

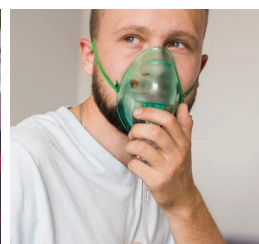
PUBLIC



ASAR

Australasian Severe
Asthma Registry

ANNUAL REPORT 2019



THORACIC SOCIETY OF AUSTRALIA AND NEW ZEALAND

AUSTRALASIAN SEVERE ASTHMA NETWORK

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PROGRESS UPDATE

SUMMARY

Severe Asthma is a public health concern responsible for significant illness outcomes and economic burden of disease in the Australasian region. Complex and heterogeneous in its presentation, severe asthma poses unique challenges to the clinical management of patients in healthcare settings.

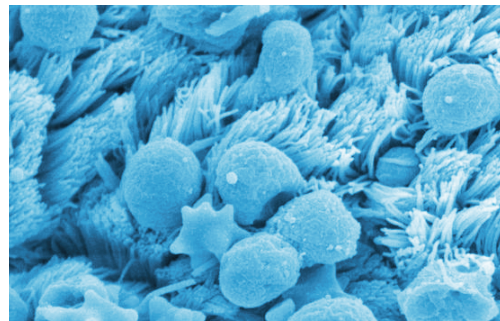
The Australasian Severe Asthma Network (ASAN) is a multi-national collaboration of health professionals with expertise in severe asthma. In 2019, the ASAN's Severe Asthma Web-based Database (SAWD) underwent a major transition to a clinical quality registry (CQR), the Australasian Severe Asthma Registry (ASAR). Prior to the transition, SAWD had registered 691 eligible patients between 2013 and 2017 across 26 sites in Australia, New Zealand and Singapore. These patients were categorised as either confirmed severe refractory asthma or non-severe controlled asthma as a comparison group and followed up for 2 years. This previously collected SAWD data has been retained and integrated into the new ASAR database. In transitioning to a clinical quality registry, extensive work has been undertaken to set up the ASAR database in addition to meeting project requirements.

The purpose of this report is to provide an overview of the transition of the registry from SAWD to ASAR. This report will also provide the final analysis of SAWD data prior to its transition to a CQR, ASAR. Finally, the status of ASAR and future directions will be described.

BACKGROUND

Severe Asthma

In Australia, it is estimated that one in nine people have asthma. International data estimates the prevalence of severe refractory asthma to be between 3% and 10% of the asthma population. Severe asthma is defined as asthma that requires treatment with high dose inhaled corticosteroids plus a second controller and/or systemic corticosteroids to prevent the disease from becoming "uncontrolled" or, asthma that remains "uncontrolled" despite this therapy. There is significant heterogeneity in the phenotypic characteristics of severe asthma and substantial complexity in the clinical management of people with severe asthma.



Scanning electron image of the bronchial epithelium

Not only is severe asthma medically complex, it is responsible for a significant burden of disease, healthcare costs and deaths. While accounting for only 3-10% of the asthma population, severe asthma consumes up to 50% of asthma-related healthcare costs. In 2015, the financial burden of asthma in Australia was estimated at \$1.2 billion, with economic costs totalling \$3.3 billion and overall burden of disease costing \$23.7 billion.

Severe Asthma Web-based Database (SAWD)

The Severe Asthma Web-based Database (SAWD) was established in 2013 with the program reaching funding completion in 2017. SAWD consisted of 1) a cross-sectional observational study, with a goal to describe the heterogeneity of severe asthma and characterise phenotypes and 2) a prospective cohort study focussed on identifying factors associated with future risk. SAWD also served as a research registry. Patients with confirmed severe refractory asthma and a non-severe controlled asthma comparison group were enrolled and extensively characterised and followed up for 2 years across 26 centres in Australia, New Zealand and Singapore. The success of SAWD lent itself to becoming an enduring clinically valuable registry and an agreement was reached to transfer governance of the project to the Thoracic Society of Australia and New Zealand (TSANZ). To preserve the data already collected, a collaborative approach was taken by the Australasian Severe Asthma Network (ASAN) and TSANZ under this agreement and in accordance with the Framework for Australian clinical quality registries.

Clinical Quality Registries

Clinical quality registries are increasingly utilised worldwide to routinely collect, analyse and report on specific clinical domains relevant to health outcomes. The utilisation of CQRs also enables the systematic monitoring of healthcare quality (appropriateness and effectiveness). The Australian Commission on Safety and Quality in Health Care (ACSQHC) has highlighted the healthcare value of Australian CQRs. The ACSQHC has a defined framework for CQRs within Australia which provides minimum standards for registry infrastructure including design, development, operational and security considerations. To identify as a CQR, registries must satisfy the detailed security, technical and operating standards to ensure the safety and security of confidential information collected. The regular reporting cycles employed by CQRs enable frequent feedback opportunities to identify and inform benchmarks and variations in clinical outcomes. Clinical quality registries are fundamental for reporting patient outcomes and ensuring compliance with existing evidence-based guidelines. Further, CQRs provide a foundation for continuous quality improvement including the development of new guidelines and standards of care and the dissemination of relevant information to interested parties.

TRANSITIONING TO A CLINICAL QUALITY REGISTRY - THE AUSTRALASIAN SEVERE ASTHMA REGISTRY (ASAR)

In 2019, TSANZ and ASAN worked collaboratively to transition SAWD into a CQR – the Australasian Severe Asthma Registry (ASAR). The primary focus of 2019 was the extensive administrative requirements and infrastructure development for the effective transition to a user-friendly CQR.

Key changes from SAWD to ASAR

Extension of the follow-up period: SAWD identified the need for long-term follow up and ASAR is now uniquely positioned to collect longitudinal data (10-year follow-up) on a well-characterised severe asthma cohort in Australia and New Zealand.

A primary dataset platform: the ASAR database has been setup with the capability to add modules of interest for example, specific data collection on patients who are on biologic treatments such as the Benralizumab Registry. This has significantly reduced data collection and entry burden for sites and is a very exciting new ability of the registry!

Method of consent: ASAR has implemented the use of opt-out consent as endorsed by the Australian Commission on Safety and Quality in Health Care endorsement for use in quality assurance activities including Australian CQRs.

Follow-up intervals: SAWD required data collection every six months. ASAR will follow-up patients once a year which reduces burden for patients and researchers.

ASAR REDCap database: built to reduce data entry burden, maximise usability, functionality and to streamline the dataset. External expert consultation was sought to develop the platform to cater for the specific requirements.

Data Collection

WHAT DATA IS COLLECTED:



ASTHMA DIAGNOSIS
CONFIRMATION
AND DURATION



COMORBIDITIES



LUNG FUNCTION



ASTHMA HISTORY



ASTHMA QUALITY OF LIFE



ALLERGY HISTORY



PATIENT-REPORTED
OUTCOMES



MEDICATIONS



SPIROMETRY



INHALER TECHNIQUE
AND ADHERENCE



BIOMARKERS



FREQUENCY AND TRIGGERS
OF EXACERBATIONS



NON-IDENTIFYING
DEMOGRAPHICS

REGISTRY GOVERNANCE

Governance is provided by the Thoracic Society of Australia and New Zealand (TSANZ) which has a reputation as a leader in lung health. In 2019, the ASAR Management Committee (Table 1) was formed and provides strategic and financial oversight, in addition to overseeing the clinical and academic aspects of the registry.

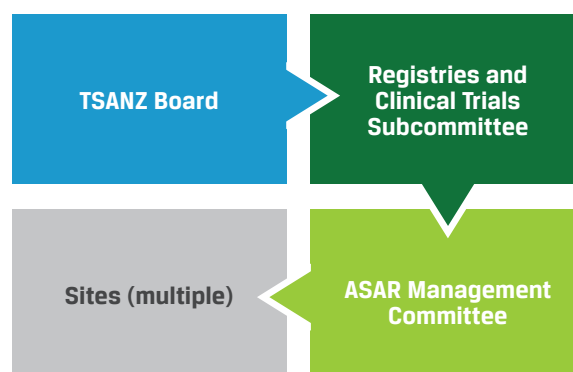


Table 1. TSANZ-ASAN ASAR Management Committee

Name	Position	Institution, State
Dr Peter Gibson (Chair)	Senior Staff Specialist	Hunter Medical Research Institute/ John Hunter Hospital, NSW
Professor Matthew Peters	Respiratory and Sleep Medicine Physician, Head Respiratory Medicine	Concord Repatriation General Hospital, NSW
Professor John Upham	Senior Respiratory Physician	Princess Alexandra Hospital, QLD
Professor Philip Bardin	Respiratory and Sleep Physician	Monash University and Medical Centre, VIC
Dr Gregory Katsoulotos	Consultant Physician and Senior Lecturer	St George & Sutherland Clinical School, UNSW Sydney, NSW
Dr Erin Harvey	Australasian Severe Asthma Network Project Manager	Hunter Medical Research Institute, NSW
Ms Ceri Banks	Clinical Research Nurse Consultant (Respiratory)	Frankston Hospital, Peninsula Health, VIC

In 2019, the TSANZ-ASAR operations team was formed. The ASAR operations team is responsible for coordinating the daily processes of ASAR including liaising with key internal and external stakeholders, site communication, data analyses and dissemination of information.

Table 2. TSANZ-ASAR Operations Team

Name	Position
Ms Tanya Buchanan	TSANZ Chief Executive Officer
Dr Hayley See	TSANZ Research and Policy Manager and Conjoint Lecturer, University of Newcastle
Dr Ezinne Igwe	TSANZ ASAR Clinical Research Analyst
Ms Laura Mitchell	TSANZ ASAR Project Officer

HUMAN RESEARCH ETHICS AND SITE GOVERNANCE APPROVALS

A substantial amendment was submitted to the Hunter New England Human Research Ethics Committee [Reference number: 12/11/21/4.04], the lead ethics committee, for the transition to ASAR. In March 2019, under the National Mutual Acceptance (NMA) scheme for sites within Australia, ASAR obtained ethics approval.

The primary ethics and governance focus of 2019 was to transition Australian sites from SAWD to ASAR. In 2020, there will be a substantial focus on progressing the registry in New Zealand.

ASAR sites in Australia

STATE

New South Wales* **8**

Victoria **2**

South Australia **1**

Queensland **1**

Western Australia **1**

*Lead Ethics site



FINAL SAWD DATA ANALYSIS: A SNAPSHOT

The final analysis of the SAWD data was undertaken in 2019 and is presented in the current report. Table 3 shows the number of patients enrolled in SAWD per year.

Table 3. Patient enrolment at baseline visit by year

Visit	Year						Total
	2013	2014	2015	2016	2017	2018	
Visit 1 (Baseline) (%)	20 (2.9)	205 (29.7)	160 (23.2)	194 (28.1)	103 (14.9)	9 (1.3)	691

A total of 691 confirmed eligible participants were enrolled in SAWD. To date, 313 participants have been followed up for 2 years and 404 have contributed data for the 18-month point.

Of the sample population, 70% (n=429) were classified as having uncontrolled asthma according to the GINA category. Of that number, 90% (n=389) were severe asthma patients. The sample population was 59% female (n=410) with a mean age of 58 years. Of the sample population, 35% (n=244) were ex-smokers and less than three percent were current smokers (2.7%, n=19).

OUTPUT

SAWD reports, presentations and publications

Type	Details	Date
Report	SAWD data report, Q4 2014 - preliminary baseline data (circulated to PIs and sponsors)	5th March 2015
Report	SAWD enrolment report, Q1 2015 (circulated to PIs and sponsors)	29th April 2015
Report	SAWD data report, Q3 2015 (circulated to PIs and sponsors)	1st Oct 2015
Poster	Harvey, E. et al., ASAN group, TSANZ Asthma & Allergy SIG 2 Poster Presentations: Characterisation of severe asthma phenotypes via a severe asthma registry: The Severe Asthma Web-based Database, <i>Respirology</i> 2016;21(issue S2):108-15. <i>Presented at the TSANZ ASM, Perth</i>	April 2016
Poster	Harvey, E et al., ASAN group, TSANZ Asthma & Allergy SIG 2 Poster Presentations: Severe asthma is associated with work productivity loss, activity impairment and reduced quality of life, <i>Respirology</i> (2016);21(issue S2):108-15 <i>Presented at the TSANZ ASM, Perth</i>	April 2016
Report	SAWD data report, Q4 2016	19th Dec 2016
PUBLICATION	Wang, G. et al. Severe and uncontrolled asthma in China: A cross-sectional survey from the Australasian Severe Asthma Network. <i>J Thorac Dis.</i> 2017; 9(5):1333-1344. doi: 10.21037/jtd.2017.04.74	May 2017
Oral Presentation	Hiles, S. et al. The Impact of Severe Asthma – Workplace productivity in the Severe Asthma Web-based Database. <i>Presented at the Newcastle Asthma Meeting (NAME), Newcastle</i>	27th Oct 2017
Oral Presentation	Hiles, S et al., TSANZ Oral: Working while unwell: Workplace impairment in people with severe asthma. <i>Respirology</i> 2018; 23 (Issue S1). <i>Presented at the TSANZ ASM, Adelaide</i>	27th March 2018
Oral Presentation	McDonald, V et al., TSANZ Oral: Severe asthma treatable traits: prevalence and exacerbation prediction. <i>Respirology</i> (2018) 23 (Issue S1). <i>Presented at the TSANZ ASM, Adelaide</i>	27th March 2018
PUBLICATION	Hiles, S. et al., Working while unwell: Workplace impairment in people with severe asthma. <i>Clin Exp Allergy.</i> 2018; 48(6):650-662.	June 2018
Poster	McDonald, V. et al., Identification of treatable traits in a severe asthma registry: prevalence and exacerbation predictors. <i>Presented at the ERS International Congress 2018, Paris</i>	18th Sept 2018
Oral Presentation	McDonald, V. et al., Treatable Traits in severe asthma. <i>Presented at the Newcastle Asthma Meeting (NAME), Newcastle</i>	25th October 2018
PUBLICATION	McDonald, V. et al. Treatable traits can be identified in a severe asthma registry and predict future exacerbations. <i>Respirology.</i> 2019; 24: 37– 47. doi: 10.1111/resp.13389	19 September 2018
Report	TSANZ-ASAN Severe Asthma Web-based Database (SAWD), Annual Report 2018 (circulated to PIs and sponsors)	December 2018
PUBLICATION	Bulathsinhala, L. et al. Development of the International Severe Asthma Registry (ISAR): A modified Delphi study. <i>The Journal of Allergy and Clinical Immunology: In Practice.</i> 2019; 7(2), 578-588. doi: 10.1016/j.jaip.2018.08.016	February 2019
Poster	Price, D. B. et al. (2019). Cross-Country Comparison of Demographic and Clinical Characteristics of Patients Managed in Severe Asthma Services Across UK, USA, Australia, South Korea, and Italy. In C44. <i>Asthma Epidemiology</i> (pp. A4899-A4899). American Thoracic Society	May 2019
Poster	Price, D. B. et al. (2019). International Severe Asthma Registry (ISAR): The Story so Far. In C44. <i>Asthma Epidemiology</i> (pp. A4900-A4900). American Thoracic Society.	May 2019
PUBLICATION	Denton, E. et al. (2019). Severe Asthma Global Evaluation (SAGE): An electronic platform for severe asthma. <i>The Journal of Allergy and Clinical Immunology: In Practice.</i> 2019;7(5), 1440-1449. doi: 10.1016/j.jaip.2019.02.042	May 2019
PUBLICATION	Eileen, W., Wechsler, M. E., Tran, T. N., Heaney, L. G., Jones, R. C., Menzies-Gow, A. N., ... & Cho, Y. S. (2019). Characterization of severe asthma worldwide: data from the International Severe Asthma Registry (ISAR). <i>Chest.</i> 157(4), 790-804. doi: 10.1016/j.chest.2019.10.053	Nov 2019

INTERNATIONAL COLLABORATION

The ASAR management committee and TSANZ executive have worked to explore collaborative opportunities with relevant stakeholders. In May 2019, TSANZ signed an agreement with the International Severe Asthma Registry (ISAR) as part of an international collaboration. This is a significant achievement for the ASAN and TSANZ. The ISAR is a global research initiative collecting anonymous longitudinal real-life data for the severe asthma cohort with collaborators from over 29 countries. The anonymous ASAR data will be contributed to this international dataset for ethically approved research. A global collaboration of this nature further demonstrates the importance of the ASAR not only regionally, but as contributors to the understanding of severe asthma on a global scale.

FUTURE DIRECTIONS – AUSTRALASIAN SEVERE ASTHMA REGISTRY

With the transition of SAWD to ASAR, as a Clinical Quality Registry there will be a key focus on continuous quality improvement of ASAR. Outputs from ASAR will help facilitate policies around severe asthma and subsequently, lung diseases. The ASAR will also foster collaborations within the ASAN and other external stakeholders.

The Australasian Severe Asthma Registry will also facilitate other projects within the severe asthma population. Specific modules of treatments, clinical and research interests may be added on to the ASAR Registry. A working example of this is the Benralizumab Registry. This has already been embedded within the ASAR database and follows patients with severe eosinophilic asthma being treated with Benralizumab.

Two pivotal aspects of ASAR are dissemination and collaboration. The ASAN and TSANZ will disseminate outcomes to patients, clinicians, researchers and interested stakeholders through newsletters, CQR reporting, publications, and presentations. In recognition of, and to facilitate ongoing collegial collaborations, TSANZ will host biennial ASAR summits. These summits will provide an opportunity for site personnel to connect, provide feedback and importantly, talk together about future directions of ASAR.

By following severe asthma patients as well as sub-populations within this group, ASAR will be well placed to be the first point of contact for all severe asthma questions in Australia and New Zealand. This will help improve patient care and provide evidence on policies around severe asthma management.

CONCLUSION

In conclusion, this report describes the progress that has been made in the SAWD transition to a CQR registry, ASAR. The TSANZ in collaboration with the ASAN have been proactive in progressing the registry and facilitating collaboration among sites and external stakeholders.

With support from clinicians, researchers, patient populations and external stakeholders, the ASAN is building a robust CQR that will contribute to improved patient care and management of severe asthma.

CONTACT ASAR

If you would like to register your interest to join ASAR or simply want more information, please email ASAR@thoracic.org.au or phone the TSANZ Central Office on +61 2 9222 6200.



ACKNOWLEDGEMENTS

The Thoracic Society of Australia and New Zealand in collaboration with the Australasian Severe Asthma Network have established the Australasian Severe Asthma Registry with the sponsorship of:





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