

Device No 1 : Somte PSG – level 2 study

Manufacturer: Compumedics
Supplier: Compumedics Limited, 30-40 Flockhart Street, Abbotsford, Victoria 3067
TGA approved device: Yes - ARTG 198298
Equipment for Level 2 study: Somte PSG recorder and input box
Oximeter probe (paediatric and adult sizes)
Respiratory bands
Electrodes: ECG, chin, head leads, eye leads, ground, leg leads
Nasal cannula and Thermistor
Position sensor
Profusion PSG (software)

Clinical use: Used for paediatric home sleep studies by groups in Melbourne and Perth. Used for adult non sleep laboratory sleep studies in Australia for MBS item 12250 studies [level 2 studies]. Compumedics products are commonly used in both adult and paediatric accredited sleep laboratory studies in Australia.

Publication examples:

Marcus C et al. Feasibility of Comprehensive, Unattended Ambulatory Polysomnography in School-Aged Children.[2]

Device No 2 : Somnotouch – level 2 or 3 studies

Manufacturer: Somnomedics

Supplier: Bird Healthcare, 18 Corporate Blvd, Bayswater VIC 3153

TGA approved device: Yes – ARTG 343713

Equipment for level 2 study: Somnotouch sleep screener plus software – BHCTOR105
Somnotouch AASM headbox – BHCTOS095
Belt set (paediatric and adult sizes)
ECG lead
SpO2 silicone finger probe (paediatric and adult sizes)
Grass Gold cup electrodes and 2 leg leads
Nasal canula
Docking station

Clinical use: Not currently used in Australia in paediatrics. However, used widely in UK and some European centres. Small size and paediatric specific components would allow for easy use in paediatric level 2 and 3 studies. There are published studies using the device for level 3 studies in children.

Publication examples:

Hill C et al. Prevalence and predictors of obstructive sleep apnoea in young children with Down syndrome.[3]

Device No 3: Nox A1 – level 2 studies

Nox T3 – level 3 studies

Manufacturer: Nox medical

Supplier: Temple Healthcare - Unit 3/13 Lyell St, Mittagong, NSW 2575

TGA approved: Yes – ARTG 232041

Equipment for level 2 study: Nox A1 device - NX563010
Noxturnal (software)
Nox RIP belts (Paediatric, small, medium and large sizes)
Paediatric EEG bundle and chin leads
ECG cable
2 leg leads
Paediatric cannula and paediatric thermistor (latter optional)
Wrist Ox2 sensors (small, medium and large sizes)

Clinical use: Used for paediatric home sleep studies by Brisbane group. Used for in-patient studies by several Australian labs.

Publication example:

Ioan I et al. Feasibility of parent-attended ambulatory polysomnography in children with suspected obstructive sleep apnea.[4]

Device No 4: Masimo Radical-7 oximeter – all studies

Manufacturer: Masimo Australia
Supplier: Masimo Australia Pty Ltd, level 5 Avaya House 123 Epping Rd North Ryde NSW 2113
Contact: ph: 1300MASIMO, email: anz@masimo.com
TGA approved: Yes – ARTG 157479

Device No 5: Radiometer TCM5 basic and flex monitors - level 2, 3 and 4 studies

Combined transcutaneous carbon dioxide and oxygen with pulse oxygen saturation monitor
Supplier: Radiometer Pacific Pty Ltd, 96 Ricketts Rd. Mt Waverley Victoria 3149
Contact: Ph: 1800247254
TGA approved: Yes – ARTG

Device No 6: Medtronic – Nellcor oximeter – all studies

Supplier: Medtronic Australasia Pty Ltd, 2 Alma Rd Macquarie Park NSW 2113
Contact: Ph 02 98579000, 1800668670
TGA approved: Yes – ARTG

Device No 7: Sentec Oxicapnograph – all studies

Combined transcutaneous carbon dioxide and oxygen with pulse oxygen saturation monitor
Supplier: Temple Healthcare, Unit 3/13 Lyell St, Mittagong, NSW 2575
TGA approved: Yes – ARTG

Other devices are likely to come to market with new technological developments.

- 17. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?**

N/A

- 18. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

Nil that we are aware of

PART 4 – SUMMARY OF EVIDENCE

19. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
Polysomnography (Level 2)					
1	Observational	Russo K, Greenhill J, Burgess S.[5] Home (Level 2) polysomnography is feasible in children with suspected sleep disorders.	Level 2 (home) polysomnography in a single centre in 55 children age 4 months to 18 years. Success defined ≥ 6 h of sleep & all channels (EEG, thoraco-abdominal bands, calculated airflow, and pulse oximetry) present $\geq 90\%$ of the study time. Questionnaire feedback from guardian & young person. First attempt successful for 48/55 (87%). No differences attributable to neurodevelopmental conditions, OSA severity or age. 76% of guardians reported the child slept same or better than usual, 12% found the study at home difficult, and 8% preferred a hospital sleep study.	PMID: 34753042 https://doi.org/10.1016/j.sleep.2021.10.024	Oct 2021
2	Observational	Withers A, Maul J, Rosenheim E, O'Donnell A, Wilson A, Stick PS.[6] Comparison of home ambulatory type 2 polysomnography with a portable monitoring device and in-laboratory type 1 polysomnography for the diagnosis of obstructive sleep apnea in children.	81 participants (age 6-18 yrs) with simultaneous T1PSG and T2PSG in the sleep laboratory, 47 participants (ages 5-16) had T1PSG in the sleep laboratory and T2PSG at home. Acceptable recordings for every home T2PSG. When T1PSG and T2PSG were simultaneous, correlation between the number of arousals, respiratory disturbance index and sleep stages was excellent. T2PSG at home < stage 2 sleep, more rapid eye movement (REM) sleep and higher sleep efficiency. Comparison of home T2PSG to T1PSG for diagnosing OSA showed a false positive rate of 6.6% and false negative rate of 3% for those performed at home.	PMID: 34323688. DOI: 10.5664/jcsm.9576	July 2021

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
3	Observational	Ioan I, Weick D, Schweitzer C, Guyon A, Coutier L, Franco P.[4] Feasibility of parent-attended ambulatory polysomnography in children with suspected obstructive sleep apnea.		PMID: 34323688 DOI: 10.5664/jcsm.9576	July 2020
4	Observational	Marcus CL, Traylor J, Biggs SN, Roberts RS, Nixon GM, Narang I, Bhattacharjee R, Davey MJ, Horne RS, Cheshire M, Gibbons KJ, Dix J, Asztalos E, Doyle LW, Opie GF, D'Ilario J, Costantini L, Bradford R, Schmidt B.[2] Feasibility of comprehensive, unattended ambulatory polysomnography in school-aged children.	Feasibility of type 2: 201 subjects, 5-12 years. Level 2, set-up by a technician in their home. PSG was initially satisfactory in 183 (91%) cases. 14 studies were satisfactory when repeated, 197 (98%) artefact-free signals $\geq 75\%$ of time in more than 92% of subjects. Nasal pressure satisfactory for $\geq 75\%$ in only 67% of subjects Thermistor signal satisfactory for $\geq 75\%$ in 92% of subjects Children slept well, with a long total sleep time (534 ± 73) High sleep efficiency ($92\% \pm 5\%$), and low arousal index ($9 \pm 3/h$). Parents and children reported a high rate of satisfaction with the study.	PMID: 25126039 DOI: 10.5664/jcsm.3970	August 2014

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
5	Observational	Goodwin JL, Enright PL, Kaemingk KL, Rosen GM, Morgan WJ, Fregosi RF, Quan SF.[7] Feasibility of using unattended polysomnography in children for research--report of the Tucson Children's Assessment of Sleep Apnea study (TuCASA).		PMID: 11766164 https://doi.org/10.1093/sleep/24.8.937	December 2001
Polygraphy (Level 3)					
1		Jones S, Hanwell R, Chowdhury T, Orgill J, van den Eshof K, Farquhar M, Joseph D, Gringras P, Trucco F.[8] Feasibility and parental perception of home sleep studies during COVID-19: a tertiary sleep centre experience.		PMID: 34551900. DOI: 10.1136/archdischild-2021-322184	Sept 2021
2	Retrospective PSG and polygraphy Home and in-lab	Michelet et al.[9] Successful home respiratory polygraphy to investigate sleep-disordered breathing in children.	Devices= Embla® Embletta® 400 studies in 332 subjects, 84% in the home. Home outcomes same as laboratory. 87% were successful (interpretable). Failures mainly due to SaO2 channel.	PMID: 32036287 https://doi.org/10.1016/j.sleep.2019.11.1264	December 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
3	In-lab PSG vs in home polygraphy	Ikizoglu et al.[10] Are home sleep studies useful in diagnosing obstructive sleep apnea in children with down syndrome?	Device = Nox T3 19 children In-lab study & home polygraphy within one week. Sensitivity 100% Specificity 83%	PMID: 31290291 DOI: 10.1002/ppul.24440	October 2019
4	Home vs laboratory polygraphy Children with Down syndrome & typical development **Assessing acceptance by families	Kingshott et al.[11] Cardiorespiratory sleep studies at home: experience in research and clinical cohorts	Device = SOMNOmedics 194/202 families encouraged to have home over laboratory studies. 87% success with repeats (74-82% success on 1 st attempt). Failures: sensors not tolerated or removed . 64-67% of families found the home test easy & 84-87% would be happy to repeat in future.	PMID: 30455364 DOI: 10.1136/archdischild-2018-315676	May 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
5	Concurrent PSG and MediByte studies	Masoud et al.[12] Validation of the MediByte Portable Monitor for the Diagnosis of Sleep Apnea in Pediatric Patients.	Device = MediByte 70 patients AHI correlated r=0.93 Oxygen saturation excellent age 12-17 but less for 7-11 years Oximeter was main source of failure (17.6%) Auto analysis AHI 1.5 Sens 97.9, Sp 21.7 AHI 5 Sens 90.9, Sp 70.8 AHI 10 Sens 100, Sp 93.4	PMID : 31053204 https://dx.doi.org/10.5664/jcsm.7764	May 2019
6	Evaluation of the quality of recordings (part of a larger RCT of treatment).	Gudnadottir et al.[13] Respiratory polygraphy in children with sleep-disordered breathing	Device = Nox T3 113 studies in 60 children. Majority had unacceptable nasal airflow signals. 11% were missing airflow and SaO2 signals.	PMID: 30932252 https://doi.org/10.1111/jsr.12856	April 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7	Cross-sectional – randomised sequence of level I & level III studies	Fishman H, et al.[14] The Accuracy of an Ambulatory Level III Sleep Study Compared to a Level I Sleep Study for the Diagnosis of Sleep-Disordered Breathing in Children With Neuromuscular Disease.	Device = Nox T3 in 28 children Ability of Level III device to detect SDB against Level I: sensitivity 61.5% specificity 86.7% positive predictive value 80.0% negative predictive value 72.0%.	PMID: 30518444 https://pubmed.ncbi.nlm.nih.gov/30518444/	December 2018
8	Prospective cohort Home study Subsequent in-lab simultaneous PSG & polygraphy	Alonso-Alvarez et al[15] Reliability of home respiratory polygraphy for the diagnosis of sleep apnea in children.	Device = eXim Apnea polygraph 50 children Home vs in-laboratory polygraphy and polygraphy vs PSG 27 children 5.3 ± 2.5 years Defined OSA >5.6 events/hr Sensitivity 90.9% (95% CI, 79.6%-100%) specificity 94.1% (95% CI, 80%-100%).	PMID 25539419 http://dx.doi.org/10.1016/j.sleep.2011.11.014	December 2014
9	Prospective Concurrent PSG and Sonomat studies	Norman et al.[16] Validation of the Sonomat Against PSG and Quantitative Measurement of Partial Upper Airway Obstruction in Children with Sleep-Disordered Breathing	Device = Sonomat 76 patients 1% failure AHI 1 Sens 83, Sp 78 AHI 5 Sens 86, Sp 96 AHI 10 Sens 60, Sp 94	PMID: 28364431 http://dx.doi.org/10.1093/sleep/zsx017	February 2017

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
10	Simultaneous recording on two devices	Scalizzi N et al.[17] Comparison of home sleep apnea testing versus laboratory polysomnography for the diagnosis of obstructive sleep apnea in children	Device = Embletta Gold Level 1 vs Level 3: 33 subjects. Significant difference in outcomes. Sensitivity for OSA 81%.	PMID: 28802385 DOI: 10.1016/j.ijporl.2017.06.013	February 2017
11	Simultaneous recording on two devices	Massicotte C et al[18] The utility of a portable sleep monitor to diagnose sleep-disordered breathing in a pediatric population	Device = PSS-AL monitor Level 1 vs Level 3: 35 children. 19% did not have adequate flow signal. Sensitivity of 91% but specificity of 16%.	PMID: 24083303 doi: 10.1155/2014/271061	Jan-Feb 2014
12	PSG recordings with channels eliminated to create polygraphy equivalent	Tan H et al.[19] Overnight Polysomnography versus Respiratory Polygraphy in the Diagnosis of Pediatric Obstructive Sleep Apnea	In-lab PSG Level 1 vs Level 3: 100 Level 1 studies, channels deleted and rescored as Level 3 study. AHI correlated but under-estimated, mostly due to underscoring hypopnoeas associated with arousal. Concerns: poor estimate of sleep time (potentially increasing the denominator). Changed management in 23% of cases.	PMID: 24497654 doi.org/10.5665/sleep.3392	Feb 2014

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
Oxiometry					
1	Meta-analysis and systematic review	Gao X, Li Y, Xu W, Han D et al.[20] Diagnostic accuracy of level IV portable sleep monitors versus polysomnography for pediatric obstructive sleep apnea: a systematic review and meta-analysis	Evaluated the diagnostic accuracy of Level IV PMs against the apnea-hypopnea index (AHI) measured using overnight in-laboratory polysomnography (PSG) in children and adolescents. 20 studies including 7062 participants were included. This study showed the potential of Level IV PMs for screening pediatric OSA patients. Oximetry based on new mathematical classifiers may provide a simple and effective alternative to PSG in the diagnosis of pediatric OSA especially in the context of appropriate clinical evaluation.	PMID 34597954 DOI: 10.1016/j.sleep.2021.08.029	Nov 2021
2		Xiao L, Barrowman N, Momoli F, Murto K et al.[21] Polysomnography parameters as predictors of respiratory adverse events following adenotonsillectomy in children		PMID: 34019475 doi: 10.5664/jcsm.9420	Nov 2021
3	Observational	Hoppenbrouwer XLR, Rollinson AU, Dunsmuir D, Ansermino JM, Dumont G, et al[22] Night to night variability of pulse oximetry features in children at home and at the hospital.	75 children, three consecutive nights of study – 1 night PSG and 2 nights at home. Night-to-night variability of results using a smartphone-based pulse oximeter sensor was investigated using linear mixed models. Overall, most pulse oximetry features showed no NtN variability. At home pulse oximetry screening shows an increasing predictive value to investigate OSA severity. Most pulse oximetry features showed no significant night to night variability and therefore could be used in future at home testing to create a reliable and consistent OSA screening tool.	PMID 34713819 doi: 10.1088/1361-6579/ac278e	Oct 2021

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
4	Observational	Thavagnanam S, H'ng SY, Nathan AM et al.[23] WRISTOX ₂ is a reliable tool to diagnose obstructive sleep apnoea syndrome.	The Nonin 3150 WristOx ₂ ™ was worn simultaneously during the PSG. 162 children, 18 excluded with poor or incomplete oximetry data. Overnight pulse oximetry with the Nonin 3150 WristOx ₂ ™ is an accurate and reliable tool in diagnosing significant OSAS in children.	PMID 34571207 doi: 10.1016/j.ijporl.2021.110930	Sept 2021
5	Meta-analysis	Wu CR, Tu YK, Chuang LP et al.[24] Diagnostic meta-analysis of the Pediatric Sleep Questionnaire, OSA-18, and pulse oximetry in detecting pediatric obstructive sleep apnea syndrome.	18 articles on oximetry, total sample size 3056. Oximetry yielded superior specificity in detecting mild, moderate, and severe pediatric OSAS (86%, 75%, and 83%, respectively) than did the PSQ and OSA-18 (all p < 0.05). Specificity better in studies using McGill oximetry. Score than those using oxygen desaturation index and in those studies including children with comorbidities. Conclusion: Thus, for early detection of pediatric OSAS in clinical settings, sleep specialists may use the PSQ combined with PO as the screening tools if OSAS is suspected after clinical interviews.	PMID: 32750654 DOI: 10.1016/j.smrv.2020.101355	July 2020
6	Retrospective case-control study	Chia C et al.[25] Predicting respiratory complications in paediatric adenotonsillectomy: a risk stratification protocol.	Describes a protocol for assessment of surgical risk using oximetry for use in determining site of surgery (secondary vs tertiary) and the outcomes/complications of each group (low vs high risk).	doi: 10.21037/ajo-19-75	June 2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7	Retrospective cohort study	Jonas C, Thavagnanam S, Blecher G, Thambipillay G, Teng AY. [26] Comparison of nocturnal pulse oximetry with polysomnography in children with sleep disordered breathing.	n=110. The sensitivity and specificity of McGill 3 and 4 in diagnosing moderate/severe OSA on PSG were 59% and 100%, respectively, and the PPV and NPV were 100% and 78%, respectively.	PMID: 31104209 doi: 10.1007/s11325-019-01861-z	June 2020
8	Prospective cohort study	Xu Z, Gutiérrez-Tobal GC, et al.[27] Cloud algorithm-driven oximetry-based diagnosis of obstructive sleep apnoea in symptomatic habitually snoring children.	432 subjects having oximetry concurrently with PSG. Used a proprietary algorithm to determine an AHI from oximetry and compared that with the traditional PSG-derived AHI. The accuracies of AHIOXI were consistently >79% for all levels of OSAS severity, and specificity was particularly favourable for AHI >10 events·h ⁻¹ (92.7%). Using the criterion of AHIPSG >1 event·h ⁻¹ , only 4.7% of false-negative cases emerged, from which only 0.6% of cases showed moderate or severe OSAS.	PMID: 30487202 DOI: 10.1183/13993003.01788-2018	February 2019
9	Prospective cohort study	Hornero R, Kheirandish-Gozal L, Gutiérrez-Tobal GC, Philby MF, Alonso-Álvarez ML, Álvarez D et al.[28] Nocturnal Oximetry-based evaluation of habitually snoring children.	n=4,191 Neural network-based automated analyses of nSpO ₂ recordings provide accurate identification of OSA severity among habitually snoring children with a high pretest probability of OSA. Thus, nocturnal oximetry may enable a simple and effective diagnostic alternative to nocturnal polysomnography, leading to more timely interventions and potentially improved outcomes.	PMID: 28759260 doi: 10.1164/rccm.201705-0930OC.	December 2017

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
10	Systematic review	Kaditis A, Kheirandish-Gozal L, Gozal D. [29] Pediatric OSAS: Oximetry can provide answers when polysomnography is not available.	Nocturnal SpO2 drops <90%, more than two clusters of desaturation events (4%) and oxyhemoglobin desaturation (4%) index (ODI4) >2.2 episodes/h are unusual in children without OSAS. At least three clusters of desaturation events, and at least three SpO2 drops below 90% in a nocturnal oximetry recording are indicative of moderate-to-severe OSAS. An ODI4 >2 episodes/h combined with OSAS symptoms also exhibits high positive predictive value for apnea-hypopnea index >1 episode/h. Children without clusters of desaturation events have low risk of major respiratory complications following adenotonsillectomy. Thus, nocturnal oximetry emerges as a valuable tool that can facilitate treatment decisions when polysomnography is not available.	PMID: 26146027 DOI: 10.1016/j.smrv.2015.05.008	June 2016
11	Review/ editorial	Gozal D, Kheirandish-Gozal L, Kaditis AG.[30] Home sleep testing for the diagnosis of pediatric obstructive sleep apnea: the times they are a changing...!	Provides useful "state-of-the-art" discussion on limited channel and home studies in children.	PMID: 26390329 doi: 10.1097/MCP.0000000000000205	November 2015

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
12	Retrospective cohort study	Horwood L, Brouillette RT, McGregor CD, Manoukian JJ, Constantin E.[31] Testing for pediatric obstructive sleep apnea when health care resources are rationed.	n=362 Normal oximetry predicts smooth post-op course. Oximetry studies evaluated with the McGill Oximetry Score expedite diagnosis and treatment of children with adenotonsillar hypertrophy referred for suspected sleep-disordered breathing. When resources for testing for sleep-disordered breathing are rationed or severely limited, our proposed diagnostic approach can help maximize cost-savings and allows sleep laboratories to focus resources on medically complex children requiring polysomnographic evaluation of suspected sleep disorders.	PMID: 24851855 DOI: 10.1001/jamaoto.2014.778	July 2014
13	Retrospective cohort study	Velasco Suárez CT, Figueroa Turienzo JM, Len F, Mansilla E.[32] Pulse oximetry recording in children with adenotonsillar hypertrophy: usefulness in the diagnostic of obstructive sleep apnea syndrome.	A total of 167 PSGs were included; the PSG showed OSAS in 75 children and simple snoring in 92; 65 oximetries were considered pathological and in agreement with the PSG in relation to OSAS; 10 children with mild OSAS in the PSGs had normal oximetries. The recorded pulse oximetry showed a sensitivity of 86.6% and a specificity of 98.9% for detecting OSAS.	PMID 23732344 doi: 10.5546/aap.2013.196	June 2013
14	Prospective cohort study	Nixon GM, Kermack AS, Davis GM, Manoukian JJ, Brown KA, Brouillette RT.[33] Planning adenotonsillectomy in children with obstructive sleep apnea: the role of overnight oximetry.	Development and validation of the McGill Oximetry Score as a tool for predicting post-operative respiratory compromise after adenotonsillectomy.	PMID: 14702490 doi: 10.1542/peds.113.1.e19	January 2004

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
15	Retrospective cohort study	Brouillette RT, Morielli A, Leimanis A, Waters KA, Luciano R, Ducharme FM.[34] Nocturnal pulse oximetry as an abbreviated testing modality for pediatric obstructive sleep apnea.	Development of the cluster analysis for interpretation of oximetry	PMID: 10654964 DOI: 10.1542/peds.105.2.405	February 2000

20. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only).

Please do not attach full text articles, this is just intended to be a summary.

	Type of study design	Title of research	Short description of research	Website link to research	Date
	Retrospective cohort study	Griffiths A, Mukushi A, Adams A.[35] Po43 Telehealth-supported level 2 paediatric home polysomnography	235 children aged 5-18yrs studied for suspected OSA. 29.4% had comorbidities. Technically adequate diagnosis by telehealth supported paediatric home PSG in 87% with 83% achieving >6hrs sleep duration and excellent family acceptability	https://doi.org/10.1093/sleepadvances/zpab014.091	Oct 2021

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

21. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):

It is our recommendation that these services be only available to paediatric and adult sleep medicine specialists (specialist recognition by RACP) who are listed on staff with a sleep laboratory that is fully accredited through the NATA/ASA Sleep Disorders Service Accreditation program for the testing of children and adolescents aged 0-12yrs and 12-18yrs respectively.

The professional bodies/organisations that represent this group of health professionals includes:

Royal Australasian College of Physicians [RACP]

Australasian Sleep Association [ASA]

Thoracic Society of Australia and New Zealand [TSANZ]

Australian Medical Association [AMA]

22. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):

There are no other organisations that we are aware of that provide a comparator service

23. List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):

Aspect - Autism Spectrum Australia

AEIOU Foundation for Children with Autism

Down Syndrome Australia

Muscular Dystrophy Australia

Prader-Willi Research Foundation of Australia

24. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:

No sponsors

25. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

Name of expert 1: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

Name of expert 2: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

26. Define the medical condition, including providing information on the natural history of the condition and a high-level summary of associated burden of disease in terms of both morbidity and mortality:

Summarise key references in terms of magnitude of impact in each area.

Natural history

Obstructive sleep apnoea (OSA) is defined as repetitive complete or partial collapse of the upper airway leading to oxygen desaturations and/or arousal from sleep. It affects children of all ages with a peak incidence in the pre-school years. OSA affects 1%–5% of children.[36] Factors contributing to the pathophysiology of paediatric OSA include male gender, obesity, enlarged adenoids and tonsils, reduced neuromotor tone and an abnormality of airway shape or size.[37]

The consequences of OSA in children include neurocognitive problems, behavioural problems, poor school performance, growth disturbances and increased cardiovascular risk.[38, 39] Unidentified and untreated OSA can lead to significant impairment of a child's health, opportunities, and quality of life.[40] If a child has severe OSA and an associated congenital structural or neuro-motor problem, it can result in respiratory failure and premature death. Adenotonsillectomy results in improvement or resolution of OSA in 50-90% children, permitting normal growth and development for the child.[41-43] The presence of any associated comorbidity with neuromuscular dysfunction, obesity or an anatomical small airway reduces the likelihood of disease resolution with surgery.[44]

Children with moderate/severe OSA that persists after surgery are usually commenced on respiratory support with CPAP or bilevel via a non-invasive interface [mask or prongs]. The efficacy of this therapy needs to be monitored and the treatment altered with growth of the child. Present Australian and New Zealand guidelines and those in the US recommend 6-12 monthly sleep studies to ensure adequate therapy in children. [1, 45, 46] A proportion will wean from respiratory support with growth, but another group continue to require respiratory support as adults. Numbers that wean from respiratory support are difficult to predict as it is dependent on age at diagnosis and comorbidities and therefore the referral cohort of individual sleep medicine centres. A small number of children/parents elect to have significant facial surgery rather than continuing respiratory support for life. This surgery usually occurs in late childhood/early adolescence when facial growth is completed.

27. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

The accepted gold standard test for the diagnosis of sleep disordered breathing in paediatric medicine is an accredited-laboratory-based polysomnogram (PSG) with trained healthcare professionals in attendance throughout the night.[47] Sleep laboratories in Australia are separately accredited for adult [18 years and over], adolescent [12-18 years] and paediatric [0-12 years] studies, and most sleep laboratories are accredited for adults only. Some are accredited for adolescents and adults [12 and over] and all paediatric sleep laboratories are accredited for children and adolescents [0-18 years]. Ideally all children with suspected obstructive sleep apnoea should have ready access to an accredited sleep laboratory study for timely diagnosis.

However, there are key limitations to sleep laboratory testing for children and adolescents which include:

- **Location in capital cities:** with the exception of Newcastle and Wollongong all accredited paediatric sleep laboratories are located in the capital cities, with Tasmania having no paediatric sleep medicine or sleep laboratory services.

- **Access:** Most of the accredited paediatric sleep units have waiting lists for non-urgent tests in excess of 12 months
- **Limited capacity:** the number of diagnostic in-laboratory sleep studies that can be performed each year is limited. Even at full capacity current laboratory services would not be able to meet the clinical demand. The result is that numbers of paediatric sleep studies performed yearly have plateaued on MBS data pre- COVID-19 pandemic. Paediatric sleep medicine services have to prioritise diagnostic studies but also manage the requirements of an exponentially growing number of children who are on respiratory support and require studies to ensure ventilation stability/adequacy with growth. As a result of this increased demand, waitlists for investigations and therapy continue to increase each year (specific information about wait lists is documented below at Q.25).
- **Labour intensive and costly:** in-laboratory studies are labour intensive and relatively expensive to perform [2 patients only to each sleep professional overnight].
- Infection risk:
 - At present children need to attend a paediatric sleep laboratory, and because most are associated with a hospital, there is increased risk of cross infection from other patients, families and staff from other areas.
 - Staff may work in other areas of a hospital or other sleep laboratories.
 - During the present COVID-19 pandemic, patients/families have been reluctant to attend sleep laboratories due to perceived risk of infection. This has been particularly true of regional and remote families.
- **Sleep quality is better at home than in a sleep laboratory especially for children with anxiety, autism or behavioural issues with adapting to change.**

Full polysomnography in out-of-sleep-laboratory setting: Level 2 study

An alternative method for the assessment of the sleep disordered breathing is polysomnography performed at home (a Level 2 study). This is a full polysomnogram comparable to an in-laboratory study, with 7 or more channels including sleep staging, measurements of airflow, respiratory effort and oxygen levels. The principal difference between Level 1 in-laboratory study and a Level 2 study is that there is a guardian but not a healthcare professional in attendance. In adult medicine, Level 2 studies [non attended studies] have been accepted as a valid alternative modality for diagnosis of sleep disordered breathing in specific circumstances.[48] This type of study in individuals over 18 years has had a MBS item number since 2016 (12250).

Two international studies have demonstrated that a Level 2 polysomnogram can produce a clinically satisfactory study in 81-91% of cases in subjects aged 3-16 years.[2, 4] In both studies the subjects had the sleep equipment applied by a trained sleep medicine professional. The most common signal which was not reliable throughout was the measure of airflow measured by a sensor at the nose/mouth (up to 20% lost overnight), but in most instances there existed enough recording for the clinician to be confident with a diagnosis from the data; it did not negate the clinical value of the study. Higher rates of signal quality are seen when the equipment is applied by a healthcare professional, and an on-call advice service is made available to the guardian.[49]

Recent Australian studies from Melbourne[35] and Brisbane[5] report on level 2 studies. In both cases the monitoring leads were applied by a health professional [Brisbane in paediatric sleep medicine service, Melbourne either in laboratory or child's home]. Parents were instructed regarding the function of equipment and basics of reapplication in instances where the child removes the leads, and phone backup with a sleep professional was provided for the parents.

The above studies confirm that a level 2 polysomnogram is a valid alternative to an in-laboratory polysomnogram.[5] Greater access to out-of-sleep-laboratory polysomnograms would improve access to this test, at a lower cost to the health care system than the current pathway. Access would also relieve the burden on present paediatric sleep laboratories so they could focus on complex cases that truly require increased trained technical staff input for successful studies.

Contraindications to an out-of-laboratory PSG are lack of access to a safe setting for the study and/or a guardian who is reluctant to supervise the study.

This submission recommends that a paediatric sleep specialist for ages 3-12 years and either a paediatric or adult sleep specialist for 12-18 years assess the appropriateness of the subject for an out-of-sleep-laboratory PSG via a consultation [face to face or telehealth], that the equipment is applied by a trained health care professional and that on-call support is offered in order to limit the failure rate of the studies.

Limitations/relative contraindications:

- i. Age – proposed age-group for out-of-laboratory level 2 studies is children over 3 years to ensure safety of the child in relation to the wires and other equipment necessary for the study.
- ii. Associated neurocognitive behavioural issues: as many children find the environment of a sleep laboratory challenging, we propose that assessment by specialist paediatric sleep physician would be required to determine the best environment (laboratory or home) for a successful study.
- iii. Children with other medical complexities. Review by a specialist paediatric sleep physician will ensure the appropriate study environment for these children.
- iv. Repeat study: < 6hours of sleep recorded or inadequate quality data that does not meet “diagnostic standard” as determined by attending specialist paediatric sleep physician and should be followed up with an in-laboratory study
- v. Instigation of therapy with CPAP or bilevel in children

Safety concerns:

- i. Adverse skin reaction to tapes and probe application will be the same as for in-laboratory studies. Parents will be advised to look at application site if child complains of discomfort/ itchiness etc. If irritation is present they would be advised to remove the implicated piece of the setup and phone for advice on how to continue the study.
- ii. Entanglement and dislodgement of the setup is less likely with the newer equipment and is likely to continue to lessen as more of the equipment introduces digital solutions. Parents will be advised to check on the child and sensors at least second hourly, to observe the child continually overnight or to sleep in same room as child after discussion between the parent, sleep medicine specialist and sleep professional who applies the equipment.

Waiting lists for children in Western Australia, South Australia and Queensland have not changed significantly over the last 2 years, but in Sydney and Melbourne the COVID-19 pandemic has had significant impact:

Queensland Children’s Hospital [QCH] – presently study 24 patients per week in a full laboratory PSG

- January 2019 – 860 children waiting for sleep study

1091 full polysomnography studies performed in 2019

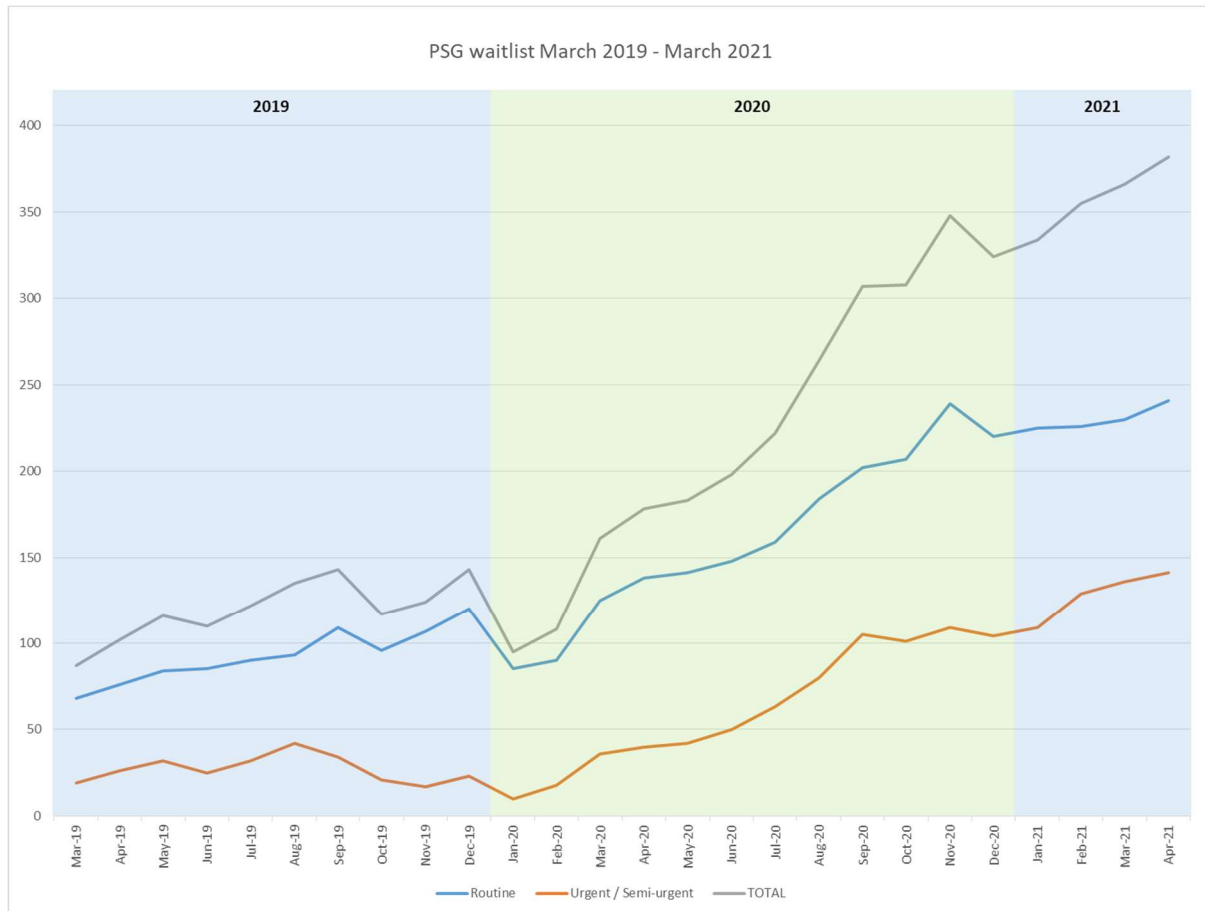
- January 2021 – 842 children waiting for sleep study
- August 2021 – 782 children waiting for sleep study
- Clinical responsibility for:
 - 156 children on CPAP of which 60% were not studied in 2020 to review therapy as per guidelines.
 - 114 children on ventilation of which 15% were not studied in 2020 to review therapy as per guidelines.

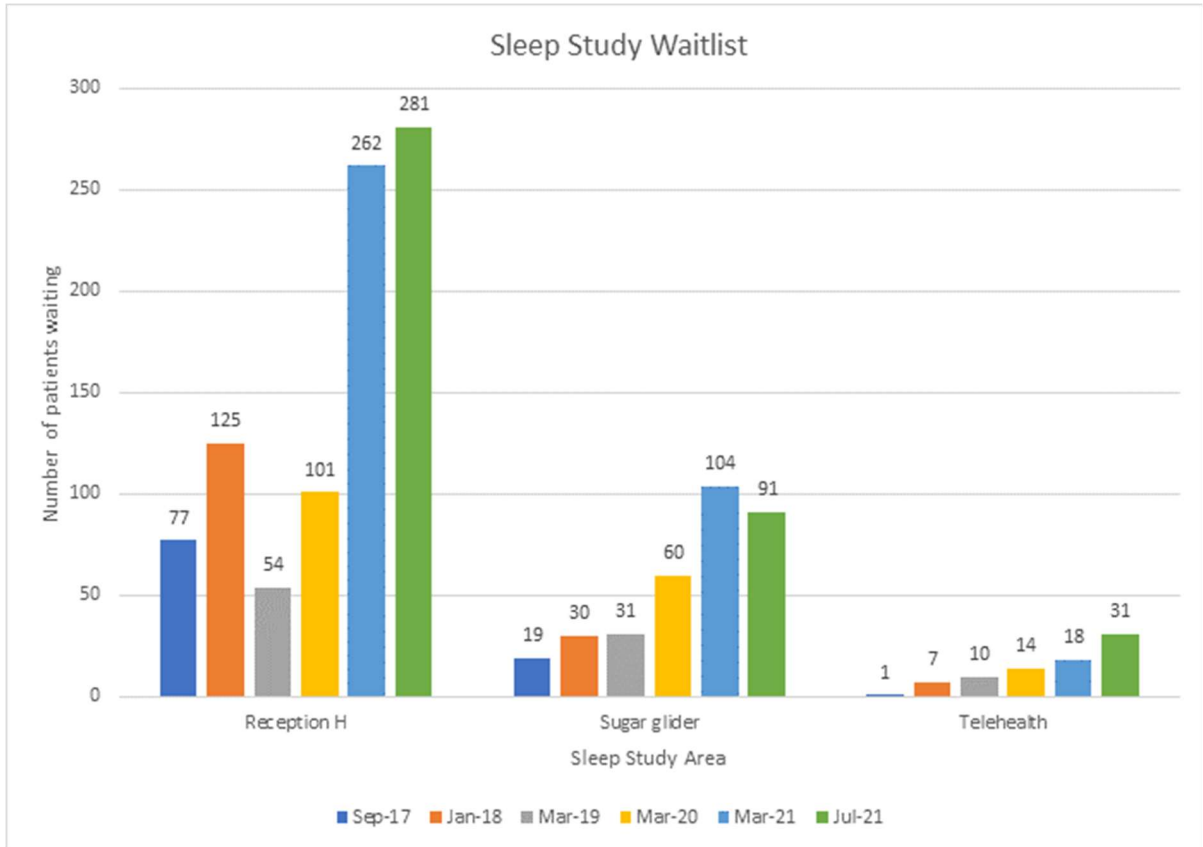
The Children’s Hospital at Westmead - were only able to study 16 patients per week during COVID. Previously they were able to study 20 patients per week (full laboratory PSG studies).

- 1219 full polysomnography studies were performed in 2017
- March 2018 – 388 children waiting for sleep study
- September 2021 – 702 children waiting for sleep study

- Clinical responsibility for 345 children on CPAP or bilevel respiratory support – in 2020 only 69.3% had PSG studies to monitor therapy as per guidelines

Royal Children’s Hospital Melbourne data:





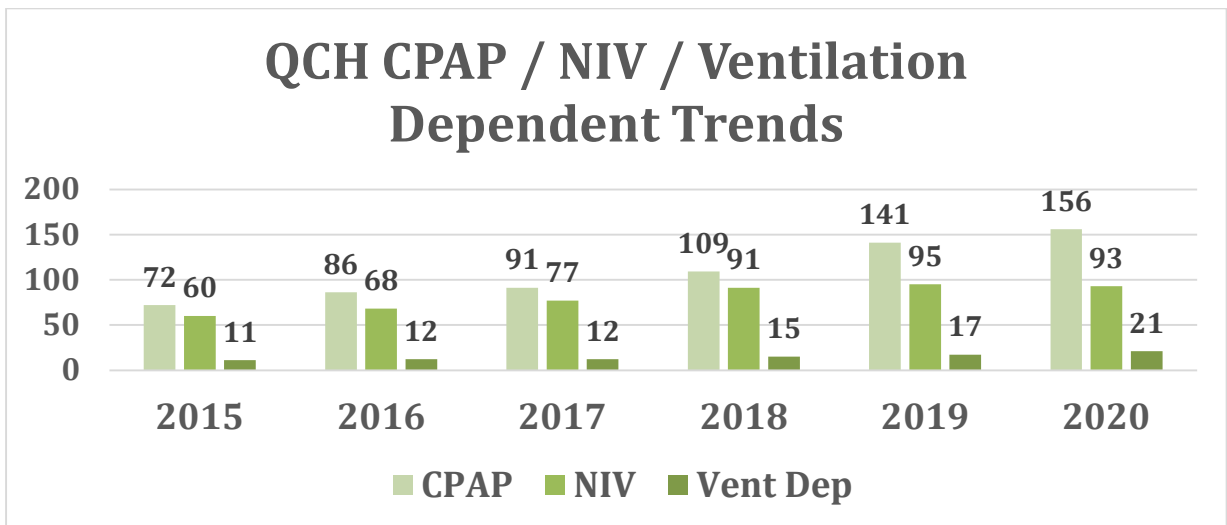
Cardiorespiratory monitoring in out-of-sleep-laboratory setting: Level 3 studies

The number of children requiring respiratory support is increasing annually. Present guidelines recommend sleep studies 6-12 monthly to ensure adequate support during growth of the child.

Queensland Children’s Hospital (QCH) sleep medicine data for last 5 years is presented for illustrative purposes. This trend is reflected in all Australian states with paediatric sleep medicine services.

QCH data:

The figure shows total numbers of children on continuous positive airway pressure (CPAP), non-invasive ventilation (NIV) or ventilator dependent (Vent Dep) the end of December each year since 2015. Over a 6-year period the number of patients on respiratory support has significantly increased, with the largest increase in patients on CPAP, which has increased 116% since 2015.



At QCH in 2020 and 2021 only 40% of children requiring CPAP for moderate-severe OSA were able to have review sleep studies within the 12 months as per guidelines[1] – therefore 60% are potentially receiving less than optimal respiratory support. The dynamics of airway pathology change with growth and some children will be under-treated while others over-treated.

A similar situation exists in NSW with the Children’s Hospital at Westmead, with 345 children in 2020 on CPAP of whom only 69% had review studies within 12 months.

Units throughout the world are having difficulties meeting the requirements recommended within existing guidelines. In the UK cardiorespiratory studies are regarded as the routine standard [personal communication, Edinburgh and London included] and Canada are exploring options for such studies out of the sleep laboratory as well [personal communication].

It is proposed that cardiorespiratory studies in an out-of-laboratory setting should be available. Children could then be involved in the decision making around investigations for their respiratory therapy; a full polysomnography in the paediatric sleep laboratory vs cardiorespiratory only study in an out-of-sleep-laboratory setting e.g. own bedroom. Many of these children are very aware of how their therapy is progressing and if a full PSG was required, they would opt for this rather than feeling unwell with sub-optimal therapy.

The EEG and EMG leads are technically difficult to apply satisfactorily to ensure 8 hours of recording; thus, children in regional and remote locations need to travel to a facility which has a health professional skilled in application if a full PSG is required. Level 3 Cardiorespiratory equipment could be applied by parents with telehealth [video] instruction from a sleep professional. The parents will have had previous experience with application of equipment when their child was diagnosed and again when established on therapy; they will have had a discussion with a sleep medicine specialist indicating home monitoring may be feasible. Equipment would be couriered to and from the patient’s home.

Technology is improving such that the correct application and data collection can be checked by a sleep professional remotely and troubleshooting overnight can also be facilitated in a similar manner (for example, newer devices are able to transmit data to be seen remotely from the acquisition site).

The efficiency and reliability of such studies has been seen in the European approach where many monitoring studies have been cardiorespiratory (level 3) studies for the last decade.

It is proposed that cardiorespiratory monitoring in an out-of-sleep-laboratory setting - level 3 studies be for the following:

1. Monitoring study for those children who are 3 years and older, assessed as clinically stable on present respiratory support [CPAP or bilevel] and where distance or wait list precludes an in sleep laboratory study as per Australian and US guidelines.
2. As an alternative diagnostic study for children with suspected OSA; where the intensity of the monitoring is distressing/challenging. The child is unable to tolerate the full setup for level 1 or 2 studies: child does not tolerate EEG and EMG head leads but requires assessment for significant obstructive breathing as per clinical assessment.[50]

Safety concerns: as for level 2 studies above.

Overnight Oximetry monitoring for OSA in out-of-sleep-laboratory setting: Level 4 studies

This would be indicated for:

Children [1-12 years] living > 50km from a paediatric sleep medicine service in whom a paediatric sleep specialist suspects significant OSA and the first line of therapy would be a surgical intervention (adenotonsillectomy).

Research has shown that oximetry alone can ‘rule in’ moderate to severe OSA but is not reliable for ‘ruling out’.[33] Thus, a positive test would permit those who require surgical therapy to access this in a timely manner rather than waiting for polysomnography. Those with a negative test would require further assessment with a level I or II study. A positive test is also predictive of an increased risk of post-operative complications after adenotonsillectomy and can thus be used to plan the location that the surgery takes place

to ensure appropriate support should a complication arise e.g., a centre with paediatric ICU services.[21, 31, 33] Therefore use of oximetry prior to adenotonsillectomy will result in improvements in the safety and timeliness of care.

Application of an oximeter is relatively simple and non-invasive, requiring only a single lead to be attached to the child. Instruction could be in person or using written and/or video instructions, with remote support from a sleep professional. Parents could be naive to the experience and yet still achieve reliable readings.

If level 4 studies occurred, the number of referrals for level 1 and 2 studies would be reduced as only those children who remained symptomatic [snoring still occurred] or were symptomatic after surgical intervention would require these. Adenotonsillectomy results in resolving 50-90% of OSA in children with no comorbidities.[43]

It is acknowledged that > 70% overnight oximetry for OSA will be inconclusive and if symptoms persist a full PSG could be required.[33]

28. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

A. New Referrals:

1. **The patient (aged 0-18 years) is referred by a medical practitioner to a paediatric sleep specialist for evaluation of a concern related to sleep quality and/or breathing.**
2. A qualified paediatric sleep medicine specialist [0-12 years] or either paediatric or adult sleep medicine specialist [12-18 years] sees the patient in a consultation (MBS item 110 or 132) or telehealth (MBS item 91824 or 92422)
3. The sleep medicine specialist makes an assessment that the patient warrants sleep investigation for OSA and refers the patient for the most appropriate test; level 1-level 4 (see Q 25 for more detail and the attached flow charts).
4. Patient will be placed on waiting list for study; time to study will depend on prioritising category. [Only Category 1 will be able to happen as per urgent need in all Australian paediatric sleep services. For Category 2 patients at QCH and Westmead, the wait time is more than 9 months and for Category 3 patients, wait times at QCH and Westmead exceed 18 months].

B. Review of existing patient:

1. Either of following:
 - a. The patient (aged 3-18 y) is an existing patient and presents for evaluation of a new concern related to sleep quality and/or breathing or following an intervention for a sleep disorder.
 - b. The patient (aged 3-18y) is an existing patient who requires respiratory support [CPAP or bilevel] and is reviewed by a paediatric sleep specialist who finds that clinical, intellectual maturation and growth status are progressing normally and the patient is clinically stable on present therapy; the patient warrants review of respiratory support as per guidelines and is unlikely to require an alteration in support.
2. A qualified paediatric sleep medicine specialist sees the patient in a consultation (MBS item 110 or 132 or 116 or 133) or telehealth (MBS item 91824 or 92422 or 91825 or 92423).
3. The paediatric sleep medicine specialist makes an assessment that the young person warrants a sleep study and refers the patient for the most appropriate test; level 1-level 4 (see Q 25 for more detail and the attached flow charts).
4. Patient will be placed on waiting list for a laboratory study; waiting time will depend on prioritising category [as per new referral].

PART 6b – INFORMATION ABOUT THE INTERVENTION

29. Describe the key components and clinical steps involved in delivering the proposed medical service:

Full polysomnography in out-of-sleep-laboratory setting: Level 2 study

1. The patient (aged 3-18 years) is set up for a full PSG by a trained healthcare professional under the supervision of a paediatric sleep medicine practitioner either in their own home or at a paediatric sleep medicine service. The healthcare professional and the sleep medicine practitioner will be listed on the staff of an accredited paediatric sleep laboratory [3-12 years] or paediatric or adult sleep laboratory accredited for adolescents [12-18 years]
2. The following leads are attached to ensure there is a continuous monitoring of cortical sleep stages, oxygen saturation, muscle activity and breathing using a multi-channel polygraph. Recordings of the following are made, in accordance with current professional guidelines:
 - i. airflow
 - ii. continuous EMG
 - iii. ECG
 - iv. EEG (with a minimum of 4 EEG leads or, in selected investigations, a minimum of 6 EEG leads)
 - v. EOG
 - vi. oxygen saturation
 - vii. respiratory movement of rib cage and abdomen (whether movement of rib cage is recorded separately from, or together with, movement of abdomen)
 - viii. +/- measurement of carbon dioxide (transcutaneous); - this to be assessed on case by case basis by paediatric sleep medicine specialist.

The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads etc. They are given a contact number or digital link for overnight support with the study.

3. Polygraphic records are:
 - i. Analysed for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and assessment of clinically significant alterations in heart rate and body movement with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and stored for interpretation and preparation of a report
 - ii. Interpretation is made and report provided by a qualified paediatric sleep medicine specialist [and/or adult sleep medicine specialist if 12 years or older] based on reviewing the direct original recording of polygraphic data from the patient
 - iii. If the study is not technically adequate and a full report cannot be generated, a paediatric sleep medicine specialist [or adult specialist as above] determines if the study should be repeated in a sleep laboratory Level 1 study.[5, 35]
4. The patient is reviewed by a paediatric sleep medicine specialist [3-12 years] or paediatric /adult sleep medicine specialist [12-18 years], results and appropriate therapy are discussed and instigated. Primary referring doctor is provided with report and recommended therapy.

Cardiorespiratory monitoring in out-of-sleep-laboratory setting: Level 3 study

1. The patient (aged 3 -18 years) is set up for a cardiorespiratory monitoring - level 3 polysomnogram by a trained healthcare professional under the supervision of a paediatric sleep medicine practitioner either in their own home or at a secondary paediatric sleep medicine service . The healthcare professional and the sleep medicine practitioner will be listed on the staff of an accredited paediatric sleep laboratory [3-18 years]
2. The following leads are attached to ensure there is a continuous monitoring of oxygen saturation and breathing using a limited-channel polygraph; recordings of the following are made, in accordance with current professional guidelines:
 - i. airflow;

- ii. oxygen saturation;
 - iii. respiratory movement of rib and abdomen (whether movement of rib is recorded separately from, or together with, movement of abdomen);
 - iv. measurement of carbon dioxide (transcutaneous); this to be assessed on case by case basis by paediatric sleep medicine specialist
3. The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads. They are given a contact number or digital link for overnight support with the study.
4. Polygraphic records are:
- i. Analysed for respiratory events with manual scoring, in epochs of not more than 1 minute; and stored for interpretation and preparation of a report;
 - ii. Interpretation and report are provided by a qualified paediatric sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient.
 - iii. If the study is not technically adequate and a full report cannot be generated a paediatric sleep medicine practitioner determines if the patient should be referred for a sleep laboratory full polysomnogram - Level 1 study.
2. The patient is reviewed by a paediatric sleep medicine specialist [3-12 years] or paediatric /adult sleep medicine specialist [12-18 years], results and appropriate therapy are discussed and instigated. Primary referring doctor is provided with report and recommended therapy.

Overnight oximetry for OSA in an out-of-sleep-laboratory setting – level 4 study

1. The patient's (aged 1 -12 yrs) parent/caregiver is phoned by a trained healthcare professional under the supervision of a paediatric sleep medicine specialist and arrangements are made to courier an oximeter to and from their home. Discussions ensure whether phone or video teleconferencing will occur to assist the parent/caregiver in applying the oximeter for an overnight recording. [Video is preferred, with phone with photos/texting only if IT does not support video]
2. A trained healthcare professional under the supervision of a paediatric sleep medicine specialist calls [phone or video as previously arranged] to assist with and ensuring oximeter probe is attached to child correctly for recording. A phone number or digital link is given for overnight backup with an accredited paediatric sleep professional or sleep laboratory.
3. Oximetry data is downloaded [oxygen saturation and heart rate] and interpreted by a paediatric sleep specialist. A report is generated.
4. The patient is reviewed by a paediatric sleep medicine practitioner, results discussed and advice re ENT surgery [adenotonsillectomy]. Referral to ENT provider is made. Primary referring doctor is provided with report and recommended therapy.

30. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

None

31. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

N/A

32. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

We are recommending that suitability and referral for out-of-sleep-laboratory sleep monitoring is assessed by an accredited paediatric (0-12yrs, 12-18yrs) or adult (12-18yrs) sleep medicine physician (specialist recognition by RACP) who is listed on the staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program.

The equipment is to be applied or video supervised by a sleep professional with expertise in the setup of sleep monitoring equipment in children and/or adolescents. This professional will be listed on the clinical staff of an accredited sleep laboratory.

33. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

None

34. If applicable, advise which health professionals will primarily deliver the proposed service:

Paediatric sleep medicine specialists (specialist recognition by RACP) who are listed on the staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program for testing of children and adolescents aged 0-12 years and 12-18 years. There will be some adult sleep medicine physicians (specialist recognition by RACP) who are listed on the staff of an adolescent and adult sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program for testing of adolescents aged 12-18 years

If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Following a sleep medicine consult (face to face or telehealth) an overnight oximetry looking for OSA - level 4 study - could be delegated to trained health professionals in a regional location for acquisition of data. All studies will be interpreted and reported by a paediatric sleep medicine physician (specialist recognition by RACP) who is are listed on the staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program.

35. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Any registered medical practitioner can provide a referral to the paediatric sleep medicine practitioner (specialist recognition by RACP) 0-12 years or paediatric/adult sleep medicine practitioner (specialist recognition by RACP) 12-18 years for evaluation of sleep disordered breathing. The decision to undertake an out-of-sleep-laboratory study in preference to an in-laboratory study will rest with the sleep medicine physician that undertakes the consultation, who will also maintain responsibility of any out-of-laboratory monitoring that is performed.

All children who require respiratory support with CPAP or bilevel will be existing patients of a paediatric sleep medicine specialist and it will be this practitioner (after review of the patient and discussion with patient and parents/caregiver) that will decide if a review of therapy study should be a full polysomnography in a sleep laboratory (level I) vs overnight cardiorespiratory monitoring (Level III) in an out-of-laboratory setting.

36. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

The investigations should be requested by a paediatric or adult sleep medicine physician (specialist recognition by RACP). This sleep medicine specialist will be listed on the staff of a sleep laboratory that is fully accredited by NATA/ASA for testing of children and adolescents aged 0-12 years and/or 12-18 years.

37. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home

- Laboratory
- Other – please specify below

Temporary residence [motel/ apartment] if regional families elect to travel to somewhere closer to the providing accredited sleep laboratory.

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

It is proposed these studies will be in an out-of-sleep-laboratory setting supervised by a parent/caregiver or non- sleep trained professional. It is envisaged these may occur in the patient’s home, a temporary residence [e.g. motel, rented apartment] or in a private hospital bed.

38. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

39. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

- The comparator is the full polysomnography within an accredited sleep laboratory - level 1 study
- Children [0-12 years] and adolescents [12-18 years] with sleep disordered breathing concerns referred to paediatric sleep medicine specialist [0-18 years] or an adult sleep medicine specialist [12-18 years] are currently managed as follows in the absence of the proposed medical service
 - Paediatric or adult sleep medicine specialist are the only practitioners who can refer for an in-sleep laboratory study full PSG – level 1 study
 - Long waitlists already existed in 2019 and have extended during the COVID-19 pandemic [wait details are included in the answer to Q25]

Management depends on the diagnostic information obtained from the sleep study. A positive study, with a diagnosis of OSA, may involve ENT referral for surgery (and occasionally maxillo-facial surgery) or medical therapy [CPAP or bilevel respiratory support] for treatment.

Due to long wait lists for in-sleep laboratory studies (level 1) using the current model, many patients proceed directly to ENT surgery. This may be unnecessary for some children (if the patient snores without obstructive sleep apnoea) or dangerous (if the OSA is severe, hypercapnia present and post-operative respiratory compromise occurs in a non-tertiary paediatric centre). Improving the access to overnight sleep monitoring will enable better quantification of OSA severity, ensuring that children do not undergo unnecessary intervention or experience unwanted complications in inappropriate settings.

Using the current model, children requiring respiratory support [CPAP or bilevel] are not able to be monitored according to the recommended national standards[1] due to the long wait-times for studies to check their treatment. These recommendations are based on the knowledge that with growth, children often require changes in ventilatory settings and regular review of therapy is required. Therefore, at present, children can either be under-treated, resulting in increased sequelae, or be over-treated, with therapy duration unduly prolonged when no longer necessary.

Children in the public health systems are often referred for a sleep study pre-ENT surgery in the tertiary hospitals as a way to prioritise a limited surgical service. For example; for adenotonsillectomy the wait times in the Queensland public system is 6-24 months depending on locality and in private 4-12 weeks.

Children with a history of snoring and possible OSA are often referred directly to ENT for surgery Australia-wide; whether they go directly to surgery or have a sleep study is dependent on the surgeon. If sleep studies were easier to obtain it is likely more children would be assessed for sleep disordered breathing prior to the decision for surgery being made.

Some children/families dislike or do not want in-laboratory studies (eg during COVID-19 pandemic) and hence either avoid treatment where it is required or proceed to ENT surgery without knowing the patient’s risk level.

40. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

Yes (please list all relevant MBS item numbers below)

SERVICE	EXISTING ITEMS
Paediatric Sleep Investigation (age < 12)	12210
Paediatric Sleep Investigation (age 12 to < 18)	12213
Treatment Implementation & Effectiveness	12204, 12205

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

- In addition to (i.e. it is an add-on service)
- Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

N/A

PART 6c CONTINUED – INFORMATION ABOUT ALGORITHMS (CLINICAL MANAGEMENT PATHWAYS)s

42. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

New referral first diagnostic in sleep laboratory study:

All patients are clinically reviewed so that results can be discussed with the patient and their parents/caregivers.

- If study is positive for OSA and
 - patient has not previously had ENT intervention, patient is referred to ENT for surgery [adenotonsillectomy +/- nasal surgery to improve airflow]. ENT surgery will resolve OSA in 50 -90 % depending on associated comorbidities of patients.
 - Patient has already had ENT intervention or is not suitable for intervention, then patient will be offered medical therapy; typically, intra-nasal corticosteroids, positional therapy or CPAP or bilevel respiratory support.

Establishing CPAP or bilevel support:

- Child and parent will spend time with staff from sleep laboratory to discuss therapy required and how this equipment works. Child is shown and fitted for an interface to deliver therapy [nasal mask, prongs, face mask etc]. It will be determined if Commonwealth [NDIS], State health department or family will fund the equipment under the various options available.
- A repeat in-laboratory sleep study will be required to determine the correct treatment settings for each patient.
- Once established on respiratory support, repeat sleep studies are needed. The frequency will be between every 3 and 12 months, depending on the child’s age and medical condition.[1]

- If study is negative for OSA
 - Results are discussed with patient and parents/caregiver, further assessment of primary symptoms that resulted in referral are assessed and a therapy plan developed for child. This can be reassurance, nasal sprays etc and child discharged back to the referring doctor.
 - Occasionally the diagnostic study will suggest another sleep disorder such as central respiratory control disorder, periodic limb movement disorder, parasomnia or a sleep movement disorder. This diagnosis will be discussed with the child and parents and appropriate therapy plan developed.

Known patient where the full PSG was not the child's first study

- Child is on respiratory support [CPAP or bilevel]: after study, the child is clinically reviewed by paediatric sleep practitioner and adjustments are made to treatment as per results; further study requested for 6-12 months.
- Child still symptomatic post ENT intervention and
 - study positive for OSA – results discussed and as per above - plans made to instigate respiratory support therapy [CPAP or bilevel]
 - Study negative for OSA – results discussed at clinical review – child discharged back to referring practitioner.
- Child had previous study for another sleep disorder and has developed new symptoms or child has a known diagnosis that has a high association with OSA or other sleep disordered breathing diagnoses or on therapy that can result in sleep disordered breathing [eg a child with Prader Willi Syndrome on treatment with growth hormone]
 - Study positive for OSA - results discussed and as per above - plans made to instigate commence or alter treatment as indicated.
 - Study negative for OSA – results discussed at clinical review – child discharged back to referring practitioner.

43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

Flowchart C [included as an attachment] details the current process in place for paediatric sleep medicine evaluation using sleep laboratory full polysomnography [PSG]. Across Australia the average wait time for a non-urgent diagnostic study is 6 - 18 months. This has extended significantly in 2020-21 by an as yet undetermined number, especially in Victoria and NSW, as a result of:

- reduced services during the COVID-19 pandemic period
- closure of services during level four shutdowns [NSW and Victoria]
- patients/parents dis-inclination to come to medical services during the pandemic – both to general practitioners with their increasing symptoms and to sleep medicine services for assessment and investigations
- regional patients not being permitted to travel to capital cities where paediatric sleep medicine services provided.

This is unsatisfactory from the perspective of paediatric sleep specialists, who hold grave concerns that children are experiencing progressively worsening delays to definitive diagnosis and treatment. This has implications for neurocognitive maturation, impairment of normal growth, and potentiating long term cardiovascular risks for these children as adults.[38, 51-54]

The introduction of out-of-sleep-laboratory assessment options will assist in tackling this issue. The primary aim of being able to do out-of-sleep-laboratory studies is to enhance the timeliness of diagnosis and treatment of sleep disorders by:

- Reducing time from referral to diagnosis and definitive treatment for suspected OSA, thus improving the likelihood the child will avoid long term sequelae from untreated OSA [38]
- Improving therapy for children requiring respiratory support [CPAP, bilevel] by meeting guidelines for 6 - 12 monthly review studies [1]
- Creating space to ensure paediatric sleep medicine services and sleep laboratories can provide urgent in-laboratory studies when required and improved services for children with complex problems either resulting in or associated with sleep disorders.

On review of the 2019 sleep laboratory activity data at 3 of the tertiary paediatric sleep medicine centres [2 private, 1 public] it is calculated that:

- Approximately 40% of diagnostic studies could be substituted by an out-of-sleep-laboratory PSG when OSA is suspected [level 2 study]
- Approximately 50% of sleep laboratory full PSG studies to review adequacy of respiratory support could be substituted with a cardiorespiratory monitoring in an out-of-sleep-laboratory setting [level 3 study]

A significant number of children with OSA symptoms in regional areas and/or in states without or with limited paediatric sleep medicine service and thus an accredited paediatric sleep laboratory [eg Tasmania, Northern Territory] are at present either not being diagnosed or being referred directly for ENT surgery if OSA is considered present on clinical grounds. These children could have their medical care improved by utilising studies in an out-of-sleep-laboratory setting – a telehealth consult with a paediatric sleep specialist and if an investigation is deemed necessary then full PSG could occur with:

- local health care workers trained to assist parents in acquiring valid overnight data [assist with closing the gap] by staff from the accredited sleep laboratory with either face to face or telehealth education packages, sleep laboratory could monitor data collection in real time and trouble shoot during study; and local health workers would be included in team meetings to discuss results and for continuing education.
- or staff from accredited paediatric sleep laboratory could travel to these areas and set up children for studies in their own homes, remain overnight and travel back with equipment. Studies in other states or remote areas could be facilitated by clustering studies from the region, staff from an accredited laboratory travelling off site, to ensure equity rather than all families being required to travel to the sleep laboratory.

If the question to be answered after sleep specialist consultation is in regard to the presence of OSA, then another alternative to full PSG could be an overnight oximetry study. It would inform who does and who does not require urgent ENT surgical intervention and the most appropriate/safest location for surgery. Oximeters could be couriered to and from regional and remote areas.

The expected changes as a result of the introduction of studies in out-of-sleep-laboratory settings will differ for metro and regional patients. Although wait times do not discriminate between these geographical areas, at present, patients in metro areas have the ability to attend at short notice for an overnight in-laboratory study, if an opportunistic slot becomes available (e.g., through cancellation at short notice by a scheduled patient). This is not feasible for regional patients and therefore earlier studies cannot be facilitated for this group. The introduction of paediatric out-of-sleep-laboratory studies will provide an option to facilitate care sooner for both metro and regional patients, as well as reducing the burden of travelling to the capital cities for regional patients, through a combination of telehealth consultation and a home sleep study if OSA is the provisional diagnosis.

Suitability for paediatric/adolescent studies [level 2, 3 or 4] in an out-of-sleep-laboratory setting will increase the total number of studies per year initially but is then expected to stabilise, as with present paediatric and adolescent in laboratory sleep studies. The number of paediatric sleep medicine practitioners is ~ 35 compared to > 200 adult sleep medicine practitioners. The number of new specialists approved by RACP is steady at 3-4 each year. To our knowledge 4 have retired in last 12 months. The number of accredited paediatric sleep laboratories in Australia [NATA/ASA] is 12 compared to 76 adult sleep laboratories. This has changed very little over the last 5 years. There are a significant number of sleep laboratories which have not

sought ASA/NATA accreditation; we are recommending that these facilities would need to acquire accreditation to have access to these proposed new MBS numbers.

Data from two paediatric sleep services (1 private and 1 public) that undertake home studies and also from existing literature suggests that the failure rate of full PSG out-of-sleep-laboratory studies is 10-13% if defined as loss of some data on any lead; but sufficient data is usually present that < 5% would need to repeat a full PSG within a sleep laboratory.[5, 35]

Examples of existing patient groups that these studies could be considered for at listed below.

Full polysomnography in out-of-sleep-laboratory setting: Level 2 study

Highly likely to be referred for full PSG in out-of-sleep-laboratory setting: Level 2 study

Children for evaluation of OSA

- Otherwise healthy children ≥3years

Possibly able to be referred for full PSG in out-of-sleep-laboratory setting: Level 2 study

- A subset of children with an underlying diagnosis of ASD (Autistic spectrum disorder) and/or neuro-disability (e.g., Down syndrome) who find the in-laboratory sleep environment too stressful and are likely to settle better in a home environment. This decision would be undertaken by a paediatric sleep specialist in conjunction with the child's primary carers.

Not able to be referred for full PSG in out-of-sleep-laboratory setting: Level 2 study

- Patients < 3 years
- Patients where there is clinical concern re medical instability and ability to gain relevant information without experienced staff present.
- Children where a sleep study is indicated for movement disorders, suspected nocturnal seizures, atypical parasomnias, hypersomnia and narcolepsy
- Initiation of respiratory support (CPAP or bilevel)

Cardiorespiratory monitoring in out-of-sleep-laboratory setting: level 3 study

Highly likely to be eligible cardiorespiratory monitoring in out-of-sleep-laboratory setting: level 3 study:

- Children ≥3 years already established on CPAP for treatment of OSA

Possibly eligible for cardiorespiratory monitoring in out-of-sleep-laboratory setting: level 3 study:

- Children for evaluation of OSA unable to tolerate EEG, EOG and EMG leads in a full polysomnography in or out-of-sleep-laboratory [level 1 or 2 studies].
- Children ≥3 years already well established and stable on bilevel support – this would be at the discretion of the child, parent/caregiver and the paediatric sleep medicine practitioner (this option may be suitable for stable older neuromuscular patients in whom the in-laboratory sleep environment does not support good sleep quality and therefore impacts on data obtained).

Not eligible for cardiorespiratory monitoring in out-of-sleep-laboratory setting: level 3 study:

- Patients on CPAP or bilevel who are thought to be medically unstable on present respiratory support
- Patients on CPAP or bilevel who are likely to require changes to respiratory support settings during the study
- Patient on CPAP or bilevel who have suboptimal adherence (as assessed from machine download data) and/or response to therapy.

Overnight oximetry for OSA in an out-of-sleep-laboratory setting – level 4 study

Highly likely to be recommended for overnight oximetry to screen for moderate-severe OSA: level 4 study

- Children 1-12 years who reside > 50km from an accredited paediatric sleep laboratory in whom significant OSA is considered a high possibility by a paediatric sleep medicine specialist at telehealth consultation. The study could be used to prioritise referral for ENT review and surgical intervention; this has the potential to be facilitated closer to the child's home and negate travel for child and family.

Introduction of out-of-laboratory paediatric sleep studies-level 4 has the potential to provide 'surgical risk management' for regional and remote ENT services.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

44. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Benefits – Improved access to sleep monitoring services; improved consumer satisfaction with home monitoring option. Reduced waiting times for level 1 studies (in laboratory) and definitive treatment for sleep disordered breathing with subsequent reduction in health care utilisation by patients with untreated disease.[55, 56]

Harms - potential need for an in-laboratory study due to failed out-of-laboratory study (expected <5%), injury from home study

Polysomnography is the diagnostic test for sleep disorders in children, with multiple studies demonstrating that history and clinical assessment are inaccurate and insufficient for this purpose. Children having sleep laboratory-based full PSG studies should be prioritised for use in children in high-risk categories with other medical comorbidities, very young infants and children and those with sleep disorders other than OSA such as abnormal neural control of respiration [57, 58] and sleep movement disorders. In this context, laboratory polysomnography is cost-effective leading to treatment intervention.[59]

Benefits

- Wait times: Current wait times for children's sleep studies in many paediatric sleep laboratories are >12 months, so the major change expected by introducing home studies is improved capacity for timely testing of children with a clinical suspicion of obstructive sleep breathing problems.
- Reduced time to diagnosis and treatment: The flow on effects of reduced time to diagnosis for all sleep disorders in children is reduced time to implement definitive management with a final result of improved clinical outcomes for children.
- Reduction in health care utilisation: Children with OSA have 226% more health care utilization than controls and adenotonsillectomy to treat OSA in these children is associated with a one third reduction in annual health care costs. Adenotonsillectomy is associated with a 60% reduction in the number of admissions to hospital, 39% reduction in emergency department visits, 47% reduction in medical consultations, and a 22% reduction in costs for prescribed drugs.[55, 56]
- Reduction in other physical and health issues outcomes: Untreated OSA increases cardiovascular risk, with children shown to have increased blood pressure by 3-5 mmHg (both systolic and diastolic). In addition, cognitive and behavioural abnormalities are commonly described along with a strong association with nocturnal enuresis.[60] Also now evidence for life long increased cardiovascular risk.[39]
- Reduction in perioperative risks: : For obstructive sleep apnoea (OSA) in children, where the first treatment is surgical adenotonsillectomy, increased susceptibility to airway collapse under anaesthesia and increased sensitivity to opioids (respiratory depression and airway collapse) increase the risk of post-operative respiratory complications.[61] Having quantification of the severity of OSA by a sleep study prior to surgery allows anaesthetists and surgeons to evaluate risk and take appropriate mitigating actions.
- Ability to undertake home monitoring option improves consumer satisfaction for a many families.[62]
- Sleep duration and sleep quality are better in the home than in the hospital[63]

Potential harms relevant to all levels of home studies, the main areas of adverse risk are:

- Risks of the monitoring devices: All home studies will use oximetry and so a potential concern is a superficial skin burn from oximetry or CO2 probes being applied incorrectly. Reports in the literature support periodic probe movement, checking skin site integrity, and careful placement to avoid pressure injury.[64] It is recommended that trained paediatric sleep medicine professionals either undertake the study set-up and/or educate parents/caregivers of these risks prior to the study. The temperature of the probes being used, and the duration of application have been shown in laboratory-supervised studies to be within safety limits.[65]
- Skin reactions: Some children appear to develop skin sensitivity to the probes/adhesives being used in these studies, and this risk applies whether the studies are undertaken in a sleep laboratory or in the home.[64]
- Increased need for operative capacity: Even though current systems are in “steady state” with throughput from diagnosis of OSA to undertaking adenotonsillectomy, wait times for adenotonsillectomy are often prolonged. Any increase in the number of children with positive diagnosis of OSA, where treatment with adenotonsillectomy is recommended, would likely add further strain to the surgical waiting lists. On the other hand, if all children presently awaiting adenotonsillectomy for possible OSA had a sleep study, many would be demonstrated not to have OSA and therefore avoid unnecessary surgery.

Specific points relevant to the different types of portable studies include:

Full polysomnography in out-of-sleep-laboratory setting: Level 2 study

Benefits

- Home sleep monitoring services that include EEG for sleep staging would favour children ≥ 3 years and those without associated complex medical conditions. Removing these children from the need for laboratory studies would free capacity for children in the high-risk groups mentioned above. Thus the children who have a high need for laboratory studies would have improved access to time sensitive medical interventions.
- Children and parents would be able to remain in home environment.

Harms

- The main risk for level 2 studies is technical failure that would require repeat collection of data so that either a repeat home study or in-laboratory PSG needs to be undertaken. Estimates of failure rates are reported in Q45. This could be minimised with parents being given support via phone/video or digital link overnight either to a paediatric sleep medicine professional or an accredited sleep laboratory and its staff.
- A potential concern is lead entanglement but there are no reports of this being a problem, despite increasing publications regarding home studies. Potential risks have decreased since the original paediatric sleep studies in the 1970's with recent digital equipment. We did find literature re the risks of other in-home healthcare now provided to children e.g. enteral feeding. The risks related to hygiene and deviations from recommended delivery protocols not to lead entanglement.[66]

Cardiorespiratory monitoring in out-of-sleep-laboratory setting: level 3 study

Benefits

- Appropriate interval monitoring for children on respiratory support. Level 3 monitoring permits timely evaluation of the effectiveness of current, or newly implemented therapies.[67]
- Reduced waiting times for in-laboratory studies will allow earlier changes to treatment where those are required.

Harms

- Similar to level 2 studies – though fewer leads for child and family to maintain
- No specific harms have been identified that would be specific to Level 3 studies.

Overnight oximetry for OSA in an out-of-sleep-laboratory setting – level 4 study

Benefits

- Overnight oximetry in the patient’s home permits rapid triaging of the 17-27% of referrals for children with suspected OSA who live regionally or remotely from an accredited paediatric sleep laboratory,[31, 33] and have moderate-severe OSA.
- Will facilitate children being referred to an ENT service closer to their place of residence.
- Regional ENT services are able to prioritise children with suspected OSA more appropriately and plan the most appropriate site for the surgery to occur.
- If a parent reports that the child’s symptoms are variable, it will help align parent-reported symptoms with disease variability during testing[68] ie a second study may be required at a time that symptoms are maximal.

Harms

- No risks specific to level 4 studies were identified.

45. Please advise if the overall clinical claim is for:

- Superiority
 Non-inferiority

46. List the key health outcomes, major and minor (prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

1. Reported failure rates needing repeat studies:

Paediatric sleep studies performed in an accredited sleep laboratory [at present the only option] have a less than 1% complete failure rate - i.e. there is insufficient data for the sleep specialist to provide a clinical report/interpretation. In approximately 5% of studies, leads are lost and unable to be replaced by a skilled paediatric professional secondary to non-tolerance from the child and/or parent, though there is often enough data for paediatric sleep medicine specialist to provide a modified clinical report from video and data acquired. (Data is from: The Children’s Hospital at Westmead, Queensland Children’s Hospital and Monash Children’s Hospital)

For full PSG in an out-of-sleep-laboratory setting (Level 2 study), failure rates vary by definition (traces lost, or acceptable for analysis). A failure rate of up to 19% is estimated.[4]

Cardiorespiratory monitoring in an out-of-sleep-laboratory setting (Level 3 study) excludes EEG but includes Nox devices, there is a 13 -18% failure rate [9, 11] and the loss of signals may affect study interpretation[14] compared to 8% failure rate when equivalent studies were performed as in-patients.[69]

For overnight oximetry for OSA in an out-of-sleep-laboratory setting (Level 4 study), we were unable to find any published reports of the number of overnight oximetries that fail to provide data. An anecdotal failure rate (defined as oximetry studies with <6 hours of data) of 3% is reported by one of the members of submission committee (data from Monash Children’s Hospital and submitted for publication).

The main issue for oximetry is that while overnight oximetry is specific, 73-78% of patients studied for a suspicion of OSA will have inconclusive results often requiring further investigation [31, 33] via further sleep studies [full PSG either in laboratory or out of : level 1 or 2 study]. This is counter-balanced by being able to avoid ENT referral, consultation and surgery [hospitalisations for adenotonsillectomy] and reducing ENT waiting times to surgery.

2. Reported “harm” incidents:

Incidents relating to the devices used for home studies are very infrequent. We expected them to be reported as isolated case reports, but were unable to find reported incidents when we searched back to 1991. However, we are recommending that a notification system can be established to monitor for these.

3. Ensuring surgery offered is appropriate:

All children being managed by otolaryngologists for suspected OSA are recommended to have objective sleep testing prior to surgery. At present due to the limited number of accredited paediatric sleep laboratory

services and their absence outside metropolitan areas, most children proceed to surgery with clinically suspected OSA without any investigation to support the patient history and clinical assessment. Introduction of home sleep testing options will increase access and accuracy of pre-operative diagnostic testing for OSA.

4. Infection risk decreased:

A significant number of children will avoid coming to a sleep laboratory where the risk of acquiring an infection is higher than if the study is performed in their own home environment. There are no other patients and the number of professional staff is limited to the one or two required to apply leads.

5. Changes in health care utilisation:

This would require detailed analysis of health care data that is beyond the scope of the applicant group. It may be accessible to the Department of Health.

Clinical Effectiveness Outcomes:

Improved access to investigations and appropriate management from time of referral for patients:

a) Full PSG in accredited sleep laboratory: The first anticipated improvement is in the wait time for children with complex pathology who require investigation for sleep disordered breathing and/or sleep pathology via full polysomnography in a sleep laboratory. At present they may wait 6-18 months for the investigation, thus delaying appropriate therapy being initiated.

b) Suspected OSA: The second wait time that would be lessened is the provision of a study to children in whom OSA is considered likely; these children could have an out-of-laboratory study, diagnosis confirmed or excluded, and appropriate therapy instigated.

Data regarding changes in waiting times after implementation of a home PSG are largely limited to adult services but they indicate improved wait times so that the time to management was reduced by 65% when a home service was used.[70, 71] One paediatric study has demonstrated reduction in time to surgery with use of oximetry screening.[33]

Changes in wait times for children will require ongoing monitoring in Australia if these out-of-laboratory investigations are approved. The assessment of wait times for paediatric sleep laboratory investigations at present requires manual data being collected from individual sleep centres and 3 are included in this application.

c) Children who require respiratory support therapy [CPAP or bilevel] will be reviewed as per existing guidelines for optimal therapy.[1] The children stable on home therapy with CPAP could be studied with cardiorespiratory monitoring in an out-of-sleep-laboratory setting, freeing up options for children who require more complex ventilatory support to have in-laboratory studies to ensure ventilation is optimal for normal neurocognitive development and normal growth.

d) Children with suspected OSA who live regionally or remotely: overnight oximetry used to determine if they may have moderate-severe OSA will enhance the timing of appropriate therapy for the 23-50% who will have a positive study.[27, 33, 72] Concern of families with an inconclusive study could be lessened when they are aware severe disease is not present in their child. Timing of the child's and family's trip to an accredited paediatric sleep laboratory could then be arranged at a time more convenient for the family and facility.

e) Children with neurocognitive impairment and/or high anxiety re sleeping out of their familiar environment will benefit with the option of a study in familial surroundings. At present many of these children do not have investigations due to non-tolerance of 'hospital like' surroundings of most sleep laboratories. Thus, their therapy can be compromised despite the best efforts of clinicians to monitor on clinical grounds only.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

47. Estimate the prevalence and/or incidence of the proposed population:

Two of the larger accredited paediatric sleep laboratories reviewed their waiting lists for PSGs and estimated the following:

We have used the MBS numbers of studies from 2019 as this was unaffected by COVID.

1. 20 – 30 % of present waiting list would meet criteria for out-of-sleep-laboratory full PSG for diagnosis of OSA. As most accredited paediatric sleep laboratories have > 12 month waiting list, out-of-sleep-laboratory studies will be additional to the 2019 data for paediatric sleep studies: 9390 total studies – 7748 in children 0-12yrs and 1621 in adolescents 12-18yrs and 21 studies in individuals who required additional studies. It is expected in the future if more paediatric sleep specialists are trained, that regional areas with larger populations and the states without services will establish paediatric sleep medicine services. If sleep studies performed for suspected OSA alone are considered, 5-10% of children have persistent snoring whereas only 2% have OSA - thus investigations could determine the children with OSA so it is these children only that receive therapy.
2. 10 – 20% of children currently on the waiting list live in regional or remote areas and overnight oximetry could be used to determine if moderate-severe OSA is present so that those children can be escalated for review and treatment. It is believed that referrals from these areas would increase if an alternative to travelling for investigations was available.
3. 50% of children presently on CPAP are estimated to be stable when reviewed clinically and could thus have review of their therapy with out-of-sleep-laboratory cardiorespiratory monitoring. Data collated in 2019 for the joint position ASA and TSANZ recommendations for paediatric ventilatory support found that 1045 children in Australia were on some form of respiratory support [CPAP or bilevel].[1] This number is doubling every 5 years (QCH data: 2015 – 76 children on CPAP, 2020 – 156 children on CPAP).

The majority of paediatric sleep medicine specialists believe the number of children who have access to paediatric sleep medicine services is still limited; referral for sleep breathing disorders has not plateaued, but the number of investigations has, primarily secondary to the limited number of specialists in this area and to the limited number of accredited paediatric sleep laboratories. When Australian children have improved access to diagnostic testing it is envisaged this number will plateau and be more predictable as a proportion of the population. We do not know yet how many children this would be - we were unable to find data on this in the literature.

4. More difficult to estimate from existing waiting lists is individual patients for whom anxiety to the sleep laboratory environment would result in a poor study and thus a study in an out-of-laboratory setting would be more suitable. Individual paediatric sleep medicine specialists would need to be contacted re the patients they have referred with existing diagnoses known to be associated with anxiety and significant sleep disorders eg: Rett syndrome, Prader-Willi syndrome, Autism spectrum disorder, Down syndrome etc. We have estimated this to be 5% of present waiting lists.

Overall, the rate limiting factor in the next decade to the number of investigations will be the limited number of paediatric sleep medicine specialists in active practice.

Current paediatric sleep laboratory data:

Centre 1:

Data for calendar year 2019

Total number studies completed in sleep laboratory in 2019= 909

Not suitable for home PSG (age<3, MSLT, CPAP/NIV): n=358 (39%)

Possibly suitable for home PSG (ADHD, autism, brain abnormalities (Chiari etc), cerebral palsy, NF1, Down syndrome, other syndromes, epilepsy): n=149 (16%)

Probably suitable for home PSG (no comorbidity, obesity, cystic fibrosis, depression, periodic limb movements, ex-prematurity etc): n=402 (44%)

48. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

Typically, once, maximum twice.

49. How many years would the proposed medical service(s) be required for the patient?

- For children referred for possible OSA we would expect a diagnostic study would be required once
- A small subset of children show initial resolution of OSA after adenotonsillectomy and then have recurrence in later childhood that will require further investigation and possibly therapy e.g., CPAP, dental intervention +/- jaw advancement splint, further nasal, or plastic surgery.
- Rare genetic diseases: Some disease categories require sleep studies for ongoing provision of medications e.g. Prader-Willi Syndrome [PWS] for growth hormone, spinal muscular atrophy [SMA] for Nusinersen. The requirement for studies in these categories will change as new advances in therapy occur.
- For children on respiratory support therapy eg CPAP or bilevel, the recent Australian and New Zealand guidelines[1] similar to the US guidelines[45] recommend 6-12 monthly studies depending on age of child, severity of disease, chronicity of disease and expected prognosis with growth. Younger patients, are expected to require more studies due to the rate of change of their disease with growth,

Minimum years: 1 year: Sleep study required for diagnosis of OSA: One year; a single study.

Maximum years: 15 years. If require long term respiratory support from 3 years of age with regular review until transferred to adult services at 18 years. It would be anticipated 50% of studies especially in adolescents could be out-of-sleep-laboratory studies.

50. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

First year:

Full PSG in an out-of-sleep-laboratory setting: Level 2 study: 30% of DOH 2019 total paediatric and adolescent sleep studies numbers [12210, 12213] – [30% of 9390 = 2817]

Cardiorespiratory monitoring in an out-of-sleep-laboratory setting: Level 3 study: 50% of children on CPAP >3 years

~ 400 [40% of 1045 total number of children on CPAP and bilevel], plus children with high anxiety to sleep laboratory environment ~ 469 [5% of 9390]

- *Overnight oximetry for OSA in an out-of-sleep-laboratory setting – level 4 study* : 20% of DOH 2019 total paediatric and adolescent sleep study numbers. [12210,12213] – 1878 [20% of 9390]
- As data from 2020 and 2021 has been influenced by COVID, a correction factor may need to be applied especially for Victorian and NSW data where there have been the longest shutdowns of service and escalation of waiting lists.
- An unknown number of children are admitted to hospital for polysomnography as in-patients or under Hospital in the Home. A proportion of those children would be eligible for out-of-sleep-laboratory studies thus shifting the cost to these new services.

51. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

- Second and subsequent years: numbers may increase as:
 - referrals to existing sleep medicine services increase when it is known waiting times have decreased, though this will transfer the waiting list to being seen by a specialist due to limited number of trained paediatric sleep medicine specialists.

- numbers of paediatric sleep specialists increase
- existing trained paediatric sleep medicine specialists establish paediatric sleep laboratories either with stand alone accreditation or associated with existing accredited laboratories.
- families of children with sleep disordered breathing symptoms that are not OSA request an out-of-sleep-laboratory study. This application has aimed to minimise this by requiring a consultation [face to face or video] prior to any investigation.

PART 8 – COST INFORMATION

52. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

Cost for any out-of-sleep-laboratory study will be additional to the present cost to Medicare per year for all paediatric and adolescent studies. Paediatric sleep laboratories cannot meet present demand and the maximum number of sleep studies are already being performed. Increases are limited by lack of resources and skilled staff to use present facilities 7 nights per week, with most paediatric sleep laboratories working 5 nights per week only.

Cost at present is additional health care and community costs from untreated disease and increased utilisation of medical services, educational and possibly early intervention NDIS funds for developmental delay.[55, 73-75] Costing of this is outside the expertise of the individuals completing this submission.

Overnight oximetry for OSA in an out-of-sleep-laboratory setting – level 4 study

- 15-30 min of sleep laboratory professional time to contact family; arrange for oximeter to be couriered out and back to sleep laboratory – return courier \$52 - \$116.60 [Brisbane – Sunshine coast (\$31.30 one way) vs Mt Isa and Thursday Island (\$55 one way): Perth – Mandurah (\$26.50 one way) vs Broome (\$58.30 one way) – 5kg by Australia Post]
- 15-30 min of sleep tech time to video family re application and to ensure data recording etc
- 30 min of sleep laboratory technician time to download and prepare data collected for report- includes archiving and storage after report completed.
- 1.0 hrs sleep tech [\$27-33/hr] = \$40.50-49.50
- 15 min for interpretation and report from paediatric sleep medicine specialist – [25% of \$159.35 – taken from MBS 110] - \$39.85
- Oximeter [\$3600 - \$4800] and CO2 [\$26,135 radiometer] together [4000/5 + 100 x 3 for leads]/100] cost per study... \$11- \$55 each unit being sent out x 2 /week for 50 weeks
- \$80 [courier] + \$45 [sleep tech] + \$39.85 [medical] + \$11.00 [equipment] = \$172.85

Recommend – **\$172.85**

Cardiorespiratory monitoring in out-of-sleep-laboratory setting level 3 study

- 2 hrs travel time to deliver and retrieve equipment to child's home – plus car at 72c/km [ATO deductible rate] – 37.5 km x 0.72 x 2 = \$54.00
- 1-2 hrs of sleep professional time setup study and ensure data recording
- 30 min of sleep laboratory staff time to contact telehealth to ensure recording occurring etc
- 30 min of sleep scientists to download and prepare data for report – includes archiving and storage after report completed
- 4hrs – sleep professional times- scientists/nurse [\$149.84– 260.72] – [nurses \$37.46 – 48.05 /hr, HP4-5 scientists \$55.22 -65.18/hr]
- 30 min for scoring / interpretation and report from paediatric sleep medicine specialist [50% of \$159.35] - \$79.19
- Somte[11,319 or NOX [\$39,800 plus software \$49,000] depreciate over 5 years – plus bands, flow sensor – X 5 sets/ year..each unit sent out - t x 2 /week for 50 weeks. = \$43.31
- \$205.28 [scientists] + \$79.19 [medical] + \$54 [car or courier] + \$43.31 [equipment] = \$381.50

Recommend – **\$381.50**

Full polysomnography in out-of-sleep-laboratory setting: Level 2 study 2-12 years

- 2 hrs of sleep professional time to travel to and from patient's home - plus car at 0.72/km ... 37.5km = \$54
- 2 hrs of sleep professional time setup study and ensure data recording – parents/caregiver aware how to trouble shoot
- 30 min with sleep laboratory staff contacting family to ensure recording progressing
- 30 min of sleep scientists to download and prepare data for report – includes archiving and storage after report completed
- 5hrs – sleep scientists/nurse [\$187.30– 325.90] – [nurses \$37.46 – 48.05 /hr, HP4-5 scientists \$55.22 - 65.18/hr]
- 60 min for scoring / interpretation and report from paediatric sleep medicine specialist - \$159.35
- Equipment costs similar to level 3 study - Somte[11,319 or NOX [\$39,800 plus software \$49,000] depreciate over 5 years – plus bands, flow sensor – X 5 sets/ year..each unit sent ou - t x 2 /week for 50 weeks. = \$43.31
- 256.65 [sleep scientist/nurse] + \$54 [car] + \$159 [medical] + \$43.31 [equipment] = \$512.96

Recommend : **\$512.96 [3-12 yrs]**

Full polysomnography in out-of-sleep-laboratory setting: Level 2 study 12-18 years

As for 3 -12 yrs with 1 hr less time for set up

Recommend : **\$461.63 [12-18 yrs]**

53. Specify how long the proposed medical service typically takes to perform:

All overnight paediatric sleep studies should aim for 8 hours of data recording.[76] Setup should commence at least 2 hours from child's bedtime especially in younger children to allow an adaption period before their usual bedtime; recoding should commence at bedtime. 6 hours minimum data should be acquired.

It generally takes 30 minutes to download and prepare data for scoring, and 60 minutes to score, interpret the study and provide a report.

54. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

1. Full polysomnography in out-of-sleep-laboratory setting for children 3-12 years

Overnight investigation of sleep for at least 8 hours of a patient aged 3-12 years to confirm diagnosis of obstructive sleep apnoea, if:

(i) the patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea; and

(ii) following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea and that an out-of-laboratory setting is appropriate for the sleep study; and

(a) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, a minimum of 7 channels that include (i) to (vii) of the following measures:

(i) airflow;

(ii) continuous EMG;

(iii) continuous ECG;

(iv) continuous EEG;

(v) EOG;

(vi) oxygen saturation;

(vii) respiratory effort

(viii) +/- measurement of carbon dioxide (either end-tidal or transcutaneous); - this to be assessed on case by case basis by paediatric sleep medicine specialist.

(b) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner who is listed on staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and

(c) either:

(i) the equipment is applied to the patient by a paediatric sleep professional [scientist, technician, nurse, or doctor listed on the staff list of an accredited paediatric sleep laboratory] either at the laboratory or at the patient's place of residence; or

(ii) if child lives > 50km from an accredited paediatric sleep laboratory by a health professional who has been trained in the application of leads by staff from an accredited paediatric sleep laboratory ; and is listed as an associate clinical staff member of the accredited sleep laboratory and thus will participate in laboratory in-house education to maintain skills.

(d) written instructions are given to parent/caregiver to monitor the child overnight and a phone contact or data link to the accredited paediatric sleep laboratory to enable trouble shooting overnight if required; and

(e) polygraphic records are:

(i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and

(ii) stored for interpretation and preparation of a report; and

(f) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist who is listed on staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program with personal direct review of raw data from the original recording of polygraphic data from the patient; and

(g) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Applicable only twice in any 12-month period

Fee: \$ 512.96

2. Full polysomnography in out-of-sleep-laboratory setting for children 12-18 years

Overnight investigation of sleep for at least 8 hours of a patient aged 12-18 years to confirm diagnosis of obstructive sleep apnoea, if:

(i) the patient has been referred by a medical practitioner to a qualified paediatric or adult sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea; and

(ii) following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric or adult sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea; and

(a) during a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:

(i) airflow;

(ii) continuous EMG;

- (iii) continuous ECG;
- (iv) continuous EEG;
- (v) EOG;
- (vi) oxygen saturation;
- (vii) respiratory effort;
- (viii) +/- measurement of carbon dioxide (either end-tidal or transcutaneous); - this to be assessed on case by case basis by paediatric or adult sleep medicine specialist: and

(b) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner [who is listed on the staff list of a NATA/ASA accredited sleep laboratory]; who has determined if CO2 recording is required and

(c) either:

- (i) the equipment is applied to the patient by an paediatric or adult sleep professional [scientist, technician, nurse or doctor] who is listed on the staff list of a NATA/ASA accredited sleep laboratory either at the laboratory or at the patients place of residence; or
- (ii) if child lives > 50km from an accredited paediatric or adult sleep laboratory from an accredited sleep laboratory by a health professional who has been trained in the application of leads by staff from an accredited paediatric sleep laboratory; and is listed as an associate clinical staff member of the accredited sleep laboratory and thus will participate in laboratory in-house education to maintain skills.

(d) written instructions are given to parent/caregiver to monitor the child overnight and a phone contact or data link to the accredited paediatric or adult sleep laboratory to enable trouble shooting overnight if required.

(e) polygraphic records are:

- (i) analysed (for assessment of sleep stage, arousals, respiratory events and cardiac abnormalities) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
- (ii) stored for interpretation and preparation of a report; and

(f) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist [who is on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; and

(g) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203 is provided to the patient

Applicable only twice in any 12-month period

Fee: \$ 461.63

3. Cardiorespiratory monitoring in out-of-sleep-laboratory setting for children meeting following criteria

- I. Child is 3 years or older and is already established on CPAP or bilevel respiratory support– and after a consultation [either face to face or video] with a paediatric sleep medicine specialist is considered stable with therapy; or
 - II. Child is 3 years or older and is considered at risk for significant OSA by a paediatric sleep specialist and has not tolerated EEG, EOG and EMG leads in the setup for full polysomnography.
1. Overnight investigation of sleep for at least 8 hours of a patient aged 3-18 years to confirm adequacy of present respiratory support [CPAP or bilevel] or for diagnosis of obstructive sleep apnoea, if:

2. The patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient is stable on current respiratory support for sleep disordered breathing OR has a high probability for symptomatic, moderate to severe obstructive sleep apnoea and is non tolerant of head leads when full PSG attempted; and
3. following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to assess respiratory support therapy [CPAP or bilevel] OR the diagnosis of obstructive sleep apnoea; and
4. During a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:
 - i) airflow;
 - ii) oxygen saturation;
 - iii) respiratory effort;
 - iv) +/-measurement of carbon dioxide (either end-tidal or transcutaneous); this to be assessed on case by case basis by paediatric sleep medicine specialist
5. The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads. They are given a contact number/data link for overnight support with recording.
6. Polygraphic records are:
 - (i) analysed for assessment of sleep stage, arousals, respiratory events and cardiac abnormalities with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
 - (ii) stored for interpretation and preparation of a report; and
7. Interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is listed on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; al(e) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Applicable only twice in any 12-month period

Fee: \$ 381

4. Overnight oximetry for OSA in an out-of-sleep-laboratory setting in children 1-12 years

Overnight investigation of sleep for at least 8 hours of a patient aged 1-12 years to determine the likelihood of a diagnosis of obstructive sleep apnoea, if:

- (i) the patient lives > 50 Km from an accredited paediatric sleep laboratory and has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea; and
- (ii) following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea; and

(a) The patient's (aged 1-12 yrs) parent/caregiver is phoned by a trained healthcare professional under the supervision of a paediatric sleep medicine specialist and arrangements are made to courier an oximeter to and from their home. Discussions ensure whether phone or video teleconferencing will occur to assist the parent/caregiver in applying the oximeter for an overnight recording [video preference, phone with photos/texting only if IT does not support video]; and

(b) A trained healthcare professional under the supervision of a paediatric sleep medicine specialist calls [phone or video as previously arranged] on the evening that study is to occur to assist with and ensuring oximeter probe is attached to child correctly for recording. Phone number or data link is given for overnight backup with an accredited paediatric sleep professional or sleep laboratory; and

(c) Oximetry data is:

(i) analysed by software to determine oxygen saturation and heart rate profile

(ii) stored for interpretation and preparation of a report; and

(d) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is on staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of oximeter data from the patient; and

(g) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Applicable only twice in any 12 month period

Fee: \$ 175.85

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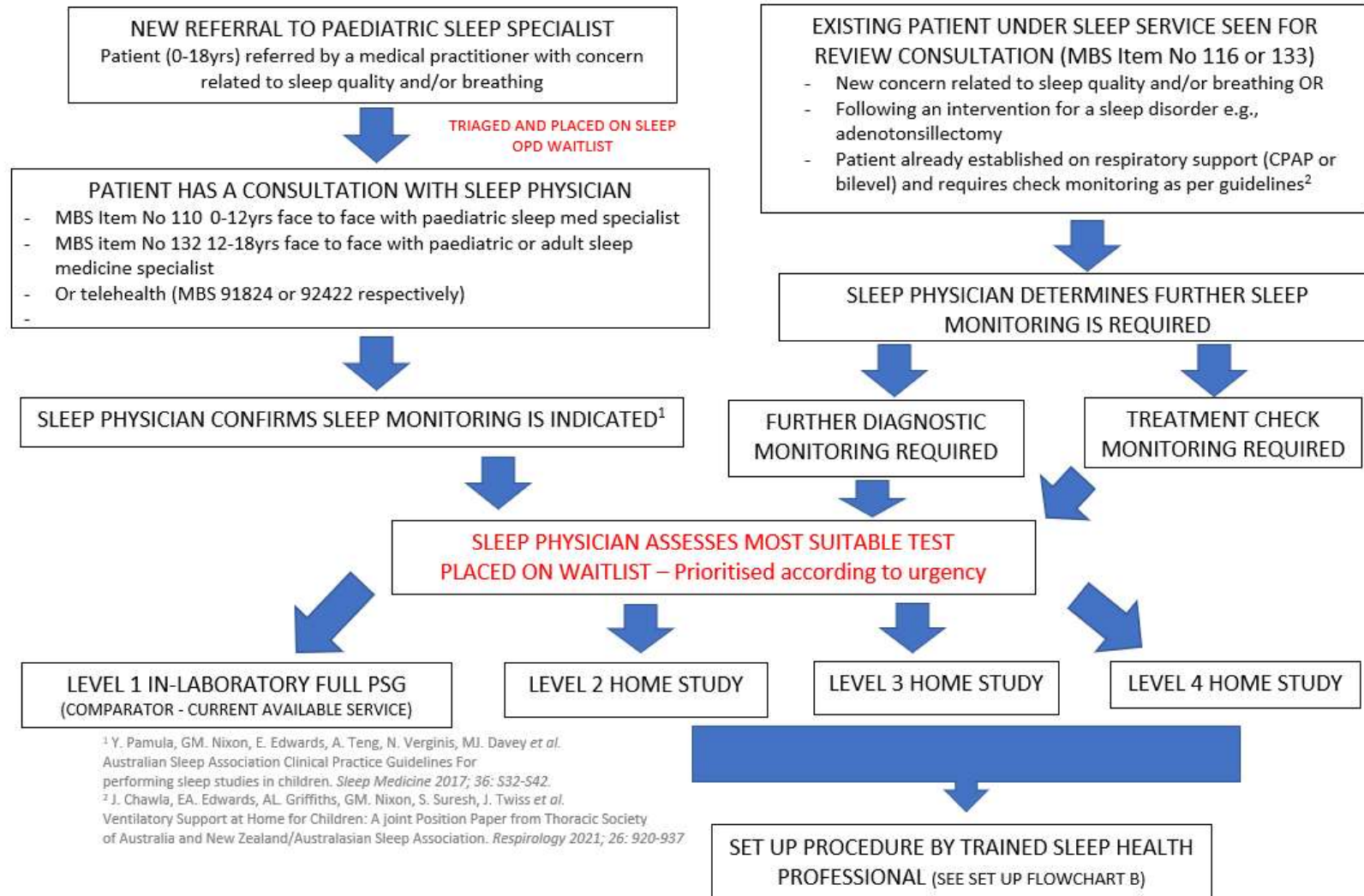
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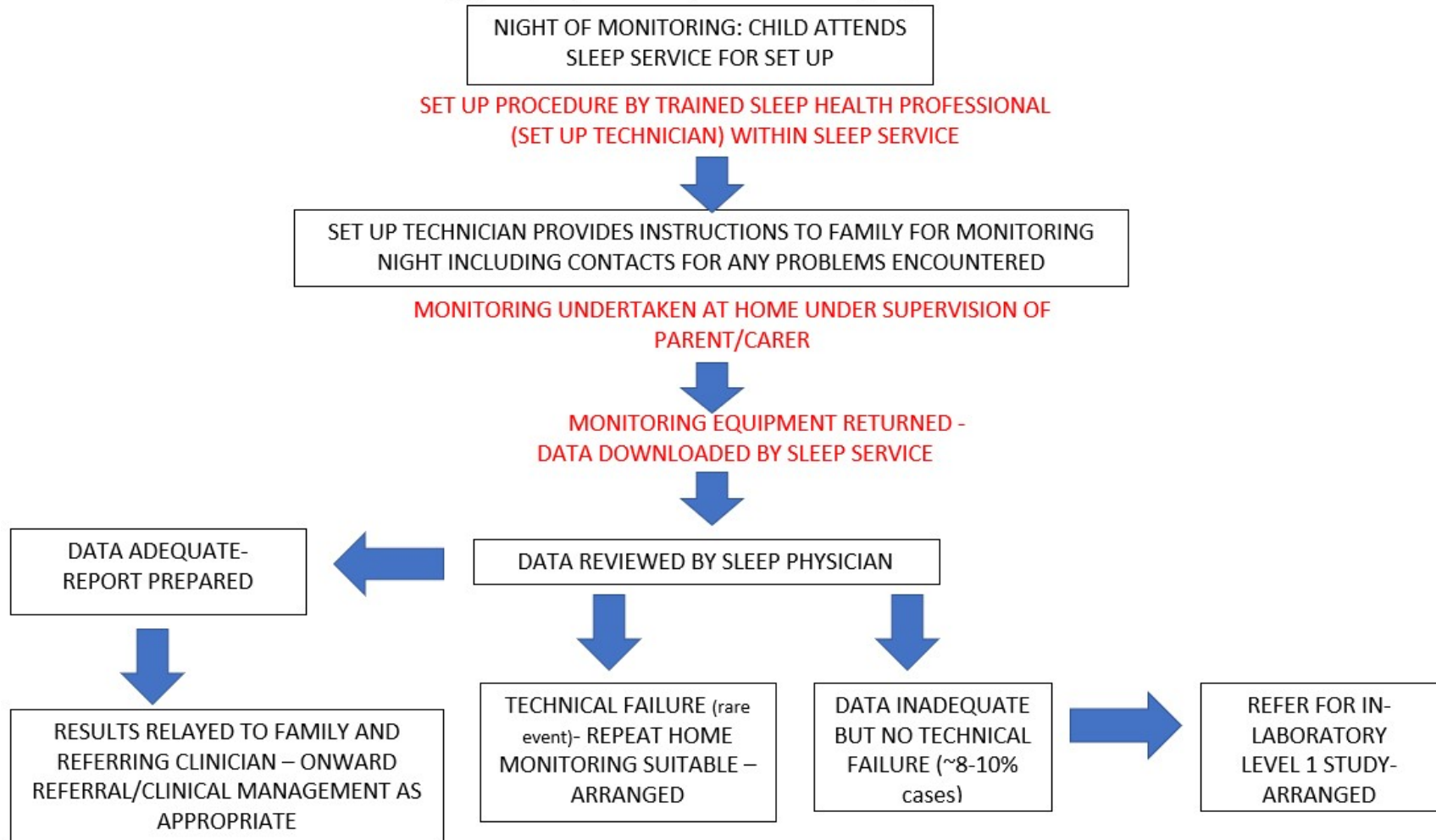
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Flowchart (A) q26 current clinical management pathway before patients would be eligible for proposed medical service



Flowchart (B) q27 key components and steps involved in delivering the proposed medical service



Flowchart (C) q40 Current clinical pathway after patient receives medical service nominated as the comparator

