THE NATIONAL SUSTAINABLE ASTHMA CARE ROADMAP - ROUNDTABLE REPORT

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ACKNOWLEDGEMENT OF COUNTRY

Asthma Australia acknowledges the Traditional Custodians of the lands on which we work and pay respect to Elders past and present, and the Aboriginal and Torres Strait Islander peoples within the community. We recognise and respect the holistic concept of health for First Nations Peoples which embraces physical, social, emotional, cultural, and spiritual wellbeing, for both the individual and the community, and which encompasses the importance of connection to land, water, culture, spirituality and ancestry. We acknowledge and uphold the intrinsic connections and continuing relationships Aboriginal and Torres Strait Islander peoples have to Country and value the cultural knowledge, strength and resilience in our work to improve the lives of people with asthma.

FOREWORD

The National Health and Climate Strategy, released in December 2023, seeks to increase resilience to the health impacts of climate change and reduce greenhouse gas emissions from the Australian health system. Recognising the relationship between health and climate outcomes, it proposes a whole-of-government approach with 4 objectives: health system resilience, health system decarbonisation, international collaboration and health in all policies. Each objective contains a series of actions to be implemented over 5 years.¹

The health system decarbonisation objective commits to building 'a sustainable, high-quality, net zero health system' with a series of actions to reduce greenhouse gas emissions associated with care delivery. Among these is Action 4.14, which commits to improving respiratory health outcomes and reducing emissions from respiratory inhalers by working with consumers, the health sector and industry peak bodies.²

Asthma Australia partnered with Deakin University's Institute for Health Transformation to conduct 2 roundtables, engaging representatives from 50 key organisations who contributed to a collaborative and systematic approach to identify actions for reducing health sector emissions. This deliberate and consultative approach put people living with asthma at the centre of the conversation and prioritised improving their asthma with emissions reduction as a co-benefit.

The roundtable discussions were structured to understand the current drivers of asthma care's disproportionately large climate footprint. We identified the opportunities and barriers to improving care and reducing emissions and developed collaborative goals and actions. The resulting National Sustainable Asthma Care Roadmap can support the development of a national implementation plan, with input from health professionals, industry and consumers to improve asthma management, while concurrently transitioning to low greenhouse gas emission inhalers.

Asthma Australia supports action across all sectors to reduce greenhouse gas emissions, including the additional actions in the National Health and Climate Strategy. Here we present a consultative, strategic and feasible approach to delivering improved asthma outcomes and environmental co-benefits.

Asthma Australia would like to sincerely thank all stakeholders, organisations and representatives who contributed their time and insights to developing this Roadmap.

¹ Australian Government Department of Health and Aged	ed Care (2023) National Health and Climate Strateg	Į۷.
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² ibid.

EXECUTIVE SUMMARY

Representatives from 50 stakeholder organisations developed a roadmap towards improving the quality of asthma care in Australia while reducing the associated environmental footprint of respiratory inhalers.

One in 9 Australians has asthma, and unfortunately around half have poor control. Asthma is the leading disease burden for children aged between 5 and 14. The total costs of asthma to Australians, including the burden of disease, was estimated at \$28 billion in 2015.

Hydrofluorocrbon propellants used in current 'asthma puffers', called pressurised metered-dose inhalers (pMDI), are potent greenhouse gases, responsible for around 90% of the asthma healthcare footprint in the UK. This contribution is predominantly from the use and overuse of short-acting beta2-agonist (SABA) relievers such as salbutamol. Hydrofluorocarbons in pMDIs are estimated to be responsible for 13% of the UK National Health Service carbon dioxide equivalent (CO_{2e}) emissions related to the delivery of care and 3% of total health sector emissions. While a comprehensive assessment of Australia's total asthma care footprint is required, the greenhouse impact of the approximately 25 million inhalers sold in Australia each year, of which around 80% are high global warming potential pMDIs, can be estimated at over 600,000 tonnes CO_{2e} – similar to the emissions of 350,000 vehicles, 45,000 households or would require 60 million eucalyptus trees per year to offset the equivalent CO_2 emissions.

Thus, reducing the high rate of poorly controlled asthma and mitigating the environmental impact of pMDIs used to treat asthma represents a major unmet need. Compelling evidence shows that transitioning to anti-inflammatory asthma medication regimens delivered using low-carbon devices can improve person-centred asthma outcomes while simultaneously reducing greenhouse gas emissions. A coordinated and strategic approach is required to expedite the translation of this evidence into policy and practice.

In Australia, SABA pMDIs are the most widely used asthma medication, and SABA reliance and overuse is associated with worse asthma outcomes. Adherence with prescribed 'preventers' containing inhaled corticosteroids (ICS) is very poor. However, in recent years, asthma best practice evidence-based guidelines have fundamentally changed; they now recommend the use of a combination inhaler containing ICS and formoterol, a specific type of long-acting beta2-agonist (LABA) that has a rapid onset of action, as an anti-inflammatory reliever (AIR), instead of SABA.

With this strategy, low-dose ICS-formoterol is both the patient's reliever medication and their maintenance treatment (if needed). These regimens significantly reduce the risk of severe asthma exacerbation and the need for urgent health care compared with regimens that use a SABA reliever, making asthma management easier, safer and more effective for most adults and adolescents with asthma.

In Australia, ICS-formoterol is readily available in pMDI and in a range of dry powder inhalers (DPI), which do not require propellants and have a low carbon footprint. This presents a co-benefit opportunity to simplify asthma management, improve asthma outcomes for patients and the health system, and significantly reduce the overall carbon footprint of asthma care, particularly for those who choose a DPI.

About 2.5% of Australians have chronic obstructive pulmonary disease (COPD), many of whom require respiratory medications via an inhaler (which are available in pMDI, DPI and mist inhaler devices). A substantial proportion of people with COPD have diagnoses or features of both asthma and COPD (asthma+COPD).

While this report's recommendations focus on asthma, much of the above co-benefit opportunity applies to the full spectrum of obstructive airway disease, including COPD, asthma+COPD and preschool asthma/ wheeze.

For those who will continue to require a pMDI (particularly for acute care, and for young children and those with frailty), new HFC propellants are in development which have a lower greenhouse impact. Supporting a transition to lower-GWP HFC pMDIs will be another important step in reducing the carbon footprint of asthma in Australia. The timing of the introduction of these pMDIs in Australia and the cost to patients is not yet known, but action to address the carbon footprint of asthma care and related poor asthma outcomes in Australia cannot wait.

Asthma Australia partnered with Deakin University's Institute for Health Transformation to facilitate a system-oriented process to respond to Action 4.14 of the National Health and Climate Strategy: reducing emissions from respiratory inhalers. A series of stakeholder roundtables, held in-person as well as online, were attended by consumer representatives, researchers, health professionals (including from the Thoracic Society of Australia and New Zealand, Royal Australian College of General Practitioners and Royal Australasian College of Physicians), peak body representatives (including from the National Asthma Council Australia and Lung Foundation Australia), pharmaceutical industry representatives, and delegates from federal, state and territory government departments.

In the roundtables, participants considered what factors influenced asthma care quality and its environmental impact, and developed recommended goals and actions that governments (federal, state and territory) and system stakeholders could take to transform asthma care in Australia.

The collaborative goals identified by the 50 participating stakeholder organisations are summarised below.

Goal 1

Establish a data dashboard to display the national indicators of high-quality asthma care and decarbonisation trends – to monitor and evaluate progress towards improved asthma care quality and reduced associated greenhouse gas emissions.

A comprehensive assessment of Australia's total asthma care footprint is required. Recommendations include developing an agreed set of indicators and enhancing the collection of multi-source inhaler prescription and sales data, including privately and Pharmaceutical Benefits Scheme (PBS)-prescribed, hospital-dispensed, and over-the-counter asthma medications; stratifying prescription and sales data by inhaler type (to estimate the overall emissions burden of propellant inhalers); and integrating these new metrics with the clinical asthma outcomes currently reported as the National Asthma Indicators.

Goal 2

Establish processes and resources to support annual/regular updating of the national asthma guidelines and for harmonising secondary recommendations and clinical tools in consultation with peak asthma bodies – to inform and facilitate a national implementation strategy.

Supporting regular updating of the Australian Asthma Handbook, published by the National Asthma Council Australia, is critical to ensuring that the clinical practice recommendations are based on the highest quality and most recent evidence. Consistency between the AAH, other asthma guidelines available in Australia and secondary clinical resources will be essential to fostering knowledge translation, minimising confusion and improving care for people with asthma. Recommendations include developing and/or supporting mechanisms to review new evidence annually/regularly to support knowledge translation across different contexts (for example, primary care versus hospital care) and to different cohorts (for example, young children, adults with frailty) and to highlight low-carbon inhaler options.

Goal 3

Increase clinician education and digital enablement to implement evidence-based guideline-concordant, low-carbon asthma care, particularly the use of AIR regimens – to increase clinician knowledge and adoption of best practice in asthma care and sustainability; enabled by digital clinical decision-making, management and prescribing tools, in order to avoid SABA overuse, increase the use of ICS-containing medications, and reduce asthma exacerbations reduce asthma exacerbations.

Recommendations include launching a comprehensive national educational initiative for healthcare providers, focusing on evidence-based guideline-concordant care from the time of diagnosis, with the use of combination ICS-formoterol for anti inflammatory reliever (AIR-only), and maintenance and reliever therapy (MART) regimens, instead of SABA-based regimens; prescribing of low-carbon inhaler options where they are available for relevant medications and suitable for patient abilities; ensuring appropriate discharge planning after emergency department or hospital admission; designing and implementing integrated digital health tools such as asthma action plan templates and associated consumer information; and embedding these tools in practice management and electronic medical record software for primary, secondary and tertiary care.

Goal 4

Inform people with asthma about how to improve their asthma control and options to reduce greenhouse gas emissions from inhalers where suitable devices are available – to increase patient/consumer knowledge, empowerment and shared decision-making.

Recommendations include launching a research-informed, multimodal national public awareness campaign targeting people with asthma and the options for them to encourage their prescribers to transition to low-carbon alternatives where available and appropriate. This campaign would be augmented by the Therapeutic Goods Administration and other regulators setting requirements for environmental product declarations and standards for careful device labelling regarding the carbon footprint of inhalers.

Goal 5

Goal 5: Reduce the imbalance between cost and ease of access to SABA compared with safer and more effective medications – to support the implementation of evidence-based guidelines and thereby improve safety and disease control.

This is a priority as there is evidence that using more than two SABA inhalers in a year is a marker of poor control, and the risk of asthma exacerbations and mortality escalates as usage of SABA increases. While Goals 2, 3 and 4 recommend reducing SABA use by transitioning to guideline-concordant asthma care, stakeholders described the need for regulatory and supply mechanisms to support this.

Recommendations include reducing the quantity and number of repeats on SABA prescriptions (currently up to 2 inhalers per dispensing episode and 12 per prescription, with no annual limit) for safety reasons because this level of SABA use is associated with a marked increase in asthma mortality; prompts for medical review if the frequency of SABA use indicates asthma control is suboptimal; and considering monitoring and limiting the purchasing of over-the-counter SABA (while retaining emergency access). Other recommendations include re-evaluating consumer costs and PBS prescribing criteria of guideline-concordant medications (particularly ICS-formoterol) to ensure equitable access.

Goal 6

Goal 6: Support research to implement and evaluate high-quality sustainable asthma care – to inform a national implementation of evidence-based, guideline-concordant, low-carbon asthma care, with continuous improvement in asthma care delivery and environmental sustainability.

Recommendations include supporting mixed-methods research, such as qualitative studies and nationally representative surveys on patient and healthcare professional experiences, to produce recommendations for improving models of care; and supplementing this research with quantitative data monitoring to track progress towards co-benefit aims (as per Goal 1).

Goal 7

Reduce greenhouse gas emissions by minimising residual hydrofluorocarbon leakage from discarded asthma inhalers – specifically targeting propellant leakage from pMDIs disposed of in household waste.

Recommendations include involving other key stakeholders to develop and establish an effective nationwide program for collecting and appropriately disposing of pMDIs with the destruction of unused propellants; exploring funding options (such as a levy on high-GWP pMDI sales); and considering incentives for consumer participation.

Goal 8

Support governments in developing a 'health in all policies' approach to reducing the modifiable inducers and triggers of asthma – to improve air quality and reduce asthma triggers while also improving respiratory health for all.

Recommendations include establishing a working group with key stakeholders to consider a cross-sectoral, systems-oriented approach to reducing asthma triggers related to air quality and climate change, informed by evidence and health economic analyses; delivering education campaigns on common asthma triggers; and incentivising households to transition from gas to electric heating and cooking.

This Roadmap presents a compelling vision for the future of asthma care in Australia.

We urge government stakeholders to acknowledge the significance of this work, to partner with the peak asthma bodies, and invest in the necessary resources to translate these recommendations into a national implementation strategy that will deliver measurable impacts to improve the quality of life for people with asthma while reducing the associated carbon footprint.

DISCLOSURES

Funding statement

Deakin University and Asthma Australia developed this workshop series independently under a research agreement.

In compliance with Medications Australia's code of conduct, Asthma Australia secured funding for this initiative through unrestricted grants from AstraZeneca, Chiesi Australia, GSK and Orion Pharma Australia.

Deakin University provided in-kind support, contributing additional resources and expertise.

Statement of potential perceived conflict of interest

The principal author of this report, Dr Mike Forrester, is a practising paediatrician and theme leader of the Sustainable Health Network at Deakin University, who recognises there will remain an ongoing need for pressurised inhalers to be used with a spacer in some populations (such as young children) and clinical settings (such as acute hospital care).

Dr Forrester is a clinical adviser on an early-stage research project at Deakin University (School of Engineering, Biomedical and Environment) focused on developing a zero-global-warming-potential pressurised inhaler. This inhaler development project has received industry-partner investment and 'Trailblazer' co-funding via Deakin Recycling and Clean Energy Commercialisation Hub (REACH). Dr Forrester has not received any payment for this advisory work.

This involvement is disclosed in the interest of transparency. The principal investigators will disseminate project findings and progress through peer-reviewed publications.

The project team has identified no other potential conflicts of interest.

ABBREVIATIONS (GLOSSARY)

AIR Anti-inflammatory reliever

An asthma management regimen using as-needed combination inhaled corticosteroid and formoterol to relieve asthma symptoms by reducing bronchoconstriction (airway tightness) and airway inflammation. This combination used in AIR regimens reduces the risk of asthma attacks when compared with regimens with a SABA reliever (See background).

CO_{2e} Carbon dioxide equivalent

A unit of measurement used to compare emissions from various greenhouse gases based on their global warming potential. It may be expressed in kg or tonnes.

COPD Chronic obstructive pulmonary disease

DPI Dry powder inhaler

No propellant is used in these inhaler devices, so they have a minimal carbon footprint. They can be used without a spacer. They require a quick, deep breath in less than 3 seconds, optimally over 2–3 seconds. Suitable for children aged 6 and over, depending on ability.

EPD Environmental product declaration

GCAC Guideline-concordant asthma care (acronym used in systems map)

GHG Greenhouse gas

Atmospheric gases that trap heat and contribute to global warming.

GINA Global Initiative for Asthma

GINA publishes a global annual strategy, based on a review of the preceding 18 m evidence. It is funded only by the sale and licensing of its publications and resources.

GLOBE Global Centre for Preventive Health and Nutrition (Deakin University)

GMB Group model building

A facilitated workshop method designed to support rich discussion between multiple stakeholders, focusing on the system-level drivers of complex problems.

GWP Global warming potential

A multiple of carbon dioxide (CO_{2e}), GWP compares the warming effect of a greenhouse gas to the warming effect of the same mass of carbon dioxide over a specific time period, typically 100 years.

HFC Hydrofluorocarbon

A propellant used in pMDIs to pump out the medication from the chamber with each actuation (puff).

ICS Inhaled corticosteroids

Preventer medication, which decreases airway inflammation and reduces the risk of asthma attack. May be prescribed with or without LABA for regular maintenance use or, in combination with formoterol, as an anti-inflammatory reliever as part of AIR/MART regimens.

LABA Long-acting beta2-agonist

A longer-acting version of the 'reliever' medication that relaxes airway muscle constriction to reduce symptoms and improve lung function. Note that formoterol is both fast-acting and long-acting, suitable for use in ICS-LABA combination devices ideal for AIR and MART regimens.

MART Maintenance and reliever therapy

Regimen for using an ICS-formoterol combination medicine via inhaler for regular maintenance and the same device is used as a reliever when required.

NAC National Asthma Council Australia

National peak body, produces the Australian Asthma Handbook, the national asthma treatment guidelines and implements these by national workshops for primary care health professionals (the next edition of the Australian Asthma Handbook is currently in development).

NHS UK National Health Service

International leader on the 'green inhaler' transition.

PBAC Pharmaceutical Benefits Advisory Committee

An independent expert body that advises the Australian Government on which medications should be subsidised through the PBS.

PBS Pharmaceutical Benefits Scheme

A government program that subsidises the cost of most prescription medications, making them more affordable for Australians.

PEF Peak expiratory flow

Measure of the maximum speed of exhaled breath, used to assess lung function if spirometry is not available, or in home monitoring.

pMDI Pressurised metered-dose inhaler

Currently contains HFC propellant. All currently available pMDIs in Australia are high-GWP devices. Lower GWP pMDIs are in development using different propellant or different technology.

A pMDI should be used with a spacer for good deposition of medication into lower airways. A slow inhalation is required. Optimal for children age < 6, and some people with frailty and inability to generate adequate inspiratory flow to be able to use a DPI. There are two different inhalation techniques for use with a spacer: a single slow inhalation, or repeated small breaths; the latter is used during asthma attacks and for very young children.

SABA Short-acting beta2-agonist

'Reliever' medication that relaxes airway muscle constriction to reduce symptoms and improve lung function for 4 to 6 hours. It does not treat asthma, and regular use can make asthma worse. Salbutamol is the most common and in Australia it is only available in a high-GWP pMDI. Terbutaline is an low-carbon SABA; it is available only as a DPI but currently has restricted prescribing criteria for PBS funding.

SMI Soft mist inhaler

Referred to in GINA guidelines as 'mist inhalers'. A non-propellant device, currently available in Australia with only 2 medications that are not relevant to most people with asthma.

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1. BACKGROUND

1.1 Climate change is a threat to health

Climate change is considered the greatest threat to human health in the twenty-first century, and also our greatest public health opportunity (Lancet Climate Commission). The Intergovernmental Panel on Climate Change Sixth Assessment Report highlighted the rapidly closing window of opportunity to act, to secure a liveable and sustainable future for all, as current data shows a likely trajectory towards 3+°C mean global warming by the end of the century (IPCC AR6 H. Lee and J. Romero (eds.) 2023).

In Australia, there is an already alarming average warming of 1.4°C, with increased rates of bushfires and extreme weather events.

At the inaugural Health Day at the 28th UN Climate Change Conference (COP28), global leaders united in endorsing the 'health and climate change declaration', to which Australia is a signatory, sounding the alarm on the severe health implications of climate change (WHO- Climate Change & Health and Environment Climate Change & Health 3 Dec 2024).

1.2 The National Health and Climate Strategy

The Australian National Health and Climate Strategy (NHCS) outlines a whole-of-government plan to respond to the health and wellbeing impacts of climate change with the following objectives:

Objective 1 – (Health system resilience) Adaptation planning, strengthening health system resilience, ensuring equity of access and cultural safety.

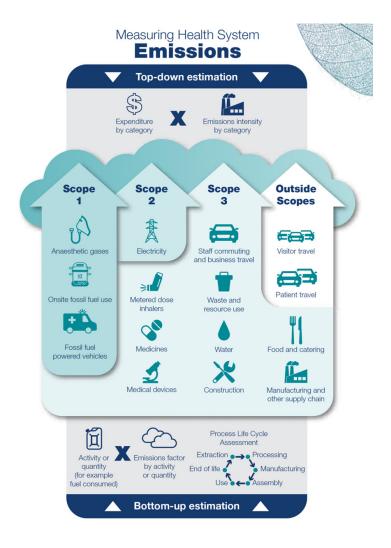
Objective 2 – (Health system decarbonisation) Mitigation planning, minimising environmental harm caused by the health system across Scopes 1, 2 and 3. Key actions are to:

- establish regular reporting of health system greenhouse gas emissions, so progress in reducing these emissions can be tracked over time
- develop a health system decarbonisation roadmap by 2025, and as part of this, negotiate an emission reduction trajectory for the health system, encompassing Scope 1, 2 and 3 emissions (see figure below). Government will seek to develop the Roadmap in partnership with stakeholders
- reduce health system emissions by reducing demand for care, keeping people healthy and ensuring appropriate, equitable delivery of care and tackling unwarranted variations
- decarbonise care delivery by tackling key sources of emissions: the built environment and energy; travel and transport; medicines and gases; food and catering; waste and resource use; and the supply chain.

Objective 3 – (International collaboration) To collaborate internationally to build sustainable, climate-resilient health systems and communities.

Objective 4 – (Health in all policies) To advocate for Health in all Policies (HiAP), by promoting the health cobenefits of emissions reductions across society and adaptation action beyond the health system to protect health and wellbeing from climate change.

(Figure 1 Scope 1,2 & 3 Emissions and methods of measurement- National Health and Climate Strategy (NHCS 2023).



1.3 Responding to Objective 4 of the Strategy

There is an opportunity to reduce asthma prevalence by reducing its inducers, while decreasing the incidence of asthma attacks by reducing triggers and aggravators.

The exacerbation of respiratory disease by the effects of climate change is significant, and individuals with asthma or COPD are among the most vulnerable. There is strong support from the lung disease community for a strategy to reduce air pollution and protect lung health (Asthma Australia 2022; Grigsby-Duffy 2023).

Climate change and its drivers increase incidence in Australia via several key mechanisms:

1. Air pollution:

- a. Bushfires: Increased frequency and intensity of bushfires due to hotter, drier conditions increases air pollution with fine particulate matter (PM2.5), which irritates airways and triggers asthma attacks. The smoke from the unprecedented 2019–20 bushfires in Australia was estimated to be responsible for over 400 excess deaths, over 2,000 hospitalisations for respiratory problems, and around 1300 presentations to emergency departments with asthma (Bui et al. 2021) (Borchers Arriagada et al. 2020).
- b. Traffic-related air pollution: Fossil fuel combustion in vehicles releases cytotoxic and pro-inflammatory pollutants, particularly PM2.5 and nitrogen dioxide. The latter has been estimated to account for 13% of global paediatric asthma incidence (Achakulwisut et al. 2019), and the Australian Children's Health and Air Pollution Study (KnibbsCortes de Waterman, et al. 2018) demonstrated a 4 ppb increase in NO₂ exposure was associated with a 54% increased risk of asthma prevalence in primary school-aged children.
- c. Ground-level ozone in smog: Rising temperatures accelerate ozone formation from pollutants emitted from other sources and is a potent lung irritant that exacerbates asthma symptoms (American Lung Association 2024).

2. Allergens:

- a. Pollen: Increased CO₂ levels enhance plant growth and pollen production, worsening asthma, especially during allergy seasons (Sly and Holt 2018).
- b. Mould: Increased ambient humidity and extreme weather events like floods and heavy rain create damp conditions, promoting mould spores which are a known asthma trigger, with an estimated 7.9% of childhood asthma estimated to be attributable to housing damp (Knibbs, Woldeyohannes, et al. 2018).

3. Combination impacts:

Thunderstorm asthma is likely to become more frequent and widespread as climate change advances. An epidemic in Victoria in 2016 caused 3,365 (672%) excess respiratory-related presentations to emergency departments and 476 (992%) excess asthma-related admissions to hospitals, 30 admissions to intensive care units and 10 deaths. This was thought to be due to a combination of high local pollen concentrations which, when ruptured by rain, released tiny allergenic granules what were then brought to ground level by thunderstorm activity and inhaled by sensitised people, two-thirds of whom were not using an ICS preventer (Kevat 2020; National Health 2023; Thien et al. 2018).

1.4 Current asthma management has a high carbon footprint

The 2 main contributors to the footprint are the healthcare resource utilisation related to the management of poorly controlled asthma and the footprint of HFC pMDIs. This presents a very real decarbonisation opportunity, both to reduce SABA overuse and to transition, where appropriate, from pMDI preventers to either DPIs or lower-GWP pMDIs (when they become available).

Currently, 57% of greenhouse gas emissions (15.2 million tonnes CO_{2e}) from health care in England is related to procurement and, of this, 24% (3.6 million tonnes CO_{2e}) is from pharmaceuticals(Jeswani, HA, A 2019, Nov). By far the largest contributor to the pharmaceutical footprint is from the HFC propellant used in asthma inhalers. The NHS estimates that the 'point of use' emissions of inhalers contribute 3% of the total footprint and 13% of the emissions related to delivery of care (UK National Health Service july-2022). The annual use of inhalers in the UK generates 1.34 million tonnes CO_{2e} , largely from HFC-134a inhalers (Jeswani, HA, A 2019, Nov).

The NHS estimates that a transition to low-carbon inhalers would have a larger health sector decarbonisation impact than transition to 100% renewable national health sector electricity supply (see Figure 2).

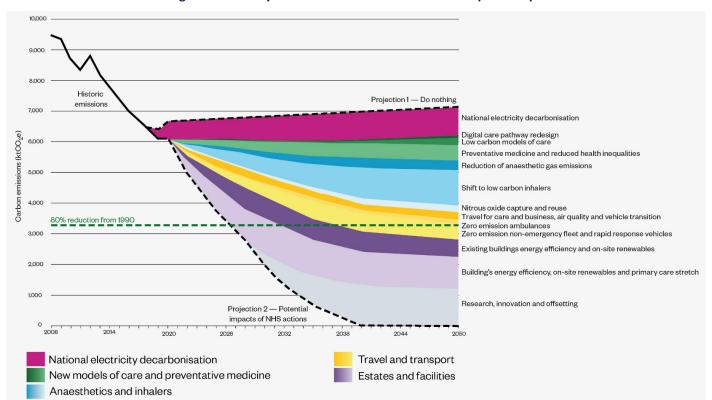


Figure 2 -Pathway to net zero for the NHS carbon footprint scope

Source: Reproduced on approval - (UK National Health Service July-2022)

1.5 Estimating the footprint of hydrofluorocarbon (HFC) propellant in Australia

Based on industry data supplied, we estimate there to be approximately 25 million inhalers sold in Australia each year. Around 10 million are preventer and combination medicines and approximately 15 million are SABAs, with an estimated 55% of these being purchased over-the-counter, without prescription.

About 80% of inhalers sold in Australia are currently pMDI, including almost all (98%) of SABA inhalers. Of preventer/combination inhalers, approximately 40 to 50% are pMDI. When assessed by medication, we see differences such as 60% of budesonide–formoterol inhalers sold in Australia are DPI, whereas only 20% of fluticasone–salmeterol inhalers sold are in DPI form.

Using this data, we can estimate the footprint of pMDI inhalers in Australia to be in the realm of 435,000 tonnes of CO_{2e} from SABA and 125,000 tonnes from preventer/combination inhalers, totalling 560,000 tonnes CO_{2e} from pMDI inhalers. Alternatively, estimating the Australian inhaler footprint by extrapolating from UK data, we expect the total pMDI footprint to be somewhere around 665,000 tonnes CO_{2e} .

If we use a median figure of 612,500 tonnes, for illustrative purposes, this is equivalent to the footprint of around 350,000 cars driving 12,000 km/year, or the emissions of 45,000 households (based on 13.5 tonnes average emissions per household in Australia). This would require about 28-60 million eucalyptus trees (the latter likely being a better estimate), to absorb the equivalent CO_2 each year (based on 10-22 kg/tree/year). (See Appendix D regarding the data, assumptions, calculations and caveats relevant to these estimates.)

1.6 Many people with asthma would consider the carbon footprint when choosing their inhalers

In 2023, Australia Institute's annual *Climate of the Nation* report indicated that 70% of Australians are concerned about climate change and its impacts (Morison 2023).

In the UK, as part of the NHS Annual Asthma Survey, asthma patients were asked about their knowledge and attitudes towards the carbon footprint of inhalers. Of 12,145 respondents, 65% were unaware of the high carbon footprint of pMDI, and 60% would consider changing device for a more environmentally friendly option. Of those surveyed, 85% responded that asthma patients should be encouraged to use lower carbon inhalers when asked specifically (yes/no), but only 42% prioritised the environmental impact, with more patients (appropriately) preferencing whether the new inhaler worked effectively, was easy to use, would not affect routine and whether they had the option to revert back to original treatment if needed. It is important to note that these survey responses may not reflect patient behaviour in consulting with their practitioner. Additionally, there were significant limitations in diversity of the demographic who responded (with the vast majority being female, aged 30 to 69 and Caucasian) (D'Ancona et al. 2021).

A New Zealand study on attitudes specifically to the global warming impacts of inhalers found that 44 out of 53 (83%) of patients agreed or strongly agreed that global warming is an important issue and 35 out of 53 (66%) considered the environmental impact of the health care that they receive (Woodall et al. 2023).

1.7 The future of low-GWP pMDIs

pMDIs previously used chlorofluorocarbon (CFC) propellants. The Montreal Protocol required the global phaseout of CFCs, including as propellants in pMDIs, due to their ability to destroy the ozone layer and the associated risks to human health and the environment.

HFCs were used as propellants in pMDIs to replace CFCs from the mid-1990s onwards. HFC-134a (GWP-100 year 1,530) and, to a lesser extent, HFC-227ea (GWP-100 year 3,600) are both used as propellants in pMDIs. HFCs, while not ozone-depleting, are greenhouse gases with substantial GWP owing to their ability to trap heat in the atmosphere.

The Montreal Protocol negotiated the Kigali Amendment to reduce the production and consumption of 18 HFCs used as replacements for CFCs, by more than 80% globally by the late 2040s. Through legal acceptance, Australia is bound by the Kigali Amendment, which entered into force globally in 2019. This requires Australia to phase down HFCs according to a schedule prescribed for developed countries (there are different HFC phasedown schedules for developing countries). pMDIs are one of many products where these controlled HFCs are used and account for less than 0.1% of total global greenhouse gas emissions.

Many pharmaceutical companies have committed to carbon-neutrality by 2030, recognising that this goal would be unachievable when emissions associated with high-GWP propellant pMDIs can constitute up to 45% of a company's carbon footprint.

Owing to these global concerns, new propellants for pMDIs are under development as alternatives to high-GWP HFC propellants The newly identified propellants have lower GWPs – HFC-152a (GWP-100 year 164) and HFO-1234ze(E) (GWP-100 year 1.37) – to the current HFC propellants. DPIs and SMIs remain as existing lower carbon footprint options in global strategies to reduce the carbon footprint of inhaler usage.

The intrinsic benefits in transitioning to low-GWP propellants, and the resulting opportunities to reduce the climate impact of inhaled therapy, are clear. HFC-152a has a GWP almost 10 times smaller, and HFO-1234ze(E) has a GWP more than 1000 times smaller, than HFC-134a. One life cycle carbon footprint study of inhalers showed that the carbon footprint of an HFC-134a pMDI could be reduced by 92% if replaced with HFC-152a propellant $(1,800 \text{ gCO}_{2e}/200 \text{ actuation inhaler})$ (Jeswani, H, Corr, S., Azapagic, A 2017, December).

Research and development of the new pMDI products is complex and involves a long process requiring clinical trials, regulatory approvals and a production transition to redesigned manufacturing lines. Three companies to date have each stated their intention to launch a product in 2025. To date, only 3 inhalers have entered clinical trials; many classes of inhaled therapies are yet to enter clinical trials; and only one company has announced reformulation plans for a salbutamol pMDI. Depending on the success of research and development, regulatory submissions and approvals, the first low-GWP propellant pMDIs may not reach the global market until after 2026 (UNEP 2024, May).

In late 2023, the European Medicines Agency issued a questions and answers document about the transition to pMDIs containing lower levels of GWP propellant (Agency 2023). Other medicines regulatory agencies globally are yet to issue formal guidance that might assist companies in understanding local requirements for the regulatory approval pathways in their countries. Regulatory agencies can smooth the transition to pMDIs with a lower GWP through the facilitation of these processes.

1.8 Current 'green' (low-carbon) DPI options available in Australia

DPIs re available for the main treatment classes for asthma in Australia (SABA, ICS, ICS/LABA, ICS/LAMA/LABA). There is a mist inhaler available for COPD—asthma.

To demonstrate the difference between inhaler footprints, in the UK it was estimated that replacing all pMDIs with DPIs would reduce the inhaler footprint by 94 to 96% (Jeswani, HA, A 2019, Nov).

UK NHS and 'Green Inhaler' researchers have demonstrated global leadership in developing resources to support shared decision-making regarding commencing or switching people with asthma to inhalers with a lower GWP, and this is a key part of the NHS Sustainable Development Unit's strategy. Wilkinson et al. note that "The British Thoracic Society recommended that prescribers and patients 'consider switching pMDIs to non-propellant devices whenever they are likely to be equally effective'; the UK's Environmental Audit Committee recommended the NHS set a target of reducing to 50% low-GWP inhalers by 2022; in January 2019, the NHS's long-term plan proposed a 50% reduction in the greenhouse gas emissions from inhalers in 10 years; and established an expert working group to evaluate potential strategies to achieve this "(Wilkinson et al. 2019).

The reduction in carbon footprint achieved by a person switching from regular pMDI use to DPI use (approximately 420 kg CO_{2e} annually) is similar to switching from a petrol car to a hybrid (approximately 500 kg CO_{2e} annually) or becoming vegetarian (approximately 660 CO_{2e} annually)^{5,6} – a substantial proportion of an individual's carbon footprint (Montgomery 2022).

Table 1 lists some of the inhaler options available in Australia by class, with estimates of the footprint per inhaler (noting that they do not all have the same number of dosages) and the PBS restrictions.

Class	Active ingredient	Trade names	Device type#	Propellant	Estimated footprint CO _{2e} (kg)	Cost to Government (July 2024)†	PBS restrictions
SABA	Salbutamol	Ventolin, Asmol, Zempreon	pMDI	HFA134a	28	\$25.13 - \$30.05 (2)	*
		Airomir	Autohaler (low volume pMDI)	HFA134a	9.7	\$41.45 (2)	Restricted benefit*
	Terbutaline	Bricanyl	Turbuhaler (DPI)		<1	\$28.13(2)	Streamlined Authority*
SAMA	Ipratropium	Atrovent	pMDI	HFA134a	14.3	\$34.61 (2)	
	Beclometasone	Qvar	pMDI	HFA134a	20	\$20.53 - \$28.32	
	Budesonide	Pulmicort	Turbuhaler		<1	\$30.14 - \$35.53	Restricted benefit
	Ciclesonide	Alvesco	pMDI	HFA134a	12	\$24.30 - \$33.24	
ICS	Fluticasone propionate	Flixotide, Axotide	pMDI	HFA134a	10-20	\$24.87 - \$40.97	
			Accuhaler (DPI)		<1	\$19.32 - \$30.78	
	Fluticasone furoate	Arnuity	Ellipta (DPI)		<1	\$30.29 - \$44.43	
	Fluticasone propionate/	Seretide, Pavtide,	pMDI	HFA134a		\$42.57 - \$56.40	Streamlined Authority
	Salmeterol	SalplusF, Evoair					Additiontry
ICS/LABA		Seretide, Pavtide, Salflumix	Accuhaler, Ciphaler, Easyhaler (DPI)		<1	\$42.57 - \$56.87	Streamlined Authority
Tooy Extent	Fluticasone propionate/ Formoterol	Flutiform	pMDI	HFA227	36.5	\$39.28 - \$51.57	Streamlined Authority
	Budesonide/ formoterol	Symbicort	pMDI	HFA227	34.4	\$42.29 - \$65.87	Streamlined Authority

Class	Active ingredient	Trade names	Device type#	Propellant	Estimated footprint CO _{2e} (kg)	Cost to Government (July 2024)†	PBS restrictions
	Budesonide/ formoterol	Symbicort, DuoResp, BiResp, Bufomix	Turbuhaler, Spiromax, Easyhaler (DPI)		<1	\$37.47 - \$64.93 (1 or 2)	Streamlined Authority
ICS/LABA	Fluticasone furoate/ vilanterol	Breo	Ellipta (DPI)		<1	\$58.49 - \$73.99	Streamlined Authority
	Beclometasone dipropionate/	Fostair	pMDI	HFA134a	10-20	\$38.29 - \$48.00	Streamlined Authority
	Mometasone/ indacaterol	Atectura	Breezhaler (DPI)		<1	\$37.97 - \$59.61	Streamlined Authority
	Beclometasone/ glycopyrronium/ formoterol	Trimbow	pMDI	HFA134a	10-20	\$79.93 - \$81.75	Streamlined Authority
ICS/LAMA/	Mometasone/ glycopyrronium/ indacaterol	Enerzair	Breezhaler (DPI)			\$73.22 - \$89.05	Streamlined Authority
LABA	Fluticasone furoate/ umeclidinium/ vilanterol	Trelegy	Ellipta (DPI)			\$89.13 - \$93.04	Streamlined Au- thority
	Budesonide/ glycopyrronium/ formoterol	Breztri	Aerosphere	HFA134a	10-20	\$78.97	Streamlined Au- thority

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Purple shading indicates low CO_{2e}

† Cost may vary with different strengths

Patient co-payments: General \$31.60, Concessional \$7.70

Safety net thresholds: General \$1647.90, Concessional \$277.50 from 1 September, asthma inhalers were eligible for 60-day prescriptions, halving the patient copayment for 1 month's supply.

Source:

 $\frac{https://ozone.unep.org/system/files/documents/MCTOC-Assessment-Report-2022.pdf}{https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/3-respiratory/the-environmental-impact-of-inhalers}$

 $\frac{https://www.blackcountryformulary.nhs.uk/docs/files/Inhalers\%20Carbon\%20Footprint\%20data.}{pdf?UNLID=9796729872024729101216}$

^{*} Available over-the-counter

Comparing DPI and pMDI efficacy and safety for management of asthma and COPD

A recent systematic review and meta-analysis compared the clinical efficacy and safety of inhaled asthma and COPD medications when delivered either by pMDIs or non-pMDI devices such as DPIs or SMIs (Loftus MJ 2024). The variables used for comparison between devices included peak expiratory flow (PEF) for asthma (24 studies) and forced expiratory volume in the first second (FEV₁) for COPD (7 studies). In adults and children with asthma, there was no statistically significant difference in PEF with non-pMDIs vs pMDIs (average difference 0.86 L/min (95% CI -1.19 to +2.90. In patients with COPD, there was no statistically significant difference in FEV, with non-pMDIs verses pMDIs (average difference 0.01 L (95% CI -0.01 L to +0.02 L (see Appendix C -Supplementary Figure S1)). For both asthma and COPD, the point estimates and the 95% confidence intervals for these differences were much less than the published minimal clinically important differences (the smallest improvement that would be perceivable by a patient) of 18.8 L/min for average daily PEF in asthma (Santanello et al. 1999) and 0.1 L for trough FEV, in COPD (Jones et al. 2014). An assessment of adverse events and serious adverse events also found no difference between inhaler types (see Appendix C - Supplementary Figures S2 and S3). This indicates that, at a population level, no difference in efficacy for lung function or in safety would be expected if patients received equivalent medications via DPIs or SMIs rather than pMDIs.

Assessing device preference and suitability 1.9

The 'greenest' inhaler remains the one that the patient can use correctly, and that will reduce their risk of SABA overuse, (the vast majority of which are high-GWP pMDIs in Australia) and of severe exacerbations requiring extra medical support and healthcare resource utilisation (Montgomery 2022; Levy et al. 2023).

A variety of inhaler devices are available for the treatment of asthma and COPD, and the choice of device for an individual depends on how the inhaler dispenses medication, drug formulation and dosing, coupled with patient education, understanding and ability (Usmani 2019).

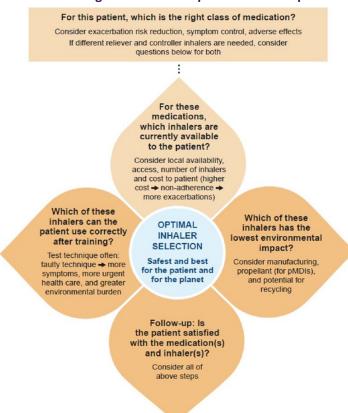
A retrospective combined analysis from the UK examined patient acceptability of devices, finding that 63% (of 339 randomised patients, across 3 double-blind trials) preferred DPIs compared to 28% preferring MDIs. The analysis showed that 67% of patients found the DPI easier to use and 82% rated the DPI dose counter as useful (Morice et al. 2022).

In the PRACTICAL trial, of those randomised to the GINA Step 2 budesonide-formoterol AIR regimen via DPI, 9 out of 10 patients expressed a preference to continue with this approach following the trial (BaggottReddel, et al.

A non-sponsored trial in Germany to compare preferences for commonly used inhaler devices found that while patient preference may vary between inhalers, DPIs were most preferred by patients after trialling a wide range of placebo devices. Patients were then asked 'which device would you prefer for everyday use?' The most popular class of inhalers were multi-dose DPIs, despite most patients in the study being pMDI users at time of enrolment (Schreiber et al. 2020).

Optimal inhaler selection should therefore include consideration of medication class, patient training and ability, and the environmental impact (see Figure 3).

Figure 3. GINA - Shared decision-making between health professional and patient about choice of inhalers



Source: GINA 2024, Box 5-1 Used by permission (GINA 2024)

Review the symptoms and objective evidence for the diagnosis Confirm Assess the patient's breathing in air, without an inhaler: Can the patient take a slow, steady breath in (taking 3 or more seconds)? Can the patient take a quick, deep breath within 3 seconds? Assess Consider the use of training devices to better assess ability Manages slow and steady Manages quick and deep + Consider a pMDI or SMI Consider a DPI Choose sider using an inhaler with a lower carbon footprint, being mindful that the 'greenest' inhaler is the one that the patient can and will use Inhaler device choices can have cost implications for the patient, which should also be explicitly considered Review Train Teach the specific inhaler technique with demonstration Ensure the patient is happy and that they know not only how Understanding to use the inhaler, but also what it is for and when to use it Provide materials such as links to inhaler technique videos. Support This is especially important for people switching inhaler types.

Figure 4. Inhaler Selection Algorithm

'The CACTUS model for the inhaler prescribing process for people over the age of six years'

Reproduced with permission from The Royal Australian College of General Practitioners from: Montgomery BD, Blakey JD. Respiratory inhalers and the environment. Aust J Gen Pract. 2022;51(12):929-934. Available at https://www1.racgp.org.au/ajgp/2022/december/respiratory-inhalers-and-the-environment

Note: Optimal DPI inhalation is a quick deep breath over 2-3 seconds, rather than < 2 seconds

The NAC and NPS have produced a helpful inhaler technique checklist.

1.10 Efficacy and usability of DPIs by school-age children

DPIs require appropriate technique and generation of sufficient peak inspiratory flow (PIF). It's accepted that most adolescent and adult patients can manage this. However, there is caution regarding their suitability for use in primary school-aged children (that is, between 5 and 11 years of age). This is reflected in discrepancies between national guidelines, with the Australian Asthma Handbook stating that a pMDI with a spacer should be first line choice in primary school-aged children(National Asthma Council of Australia), whereas recent guidelines from Wales state that a DPI should be considered first line in all children aged 6 years and over given 'they can be taken effectively with appropriate training' (Respiratory Heath Implementation Group 2023).

A recent systematic review examined the evidence regarding whether primary school-aged children could use a DPI with adequate technique (Kuek et al. 2024). The review identified 38 studies, 25 of which used PIF measurement as the outcome of interest, 10 used physician assessment, and 3 studies measured the efficacy of a DPI compared to an MDI with spacer. Of the 38 studies, only 5 included assessed children during acute asthma exacerbations.

The evidence demonstrates that most primary school-aged children can use a DPI. Fifteen studies examining the Turbuhaler (the most commonly used DPI) revealed 321 of the 398 participants (80.7%) generated a PIF of greater than 60L/min, which the most cited threshold for optimal Turbuhaler use. There were higher rates of adequate PIF for other DPI devices which require a lower PIF. For example, 194 of 201 participants (96.5%) were able to use the Diskus, which requires a PIF of >30L/min. A total of 13 studies evaluated other devices, including the Aerolizer, Easyhaler and Clickhaler, and found 77.5 to 100% of children could generate adequate PIF. Factors consistently associated with the ability to generate adequate PIF were older age (that is, closer to adolescence) and education. Studies that used physician assessment demonstrated that children frequently made errors when using a DPI, however the proportion who made errors was similar or less than when compared to an MDI and spacer. There was no difference in efficacy of treatments delivered via a DPI or an MDI and spacer.

Evidence regarding DPI use in acute asthma is limited. The systematic review found that many children. especially younger primary school-aged children, could not use a DPI adequately while experiencing acute symptoms. For example, in one study only 40% of 4- and 5-year-olds could generate sufficient PIF to use a Turbuhaler (Pedersen et al. 1990). Another study showed that no children 6 years or under could use a Rotahaler device during acute asthma (Ruggins et al. 1993). One acute care study of 112 children who had already been assessed as being capable of using a DPI found no significant difference in FEV,, heart rate and oxygen saturations when comparing children treated with terbutaline via DPI (Turbuhaler) verses pMDI in a moderate to severe asthma episode (Drblik et al. 2003).

Together these data show that the majority, but not all primary school-aged children, can use a DPI for maintenance treatment. Therefore, a DPI can be considered by clinicians caring for this age group, but alternate options such as an MDI and spacer must remain available.

1.11 The state of asthma care in Australia

One in 9 Australians has asthma (Australian Institute of Health and Welfare 2023b), a chronic respiratory disease that causes people to experience wheezing, breathlessness and chest tightness due to widespread narrowing of the airways. Good management can control the disease and prevent symptoms from occurring or worsening (National Asthma Council 2018), with therapies that are widely available and subsidised by the Australian Government.

Among all children 5 to 14 years of age, asthma is the leading cause of disease in Australia (Australian Institute of Health and Welfare 2022), causing both physical morbidity and a greater risk of developing anxiety (Garcia-Sanchez et al. 2023).

An Australian Institute of Health and Welfare (AIHW) data snapshot (Australian Institute of Health and Welfare 2023b)

- just under 2.8 million (10.8%) people had asthma in 2022 (compared to 4% prevalence globally) (To et al. 2012)
- in 2021–22, there were 25,480 hospitalisations for asthma, of which 90% were considered potentially preventable (AIHW 2023)
- people living in areas of most disadvantage were more likely to have asthma than those living in areas of least disadvantage (13.2% compared to 10.2%)
- of those with asthma:

- 2 in 3 (67.2%) of children had a written action plan
- only one in 4 (24.5%) of adults had a written action plan
- 27.7% of people aged 15 and over rated their health as fair or poor (compared to 19% for those with any other long-term health condition)
- 18% of people aged 40 and under met the definition for poorly controlled asthma (dispensed 3 or more reliever prescriptions per year)
- disability-adjusted life years (DALY) in Australia 5.34/1000 is unchanged from 2003 to 2023.

Data from more 7,868 health records of people with asthma in Australia indicates a high severe exacerbation rate and oral steroid-related burden of osteoporosis and sleep apnoea (Hancock et al. 2022). A cross-sectional survey of 2,686 adults found that 22.7% were classified as not well controlled and 23.4% as very poorly controlled. Of the participants with uncontrolled asthma symptoms, 23% used preventer medication less than 5 days a week, while 34% did not use any preventer, indicating a significant opportunity to improve asthma control and reduce the associated costs (Reddel et al. 2015). Of respondents who only used reliever medication for their asthma, one-quarter had needed urgent asthma health care in the previous year (Reddel, H. K. et al. 2017).

The mean level of adherence to ICS preventer was found in a systematic review to be between 22 and 63%, with improvement up to and after an exacerbation. Overall, 24% of exacerbations and 60% of asthma-related hospitalisations could be attributed to poor adherence (Barnes and Ulrik 2015).

Asthma remains one of the Australian Government's 10 priority chronic conditions requiring surveillance. Progress is monitored by the AIHW's National Asthma Indicators. Comparing 2017–18 data to 2020–21 data, emergency department presentations and hospital admission rates have decreased, with some of this improvement due to reduction in viral infections during Covid-19 restrictions, but there was no improvement in measures of suboptimal disease control or adherence to preventer medicines, and annual health expenditure on asthma continues to rise (\$851.7 million in 2021) (Australian Institute of Health and Welfare 2023c).

1.12 The Australian Asthma Handbook

The Australian Asthma Handbook is published by Australia's lead authority on asthma, the National Asthma Council Australia. The handbook provides best practice, evidence-based guidelines translated into practical advice for primary care health professionals, emphasising a team approach to asthma care.(National Asthma Council of Australia).

A guidelines committee oversees the handbook's development, comprising adult and paediatric respiratory specialists, general practitioners, a pharmacist and a nurse. The guidelines for the next edition of the handbook are currently under review.

1.13 International asthma treatment recommendations are fundamentally changing – safer, easier, with a lower carbon footprint

The first asthma guidelines were published from Australia in 1989 (Woolcock et al. 1989) in response to an epidemic of asthma deaths in the 1980s that was associated with high use of SABAs and low use of ICS (Abramson et al. 2001). The subsequent increase in use of ICS was associated with a marked reduction in asthma mortality (Marks et al. 2011). Decades of high-quality evidence have confirmed that ICS also reduced asthma symptoms, improved quality of life and reduced the risk of severe asthma exacerbations, even in patients with newly diagnosed mild persistent asthma (Pauwels et al. 2003).

1.13.1 The paradoxical preference for short-acting beta2-agonists (SABA) over ICS

Despite the clear evidence of benefit with ICS, adherence with ICS-containing medications in the community has always been poor. Many patients use SABA as their main or only asthma treatment, contributing to high ongoing rates of asthma attacks and the need for urgent health care (Australian Institute of Health and Welfare 2023b).

Patient preference for SABA is not surprising, given their extremely rapid effectiveness (within a few minutes) in relieving symptoms and bronchoconstriction. However, the effect of SABA lasts for only 4 to 6 hours and it does not actually *treat* asthma. Furthermore, research has established that regular use of SABA, as few as 2 to 4 times a day for as little as one to 2 weeks, is associated with increased airway hyperresponsiveness, increased

allergic response, increased airway inflammation and reduced bronchodilator effect (Cockcroft 2006). These factors can lead to a vicious cycle of SABA overuse.

In addition, starting treatment with SABA, as was recommended in guidelines for many years, trains the patient to regard SABA as their primary asthma treatment, making poor adherence almost inevitable when ICS medications are subsequently prescribed.

1.13.2 SABA overuse is common in Australia and is associated with increased risk of asthma attack

There is increasing evidence that SABA overuse is associated with an increased risk of severe exacerbations and asthma mortality. Dispensing of 3 or more SABA canisters in a year, an indicator of poor symptom control, is also associated with a doubling of emergency department presentations in both adults and children (Stanford et al. 2012) and, according to a study conducted in multiple countries, it is associated with an increased risk of severe exacerbations (Bateman et al. 2022). In a data linkage study in Sweden, dispensing of 11 or more canisters in a year was associated with a hazard ratio of 31.7 (11.9-84.7) for asthma-related death (NwaruEkström, et al. 2020).

SABA overuse in Australia is facilitated by the availability of SABA over-the-counter without a prescription and, by the fact that with an ordinary PBS-subsidised prescription, 12 SABA inhalers can be prescribed without medical review. In a recent survey, In a recent survey, more than 50% of Australian adults with asthma were prescribed 3 or more canisters of SABA in a year (Bateman et al. 2022) and, in a primary care study, 90% of patients issued with a SABA prescription could have received 3 or more inhalers in a year (Price, D et al. 2024). This study also confirmed the increased risk: patients reporting overuse of prescribed SABA experienced 2.52 (95% CI 1.73-3.70) times more severe exacerbations, with a similarly high risk among patients who obtained their SABA without a prescription (Price, D et al. 2024).

1.13.3 Patients with 'mild asthma' can also have severe or fatal attacks

Much attention in recent years has been on patients with difficult-to-treat or severe asthma, that is, patients who have frequent symptoms and exacerbations despite being prescribed medium- or high-dose ICS-LABA. In a recent nationally representative survey, patients with difficult-to-treat or severe asthma comprised 21.7% of 6,048 Australian adults with asthma and they were almost 5 times as likely as other asthma patients to have required urgent health care for their asthma (Davis et al. 2024).

However, what is often overlooked is that asthma exacerbations are not limited to patients with poorly controlled asthma or with SABA overuse; patients with infrequent or well-controlled symptoms can also have severe, life-threatening or fatal asthma exacerbations. For example, among patients presenting to an emergency department with an acute severe exacerbation, up to one-third had symptoms less than weekly in the previous three months (Dusser et al. 2007) and, in a study of asthma deaths in young people, 28% previously had sporadic mild symptoms (Bergstrom et al. 2008).

1.13.4 ICS are highly effective, but markedly under-used

In a large long-term study of patients with recently-diagnosed mild asthma, regular low-dose ICS reduced the risk of serious exacerbations requiring an emergency department visit or hospitalisation by almost half, even in patients with symptoms less than twice a month (Reddel, HK 2017)

Benefits like these were demonstrated in clinical trials, but adherence is difficult to achieve in community patients. Systematic reviews have reported that adherence by people with asthma is between 22% and 63% (Barnes and Ulrik 2015) and, in young people, it is 28% (Murphy et al. 2021). Overall, it is estimated that 24% of exacerbations and 60% of asthma-related hospitalisations may be attributable to poor adherence (Barnes and Ulrik 2015).

Factors contributing to ongoing poor adherence with ICS-containing inhalers in Australia and patient preference for, and reliance on SABA, include the availability of SABA over-the-counter without a prescription, the need for a prescription or authority prescription for ICS and ICS-LABA, their much higher cost, patient concerns about adverse effects of corticosteroids, and the need for daily treatment even when the patient has no symptoms. Many education and implementation programs have been undertaken, but improvements in adherence have been temporary at best.

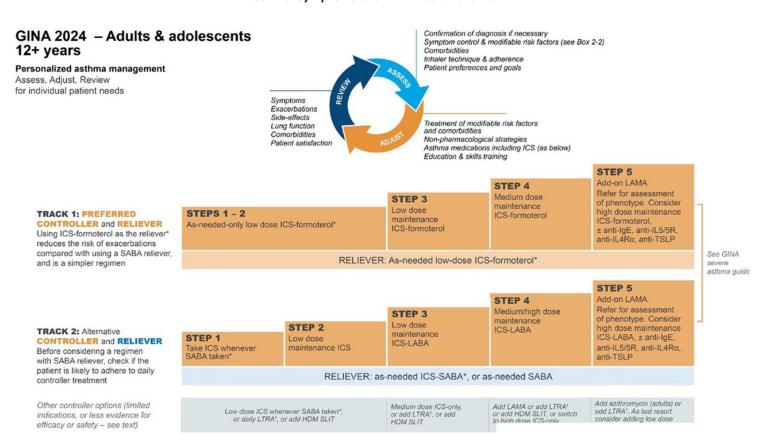
1.13.5 Anti-inflammatory reliever (AIR) and maintenance and reliever treatment (MART) recommendations are based on strong evidence from high-quality research

Research published in the 2000s using low-dose combination ICS-formoterol as both the patient's quick relief inhaler and their daily maintenance treatment ('maintenance and reliever therapy', or MART), demonstrated a significant reduction in severe exacerbations compared with regimens using the same or higher dose ICS, or ICS-LABA plus as-needed SABA, with similar symptom control and lung function (Sobieraj et al. 2018). This is possible only with ICS-formoterol.

This led to the concept of using low-dose ICS-formoterol as-needed-only for mild asthma. By 2019, this had been studied in almost 10,000 adults and adolescents with mild asthma (Bateman et al. 2018; Beasley et al. 2019; Hardy et al. 2019; O'Byrne et al. 2018). Based on the results, including a very large reduction in severe exacerbations with ICS-formoterol compared with SABA-alone treatment (O'Byrne et al. 2018), GINA made a fundamental change to asthma recommendations in 2019: that asthma in adults and adolescents should not be treated with SABA alone; instead patients with mild asthma should receive as-needed-only ICS-formoterol or (if likely to be adherent), daily ICS-containing therapy.

This change also provided a continuum of AIR therapy with combination ICS-formoterol across treatment steps from mild asthma to moderate-severe asthma. In 2021, with emergence of further evidence, this approach was recommended by GINA as the preferred treatment strategy, shown as 'Track 1' in the current GINA treatment figure for adults and adolescents (see Figure 5).

Figure 5. Asthma treatment steps in adults and adolescents – personalised management for adults and adolescents to control symptoms and minimise future risk



*Anti-inflammatory reliever. †If prescribing LTRA, advise patient/caregiver about risk of neuropsychiatric adverse effects. See list of abbreviations (p.11). For recommendations about initial asthma treatment in adults and adolescents, see Box 4-4 (p.75) and Box 4-5 (p.76). See Box 4-2 (p.71) for low, medium and high ICS doses for adults and adolescents. See Box 4-8 (p.84) for Track 1 medications and doses.

Source: GINA 2024 (GINA 2024) - Used by permission

GINA Track 1 (preferred) uses low-dose ICS-formoterol as the patient's reliever across all treatment steps, as-needed-only in mild asthma, and as maintenance and reliever therapy (MART) in moderate-severe asthma.

GINA Track 2- Because not all countries have access to ICS-formoterol, and because some patients are stable on and adherent with conventional ICS-containing therapy with an as-needed SABA, Track 2 is an alternative with the reliever as-needed SABA or as-needed ICS-SABA, but with a strong caution about the need for good adherence with ICS-containing maintenance therapy.

The GINA 'Track 1' recommendations are supported by evidence from multiple large randomised controlled trials and systematic reviews, with particularly striking benefits seen in reduction of risk of severe exacerbations, reduction in need for urgent health care, and reduction in exposure to long-term adverse effects of even occasional courses of oral corticosteroids (Price, DB et al. 2018).

Brief summary of AIR / MART evidence

Anti-Inflammatory Reliever (AIR)-Only- As-needed-only ICS-formoterol in patients with mild asthma, compared with as-needed SABA, reduces the risk of severe exacerbations requiring OCS by 65%, and reduces severe exacerbations requiring emergency department visit or hospitalisation by 65%, a very large population effect (Crossingham et al. 2021). As-needed-only ICS-formoterol also significantly reduces the risk of ED visit or hospitalisation for asthma by 37% compared to daily ICS plus as-needed SABA (Crossingham et al. 2021), with no clinically important differences in symptom control or lung function (Crossingham et al. 2021), or exhaled nitric oxide (Beasley et al. 2019; Hardy et al. 2019), and no new safety signals (FitzGerald et al. 2021). These benefits were independent of patients' baseline characteristics, including symptom frequency, lung function, history of exacerbations, and type 2 biomarkers (Beasley et al. 2019; Hardy et al. 2019), and were achieved with a substantially lower average dose of ICS (Crossingham et al. 2021), and without the need for daily medication. In qualitative research, most patients preferred the combination ICS-formoterol reliever than daily ICS plus as-needed SABA (Baggott, et al. 2020; Baggott, et al. 2020; Foster, J et al. 2022; Foster, JM et al. 2020). In all of these studies, the AIR was budesonide-formoterol 200/6 mcg Turbuhaler.

Maintenance And Reliever Therapy with ICS-formoterol (MART) in patients with moderate-severe asthma significantly reduces the risk of severe exacerbations requiring OCS compared with the same dose of ICS-LABA (32% reduction) or a higher dose of ICS-LABA (23% reduction) plus as-needed SABA (Sobieraj et al. 2018). MART also significantly reduces the need for asthma-related ED visits or hospitalisation by 25% compared with a higher dose of ICS-LABA plus as-needed SABA (Sobieraj et al. 2018). Symptom control and lung function were similar or better than in the comparator groups, despite using lower ICS doses. In open-label community studies of patients who were not required to have a history of exacerbations, MART significantly reduced the risk of severe exacerbations requiring OCS by 17% compared with conventional best practice (Cates and Karner 2013), MART is more effective than the same dose of ICS-LABA plus as-needed SABA even in patients with low baseline blood eosinophil count, and the magnitude of reduction in severe exacerbations increases further with higher blood eosinophil counts (Brusselle et al. 2021). Most of these MART studies used budesonide-formoterol 200/6 mcg via DPI (Turbuhaler), with one study using budesonide-formoterol 200/6 mcg pMDI (Patel et al. 2013), and one using beclometasone-formoterol 100/6 mcg pMDI (Papi et al. 2013).

To date, as-needed-only budesonide-formoterol is approved for treatment of mild asthma by regulators in about 50 countries. MART with budesonide-formoterol has been approved for many years in over 120 countries (since 2007 in Australia) and, in some countries, also with beclometasone-formoterol.

Additional considerations supporting GINA 2024 Track 1 recommendation for AIR therapy with ICS-formoterol across treatment steps

- 1. Airway inflammation is treated from the time of diagnosis, rather than waiting for patients to develop more persistent symptoms and lower lung function.
- 2. As-needed ICS-formoterol provides both rapid symptom relief and risk reduction. Patients with infrequent asthma symptoms (often called mild asthma) can still have severe or even fatal asthma exacerbations. The risk of severe exacerbations is dramatically reduced with as-needed ICS-formoterol (Crossingham et al. 2021).
- 3. Starting treatment with an AIR completely avoids SABA reliance and SABA overuse. By contrast, starting treatment with SABA effectively trains the patient to regard it as their main (or only) asthma treatment.
- 4. AIR therapy provides a simple treatment regimen, using ICS-formoterol for symptom relief, maintenance treatment (if required), before exercise (Lazarinis et al. 2014) and before or during allergen exposure if needed (Duong et al. 2007) across treatment steps. This greatly simplifies asthma pharmacotherapy for adults and adolescents, avoiding the need for at least 2 inhalers (as with conventional SABA-based asthma therapy), and avoiding the sequential changes in medications (and often inhaler devices) with a conventional treatment algorithm if treatment needs to be stepped up. By contrast, changes between AIR-only treatment and MART can be achieved seamlessly, with a single medication.
- 5. AIR therapy mitigates the effects of poor adherence, by ensuring that patients always receive some ICS whenever they use their reliever inhaler.
- 6. AIR therapy provides an integrated asthma action plan, with no need for an additional medication to be added when asthma worsens. Templates for <u>AIR-only/MART action plans</u> were first developed in Australia and are available in many translations.
- 7. AIR-only or MART by DPI provides the lowest carbon footprint of any asthma management regimen by eliminating use of SABA pMDI and reducing health care utilisation (Hatter et al. 2024; Pernigotti et al. 2021).
- 8. ICS-formoterol formulations are widely available from several manufacturers, often as a DPI, and there is extensive post-marketing experience as MART is approved by regulators in over 120 countries, including Australia since 2007, and AIR-only has approval in over 50 countries, including Australia since 2020., and AIR-only has approval in over 50 countries).

1.14 Adolescent (12+) – anti-inflammatory reliever therapy (AIR-only or MART) recommendations are the same as for adults

GINA and the Australian Paediatric Improvement Collaborative guideline recommend anti-inflammatory reliever therapy (AIR-only or MART) for adolescents, as for adults.

As-needed-only ICS-formoterol in adolescents: two studies with 889 adolescents with mild asthma showed similar benefits as in adults: a large (77%) reduction in severe exacerbations compared with as-needed SABA, and a similar exacerbation rate as with daily ICS plus as-needed SABA, with a lower average ICS dose (Reddel et al. 2021). In younger adolescents, change in height from baseline was greater with as-needed-only ICS-formoterol compared with daily ICS (Reddel et al. 2021).

MART in adolescents: evidence from pooled results for 1,847 adolescents in 6 randomised control trials showed a significant reduction in severe exacerbations (pooled hazard ratio 0.49 [0.34–0.70]), with similar safety as in adults (Jorup et al. 2018).

1.15 Evidence and guidelines are evolving for primary school-age children for **AIR and MART regimens**

For children goed 6 to 11 years, the only study of MART to date found a large reduction in severe exacerbations requiring oral corticosteroids with budesonide-formoterol 100/6 mcg Turbuhaler one inhalation once daily plus one inhalation as-needed compared with the same dose of budesonide-formoterol taken once daily plus asneeded SABA, or 4 times higher dose of budesonide plus as-needed SABA (Bisgaard et al. 2006; O'Byrne et al. 2005). Multiple studies of AIR-only and MART are underway regarding the AIR regimen with budesonide-formoterol in primary school-age children.

An earlier, more cumbersome version of anti-inflammatory reliever therapy was examined in 2 small randomised controlled trials in children and adolescents, using separate ICS and SABA inhalers. In the double-blind doubledummy TREXA study, children with mild persistent asthma were randomised to as-needed SABA-alone, twice daily ICS and as-needed SABA, as-needed ICS plus SABA (taking ICS whenever SABA was taken), or twice daily ICS and as-needed ICS plus SABA. When compared to the as-needed SABA-alone group, all 3 ICS containing trial arms had reduced frequency of severe asthma exacerbations (Martinez et al. 2011). An open-label study of African-American primary school-aged children demonstrated that taking ICS whenever SABA was taken provided similar asthma symptom control (measured by the Asthma Control Test), lung function and exacerbation frequency when compared to physician-adjusted daily ICS treatment plus as-needed SABA, and with less overall steroid exposure (Sumino et al. 2020).

While not an evaluation of an AIR or MART regimen, the START study compared daily low-dose ICS compared to a placebo in children with mild persistent asthma with symptom onset in the last 2 years, showing that daily ICS reduced severe exacerbations by 40% as well as reducing days away from school, increasing symptom-free days and improving lung function (Chen et al. 2006; Pauwels et al. 2003). Together these studies suggest that in primary school-aged asthma, SABA-alone regimens are suboptimal.

This is reflected in some guidelines such as GINA (GINA 2024), which recommends all primary school-aged children with asthma should receive ICS, either daily or, for children with infrequent symptoms, taking ICS whenever SABA is taken. The Australian Paediatric Improvement Collaborative recommends that only the children with the very mildest asthma with no risk factors for severe exacerbation use SABA alone. The Australian Asthma Handbook currently has a higher threshold for commencing ICS in this age group.

There are significant implementation challenges that need to be addressed in Australia. For example, asneeded-only budesonide-formoterol is not approved for children under 12 years of age, and budesonideformoterol MART and AIR-only regimens are not subsidised by the PBS for the primary school-age group. Furthermore, using ICS whenever SABA is taken can be challenging as 2 separate inhalers are needed, which is cumbersome and leaves the potential for selective adherence with the SABA inhaler. This regimen has not been evaluated during acute asthma exacerbations in any age group.

In the preschool age group, there are no completed trials of AIR or MART regimens.

1.16 AIR and MART regimens via DPI –an opportunity to reduce the footprint of low-value care and the greenhouse gas emissions of current pMDIs

In the landmark SABINA CARBON study, data was derived from half a million primary care asthma patients with linked hospital episode data, to assess the footprint of all aspects of their care: inhalers, primary care visits, other medications and emergency stays/admissions, including intensive care units. Ninety per cent of the greenhouse gas emissions of asthma care were due to the inhalers (60% from SABAs and 30% from the ICS-containing preventers). Surprisingly, only 5% of the footprint was due to health care resource utilisation and 5% was due to other medications involved in treatment. The carbon footprint of asthma care was about 3 times greater when asthma was not well controlled (Wilkinson, A 2021; Wilkinson et al. 2024), reinforcing the concept that low-value care is high-carbon care (see Figure 6).

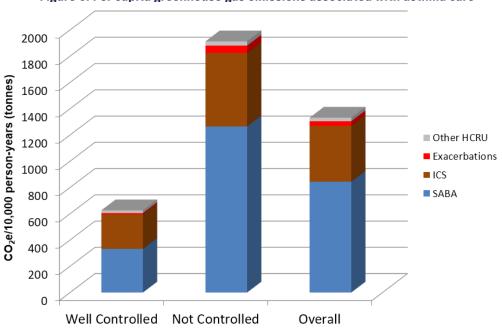


Figure 6. Per capita greenhouse gas emissions associated with asthma care

 $Source: Author's \ graph \ reproduced \ by \ permission-Results \ from \ SABINA \ CARBON \ study \ (Alexander \ Wilkinson \ 2021 \)$

Participants in the Novel START trial were randomised 1:1:1 to treatment with: as-needed budesonide—formoterol DPI, as-needed salbutamol pMDI, or maintenance budesonide DPI plus as-needed salbutamol pMDI. As-needed budesonide—formoterol DPI was associated with a 95.8% and 93.6% lower carbon footprint compared with as-needed salbutamol pMDI and maintenance budesonide plus as-needed salbutamol pMDI respectively (Hatter et al. 2024).

Though not a MART trial, the Salford study reported improved asthma outcomes with a reduced footprint. In this study, 2,236 primary care patients were randomised to continue usual maintenance treatment including a range of pMDI preventers, or DPI maintenance ICS-LABA with pMDI SABA reliever. Patients randomised to DPI-based fluticasone-vilanterol maintenance had consistently superior disease control and a greater than 50% reduction in inhaler carbon footprint compared with those on a pMDI-based maintenance ICS. Both groups continued with SABA reliever pMDI, accounting for the majority of the residual footprint (Woodcock et al. 2022).

The <u>SENTINEL program</u> in the UK aimed to identify and address SABA overuse through supported asthma guideline implementation prioritising MART, within 6 English primary care networks. Prescribing data were analysed for adult asthma patients (n=2,571). The data shows reduced SABA use and fewer exacerbations post-implementation. The carbon footprint of asthma prescribing fell by 38% post-SENTINEL, 85% of which was achieved through SABA reduction and 15% due to increased DPI use. SABA accounted for 65.5% of the carbon footprint of asthma prescribing 12-months pre-implementation and then 53.1% 12-months post-implementation (Publication pending- Crooks, (M G Crooks 2024). Within the subgroup of patients who transitioned to MART, SABA prescriptions reduced, with a corresponding 52% decline in frequent (≥ 3 exacerbations) in the same period (Crooks et al. 2023).

A health economic analysis of the SENTINEL program is underway. As budesonide—formoterol has now been approved for the AIR regimen in the UK, the next phase of the program will support people with milder asthma to transition to as required anti-inflammatory-reliever (AIR-only), to further reduce SABA reliever overuse.

2. METHODOLOGY

2.1 **Aims**

This system-oriented stakeholder roundtable series was hosted by peak consumer body Asthma Australia, conceived in conjunction with Doctors for the Environment Australia, and developed and facilitated by researchers from the Sustainable Healthcare Network and Institute for Health Transformation, Deakin University.

The roundtable series aimed to:

- 1. Foster stakeholder consensus: Share and critically assess relevant evidence, gather diverse participant insights and establish a shared understanding of the potential co-benefits associated with addressing the high emissions footprint of asthma care in Australia.
- 2. Map system drivers: Collaboratively develop a comprehensive system map to identify and analyse the key drivers contributing to the high emissions footprint of asthma care in Australia, considering environmental, social, and economic factors.
- 3. Develop actionable recommendations: Collectively generate evidence-informed, high-impact implementation goals and strategies to achieve improved asthma care with a significantly reduced environmental impact; focusing on practical solutions and actionable steps for stakeholders across the healthcare system.

2.2 Roundtable workshops as the preferred approach

The use of roundtables was determined the most effective methodology to engage stakeholders to develop a 'system map' of the drivers of asthma care's current high carbon footprint. Using techniques from a participatory approach called group model building these maps were then used to develop recommendations about how to improve the quality of asthma care and reduce the associated greenhouse gas emissions.

Stakeholders in the roundtables were asked to consider the following question:

'How can we improve the quality of asthma care in Australia and reduce the climate impact of this care'?

Identifying roundtable stakeholders 2.3

Asthma Australia, in consultation with other key stakeholders across Australia, identified and invited participants to the roundtables. Invited stakeholders included a broad range of organisational representatives from the healthcare sector, peak bodies, professional societies, pharmaceutical companies, government, and consumer representatives.

Two in-person roundtables and two online alternatives were convened. Participants in the first roundtable included a smaller group of representatives from organisations with input into asthma care delivery in Australia and its potential climate impact. The second roundtable included a broader group of stakeholders identified for their potential to influence asthma care through their work in research, policy development, health care service delivery, or other relevant expertise.

Participants who could not attend the in-person roundtable workshops were invited to participate in an online session following roundtables 1 and 2.

2.4 Conducting roundtables

The roundtable used participatory approaches designed by the Global Centre for Preventive Health and Nutrition (GLOBE) at Deakin University. The systems-science approach included group model building (GMB), a facilitated workshop method used to support rich discussion between multifiple stakeholders focusing on the system-level drivers of complex problems.

The main outputs of this approach are:

- a visual system map describing the interconnected drivers of the problem, as described by workshop participants
- recommended actions in response to the problem drivers identified in the visual system map.

Roundtable 1 activities included an evidence pre-brief followed by stakeholder collaborative activities, including describing the relationships between variables (connection circles) to develop the system map and developing the initial stakeholder system-oriented priority recommendations (action capture).

Roundtable 2 incorporated an evidence pre-brief, a review of the systems map to inform the generation and prioritisation of focused, high-impact action ideas, and the formation of smaller working groups that considered the feasibility and fit of their chosen potential action, using the National Implementation Research Network's hexagon.tool.org/ and the collective impact framework.

The purpose of using these methods, tools and framework was to efficiently establish:

- system-oriented stakeholder insights
- a common agenda for change
- co-developed recommendations (goals and actions) to inform the development of a national collaborative co-benefits-oriented asthma care implementation program.

The insights from participants in each roundtable were used to build a visual systems map that presented the factors that influence the quality of asthma care in Australia and the greenhouse impact of this care. Throughout each of the roundtables notetakers were tasked with capturing the discussion at each table (in-person roundtables) and in the online forums.

These notes, in addition to annotations made to paper copies of the draft visual systems map provided to the roundtable participants in each session, were then used to further develop and refine the visual systems map, including identifying themes for the factors included.

Paper-based collective impact framework documents were transcribed and refined (using insights from the research team) to develop the final goals and recommendations for future action. Before publication, these were shared with stakeholders for review to ensure they represented the collective insights.

Three participants who expressed interest but could not attend in-person or online roundtables were contacted for a subsequent one-on-one consultation to share their insights.

Thirty-three people participated in Roundtable 1 in person, six subsequently online, fifty-seven participated in Roundtable 2 in person, and eleven attended subsequently online, with fifty different organisations engaged.

(A complete list of roundtable participants is provided in Appendix A.)

Figure 7. Sustainable Asthma Care Roundtable Series process

Online roundtable briefing #1: overview of activities and outputs and invited to add input Online roundtable briefing #2: overview of activities and outputs and invited to add input

Roundtable 1 (Nov '23) GMB workshop #1 (am)

#1 (am) #2 (pm)

Roundtable 2 (March '24) GMB workshop #3 (am & pm)

Recommendations for action

Engage participants and create an initial systems map (graphs over time and connection circles activity) Revise and develop insights captured in systems map (model review, model update activities)

Roundtable 1

(Nov '23)

GMB workshop

Engage a broader group of stakeholders, identify and prioritise actions using systems and implementation science methods (map presentation, action ideas activities)



3. STAKEHOLDER INSIGHTS

3.1 Drivers of the high carbon footprint of asthma care in Australia

The map developed throughout the roundtable series shows the interconnected drivers of the complex challenge of improving the quality of asthma care in Australia while simultaneously reducing the climate impact of this care (Figure 8).

To further understand the relationship between the variables included in the map, these relationships were categorised according to one of the seven themes identified by the research team.

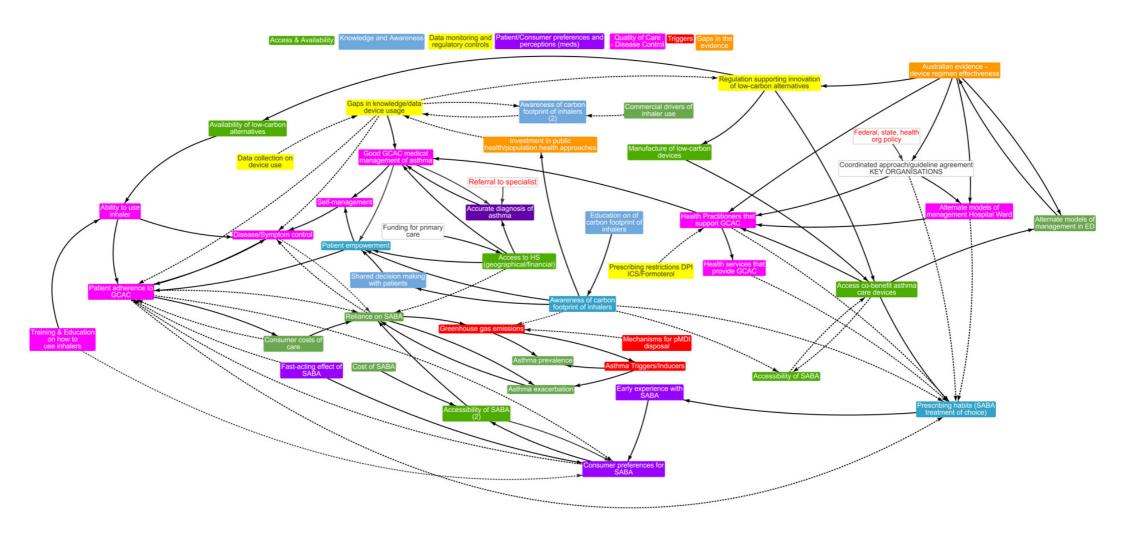
These seven themes were:

- Access to and availability of guideline-concordant health care and low-carbon inhalers
- Knowledge and awareness of the carbon footprint of asthma care
- . Data, monitoring and regulatory controls relating to the carbon footprint of asthma care
- Patient/consumer preferences and perceptions regarding asthma medications and devices
- Quality of asthma care and disease control, particularly related to guideline-concordant-asthma-care (GCAC)
- . Asthma triggers, particularly related to air pollution and climate change
- Gaps in the evidence to support the delivery of quality asthma care in Australia while reducing the associated carbon footprint

For details on how to read a visual systems map, refer to Appendix B.

For a description of terms and acronyms in the map, refer to the Glossary.

Figure 8: Mapping the factors that influence the high carbon footprint of asthma care in Australia- (Post-roundtable final map)



'GCAC' - Guideline-concordant asthma care

Deakin University under license to Cindy Needham Project: Sustainable Asthma Care Roadmap - Roundtable series Create with STICKE software https://sticke.deakin.edu.au

3.2 Stakeholder collaborative goals and recommendations

In Roundtable 2, following a review of the evidence (via an expert pre-brief), the researchers presented the participants with the twenty-four refined actions (across seven themes) that participants in Roundtable 1 had proposed. Participants were each asked to nominate an action that they believed would be most effective in improving the quality of asthma care in Australia while reducing climate impact. Thirteen working groups developed their selected actions.

What follows is a description of the stakeholder-recommended actions arranged under eight proposed goals, with the supporting recommendations, associated immediate priorities, actions for sustained implementation and scaling, and potential measures of success.

These goals and actions are not intended to represent a detailed consensus plan but are recommendations for key stakeholders to consider when developing a comprehensive and collaborative implementation plan.

3.2.1 Goal 1 – Establish a data dashboard to display the national indicators of highquality asthma care and decarbonisation trends

Current state and future vision

A comprehensive assessment of Australia's total asthma care footprint is required. An enhanced set of indicators needs to be developed. Poor asthma outcomes and high greenhouse gas emissions are significantly related to use and overuse of SABA pMDIs in asthma management; however, benchmarking and trend data regarding asthma medication and device usage in Australia are lacking. In particular:

- the AIHW <u>National Asthma Indicators</u> include metrics on medications dispensed from PBS prescriptions but not on the type of medications (e.g. SABA, ICS or ICS-formoterol), which is required to monitor the trends regarding guideline-concordant prescribing
- metrics are not currently reported regarding the device type (pMDI vs DPI, SMI), or brand (as different brands may use different hydrofluorocarbons, which are necessary for greenhouse gas emission estimates
- privately prescribed medication and device sales data are not currently available to government or peak asthma bodies
- over-the-counter SABA medication and device sales data are not currently available to government or peak asthma bodies
- hospital dispensing data on medications and devices (including in Emergency Department and ward care) are not included in the currently reported National Asthma Indicator data

Stakeholders envision comprehensive data collection (including measures that matter- see Recommendation 6) and public reporting of asthma medication and device sales to benchmark and monitor progress towards the cobenefit aims of improved quality and reduced footprint of asthma care.

Recommendation 1: Enhance the measurement and monitoring of asthma management trends and inhaler dispensation data

New data should be provided by private pharmacies including PBS-prescribed and privately prescribed medications and devices, and over-the-counter medication and device sales.

Hospital pharmacies should provide data on dispensed medications and devices. This will allow a comprehensive estimate of total greenhouse gas emissions from inhalers.

The AIHW should integrate these data with other markers of high-quality care, such as metrics on asthma action plans, that are currently publicly reported in the National Asthma Indicators.

Immediate priorities

- Work with AIHW, PBS and pharmacy stakeholders to investigate and establish mechanisms for the collection
 - expanded inhaler dispensing data from all private and hospital pharmacies. The required details include the type of device (pMDI, DPI, SMI) and brand chosen by the prescriber/consumer (which in the future will be particularly relevant to the propellant type used in pMDIs)
 - primary, secondary, and tertiary prescribing trends data. Details required include the type of medications prescribed (to monitor guideline-concordant prescribing) and device prescribed (pMDI, DPI, SMI)
 - non-prescribed (over the counter) medication and device (type and brand) dispensing data to understand consumer-management trends
- These dashboard data should be incorporated into the current National Asthma Indicators, with the capacity to analyse state and regional data subsets.
- Decarbonisation metrics could be estimated and reported in a similar way to the UK's NHS Respiratory-Carbon impact dashboard.
- Gather patient-reported data on medication use from nationally representative surveys (such as from the Australian Centre for Airways disease Monitoring (ACAM)
- Identify potential data collection pilot sites across Australia to trial the effectiveness of these data collection systems

Sustained implementation and scaling

- Consider expanding the collection of primary care data extracted from electronic medical records, such as the Optimum Patient Care Research Database Australia (OPCRDA), to support centralised progress monitoring and provide data for evaluation by health services and practices.
- Conduct a pilot study in which data collection mechanisms are trialled to benchmark and monitor the impact of a multi-regional implementation of high-quality evidence-based asthma care. An example of this approach is the UK's <u>SENTINEL Plus</u> implementation trial across 6 primary care networks in the UK, which has published the progress (see background) on two core aims-
 - 1. Improve asthma outcomes for patients while reducing the environmental impact of asthma treatments by addressing SABA over-reliance, increasing appropriate anti-inflammatory treatment and implementing a maintenance and reliever treatment (MART) strategy for appropriate patients.
 - 2. Reduce the environmental impact of adult asthma management through reduction in SABA overreliance, reducing health care resource utilisation, and use of preventer dry powder inhalers (DPI) where appropriate.

Measure of success

Implementation and utilisation of a data dashboard with metrics to monitor asthma management trends, including guideline-concordant treatment, asthma action plans, prescribed and over-the-counter medications and device sales, in-hospital use, patient-reported usage data, and trends in the estimated carbon footprint.

3.2.2 Goal 2 – Establish processes and resources to support annual/regular updating of the national asthma guidelines and for harmonising secondary recommendations and clinical tools in consultation with peak asthma bodies

Current state and future vision

Prescribers and people with asthma in Australia currently have access to a range of asthma treatment guidelines, clinical recommendations (including paediatric-specific), position statements, algorithms, pathways and tools from national, international, primary health, hospital, college, society, and commercial organisations. There are currently some crucial differences between these resources and some inconsistencies with current high-quality evidence. Stakeholders advised that these differences are confusing and that this lack of consistency will be a significant barrier to a coordinated and collaborative national implementation approach to high-quality, low-carbon asthma care. It is also considered highly inefficient to expect each of the relevant organisations to carry out their own regular evidence reviews and updates.

The vision is that Australians with asthma receive the best care possible, guided by clear and consistent recommendations based on current high-quality evidence. This needs to be accompanied by harmonisation of the various other resources and implementation tools with these guidelines nationwide. This would empower healthcare professionals to confidently prescribe effective treatments and equip people with the necessary knowledge to manage their asthma effectively. A unified approach would reduce confusion, improve adherence to treatment plans and promote the use of environmentally friendly inhalers.

Recommendation 2a: Support a regular evidence review mechanism to update the national asthma guidelines

Immediate priority

Support regular review (direct or indirect) by the Australian Asthma Handbook (AAH) Guidelines Committee of new evidence relevant to asthma management and of its potential impact on clinical recommendations. Identify mechanisms for collaboration across relevant peak bodies and stakeholder groups to advise the AAH Guidelines Committee of topics that may be considered for evidence review and/or updated clinical recommendations.

Recommendation 2b: Establish and support a regular collaborative mechanism to harmonise other guidelines and secondary resources with the national asthma guidelines.

This will ensure that the various asthma recommendations and resources are harmonised with the national guidelines (AAH), and that implementation resources are developed and/or updated to suit primary, secondary, and tertiary care settings and different consumer/patient cohorts. Consistency between these resources and the national guidelines will be essential to inform a collaborative national co-benefits-oriented implementation plan.

Immediate priority

Ensure that further implementation resources are developed and/or updated to support knowledge translation of the AAH (which is currently being updated)-

- across different contexts e.g. treatment recommendations for primary care versus hospital care, including emergency department and intensive care units
- and applicable to different cohorts such as paediatrics, particularly preschool and primary school; older adults with frailty; and patients with features of both asthma and COPD ('asthma+COPD').

Sustained implementation and scaling

Consider mechanisms to ensure practice and prescribing software in primary, secondary and tertiary care settings are harmonised with updated evidence-based guidelines (see Recommendation 3b).

Measures of success

- Australia's national guidelines are updated regularly/annually to deliver evidence-based asthma recommendations
- The national guidelines are incorporated into all public health services and primary health guidelines (such as HealthPathways)
- Implementation resources are consistent with the national guidelines and are available for relevant patient groups and clinical contexts
- Practice and prescribing software in primary, secondary and tertiary care settings are harmonised with updated evidence-based national guidelines (see Recommendation 3b)
- Improved asthma outcomes as per the National Asthma Indicators.

Goal 3 - Increased clinician education and digital enablement to implement evidence-based guideline-concordant, low-carbon asthma care, particularly the use of AIR regimens

Current state and future vision

Stakeholders advised that there are several challenges to clinician awareness and understanding of the evolving evidence and guidelines for asthma care.

- Highlighted in Goal 2 is the challenge of harmonising different asthma guidelines and translating them for various contexts and cohorts, which has led to confusion and delayed uptake by some prescribers.
- Asthma prescribing guidelines and guideline-concordant asthma action plan templates are not currently embedded in clinical prescribing software or electronic medical records (EMR).
- The carbon footprint of inhalers, particularly high-GWP pMDIs is new to most clinicians and there is currently no requirement to declare details on the carbon footprint of inhalers.

Stakeholders envision a knowledge translation program that equips clinicians with the information and resources to consistently deliver high-quality, evidence-informed asthma care. This program would prioritise disseminating the national guidelines, developing resources and implementation tools that are harmonised with the guidelines, providing coordinated and targeted education, and developing digital resources to enable guideline-concordant prescribing and asthma action plan generation. This will ensure optimal outcomes for people with asthma and sustainable practice.

Recommendation 3a: Launch a comprehensive national educational initiative for healthcare providers

The focus would be to provide healthcare practitioners with the latest evidence-based asthma management guidelines, including:

- targeted training and resources, focusing on the benefits of AIR and MART regimens for optimal asthma control and on the availability of DPIs to reduce the carbon footprint. This would include training on assessing what the optimal medication for an individual is, what is the most suitable available inhaler type for this medication in this individual (including young children, frail elderly, etc.) and effective techniques for maximal lung deposition.
- collaborating with representative bodies to disseminate information and promote best practices through existing channels and networks
- raising awareness of the environmental impact of high global-warming-potential (GWP) pMDIs when compared to low-carbon options, encouraging a shift towards more sustainable choices if available for medications suitable to the patient/consumer.

Immediate priorities

- Develop a project plan and identify funding and resources available to undertake this initiative.
- Engage clinical care stakeholders in research and consultation to develop and trial a co-benefit-oriented
 asthma education and training program. This program would identify opportunities to enhance healthcare
 practitioners' knowledge of evidence-based asthma care and sustainable prescribing practises. Note two
 relevant research projects focussed on improving guideline-concordant paediatric asthma care:
 - The 'Improving Childhood Asthma Management' (ICAM) project in Victoria is focusing on guidelineconcordant care, establishing a community of practice and strengthening integrated care pathways
 - The National Paediatric Applied Research Translation Initiative (N-PARTI) collaboration will work with GPs to support the provision of guideline-concordant care
- The National Asthma Council Australia advises that it has conducted national training workshops for primary care since 1989 to implement the Australian Asthma Handbook, with DoHAC funding and independent evaluation. Course development and revision is regularly conducted with presenters, participants, and relevant experts. It will be essential for new training to be undertaken when the Australian Asthma Handbook is updated based on current evidence.
- Support the National Asthma Council Australia initiative to include simple greenhouse gas footprint advice
 regarding the device options in the next version of the <u>Asthma & COPD Medications chart.</u> Any changes
 should be co-developed with patients/consumers and would remain at the discretion of the National Asthma
 Council Australia.

Sustained implementation and scaling

- Deliver a national co-benefits-oriented asthma education and training program, updating and upskilling healthcare practitioners and agencies on evolving evidence-informed practice for asthma care and providing information and resources regarding the greenhouse gas emissions associated with high-GWP pMDIs.
- Integrate information regarding inhaler carbon footprint into treatment guidelines. For example, the NHS Wales Green Agenda has set a target to reduce the proportion of high GWP inhalers from >70% to <20% by 2025. For example, The All Wales Paediatric Asthma Management and Prescribing Guideline incorporates advice on evidence-based treatment recommendations with information on the footprint of inhalers and the suggestion to 'consider DPI in children □6 with appropriate training'.
- Asthma peak bodies and the relevant authorities (Therapeutic Goods Association, National Prescribing Service, Health Departments, etc.) could work with pharma companies to ensure any information provided to clinicians about inhalers includes accurate carbon footprint data.
- Resources exist to assist clinicians and people with asthma in considering the optimal inhaler, including
 this <u>device-specific checklist</u> (by National Asthma Council Australia and NPS MedicineWise), <u>how-to videos</u>
 (National Asthma Council Australia), and this would be augmented by ready access to placebo devices and
 devices to measure peak inspiratory flow or information on surrogate markers such as <u>inspiratory breath</u>
 time.
- Establish innovative integrated models of care to support the patient journey across the primary, secondary
 and tertiary sectors. This requires co-development and could be led by the RACGP working with the Primary
 health networks (PHN), RACP, The Commission (ACSQHC) and other relevant stakeholders

Measures of success

- Continuing development and implementation of an evidence-based sustainable asthma care education and training program for healthcare practitioners at the national, state, territory and regional levels. This program will be informed by comprehensive research and stakeholder consultation.
- A significant reduction in SABA prescriptions and over-the-counter sales, accompanied by an increase in high-quality care metrics and improved health outcomes, tracked through the data dashboard (**Goal 1**).
- A significant decrease in high-GWP pMDI prescriptions, with increased prescribing of low greenhouse gas emission inhalers.

Recommendation 3b: Design and implement integrated digital health tools and resources for healthcare providers

Digitally integrated health tools and resources would enable healthcare providers (including GPs, nurse practitioners, hospital staff, and pharmacists) to deliver and maintain optimal asthma care.

Immediate priorities

- Establish a working group comprising peak asthma organisations, clinicians and health software leaders to develop tools and resources such as:
 - A version of the national guideline-aligned asthma action plan electronic template for AIR and MART regimens to integrate into EMRs for primary, secondary and tertiary care
 - clinical decision support system(s) (CDSS) to prompt clinicians regarding confirming the diagnosis, assessing asthma control, and guideline-concordant prescribing including prompts for AIR and MART regimens
 - Australian-specific device information and selection algorithms and consumer information resources (noting the existing resources from the National Asthma Council Australia, GINA, and UK resources, (NHS & British Thoracic Society / NICE / GreenInhaler / Greener Practice web resources / Prescgipp)
- Establish mechanisms to embed these tools and resources into all primary, secondary and tertiary care electronic medical record (EMR) software, with the capability for rapid update when asthma guidelines are updated.

Sustained implementation and scaling

- Implementing changes in electronic medical software is challenging and would require co-design. It would be important to work with EMR providers to undertake a trial of these resources and evaluate the usability of the templates, prescribing prompts, and associated resources for asthma care in primary, secondary, and tertiary care settings.
- Of relevance to the transition in the tertiary sector The Australian Commission on Safety and Quality in Health Care has established a pilot module in 2024, that health service organisations can use to address environmental sustainability with a view to informing the next edition of the standards due for release in 2027. This pilot will be utilising the Hospital Sustainability Project Tracker, which has been designed by Doctors for the Environment Australia. Hospitals can generate and monitor progress on their own SMART goals, including reducing emissions from hospital-prescribed and dispensed inhalers.

Measure of success

- Integration of guidelines, action plan template and other digital enablement resources into practice software, EMR and prescription tools used by primary, secondary and tertiary-care clinicians
- Improved outcomes as in Recommendation 3a
- Goal 4 Inform people with asthma about how to improve their asthma control and options to reduce greenhouse gas emissions from inhalers where suitable devices are available

Current state and future vision

Many people with asthma would like more information about the advances in asthma treatment regimens, and some want information about the carbon footprint of their inhalers.

By improving community understanding of the benefits of personalised asthma action plans and low-carbon inhaler options, we can create a positive ripple effect that enhances wellbeing and promotes sustainable practices.

Shared decision-making will empower individuals with asthma to embrace evidence-based care, leading to improved health outcomes and a significant decrease in the use of SABAs, reducing the greenhouse impact of pressurised metered-dose inhalers (pMDIs) using high-GWP propellant.

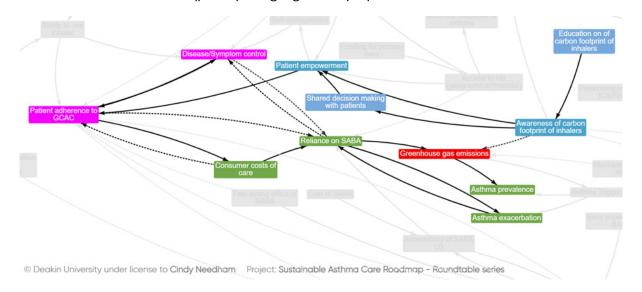


Figure 4. Influence of education regarding the potential greenhouse gas emissions of inhalers

What did the map tell us? The causal loop diagram shows that increasing education on inhaler potential greenhouse gas emissions would raise awareness and patient/consumer adherence to evidence-informed practice, reducing asthma attacks and reducing greenhouse gas emissions.

(For details on how to read a visual systems map, refer to Appendix B.)

Recommendation 4: Launch a research-informed national multimodal public awareness campaign targeting people with asthma. Provide comprehensive information on current asthma management guidelines and low-carbon inhaler options to empower informed decision-making.

Immediate priority

Undertake co-design research, including consultation with people with asthma and other stakeholders, to inform the design and testing of a socially and culturally appropriate campaign strategy and associated resources to educate and empower people with asthma regarding these co-benefit aims.

Sustained implementation and scaling

- Develop and deliver a comprehensive multimodal national education and awareness campaign regarding the current evidence-informed practices for asthma care and low-carbon inhaler options available
- Stakeholders were clear that any campaign needs to consider the messaging recommending a transition from high-GWP pMDIs to current options such as DPIs to ensure current users of SABA and pMDIs are not made to feel guilty. Campaign material should clarify that transitioning to DPIs ('going green' with your inhaler) would suit most adolescents and adults, and some children 6–11, but the priority is for individuals and their clinicians to consider medical appropriateness and individual suitability- see GINA report p109 re shared decision making for choice of inhaler device
- Therapeutic Goods Administration and relevant authorities should establish requirements for environmental
 product declarations and device labelling standards regarding the carbon footprint of inhalers to ensure
 consumers have an informed choice about the greenhouse gas emissions of their asthma medications when
 discussing their management with their prescriber
- Develop service navigation aids and resources to assist people with asthma in navigating the health system (for example, clear communication regarding what clinics, services and resources are available to people in their local area)[†]

Establish and implement a change initiative that supports people with asthma in adhering to their prescribed asthma medications as per their plans[†]

(† Action from Roundtable 1, not developed in Roundtable 2 due to time constraints.)

Measures of success

- Improved qualitative data trends regarding patient awareness and understanding of recommended guideline-concordant asthma care, and the options of devices to reduce greenhouse gas emissions
- All asthma inhalers are labelled to inform consumers of the greenhouse gas emissions of asthma medications and devices
- A reduction in the prescribed and over-the-counter SABA sales and increased dispensing of guidelineconcordant lower carbon devices for asthma management (supported by Goal 1)

Goal 5 - Reduce the imbalance between cost and ease of access to SABA compared 3.2.5 with more effective medications

Current state and future vision

While Goals 2, 3 and 4 offer recommendations to reduce SABA use by transitioning to high-quality guidelineconcordant asthma care, stakeholders described the need for regulatory and supply mechanisms to support this. They advised that the current overuse on SABA is driven by the following challenges:

- Lack of awareness about, and limited implementation of, evidence-based guidelines about use of antiinflammatory reliever therapy with ICS-formoterol (AIR/MART)
- Unrestricted over-the-counter access to SABA ('Schedule 3' no prescription required)
- Pharmaceutical Benefits Scheme (PBS) regulations allow prescribers and pharmacists to issue up to 2 inhalers per dispensing episode and 12 per prescription, with no annual limit. This corresponds to an average of 13+ inhalations/day, which is associated with a very high risk of asthma death (Nwaru, et al. 2020) There is strong evidence that dispensing of even three or more SABA devices in a year is an accepted marker of SABA over-use and poor symptom control, and that there is an increasing risk of severe exacerbations and death with increasing SABA over-use.
- The cost per device of guidelines-concordant medications is currently higher than the cost of SABA inhalers, and PBS limits the prescribing of some guidelines-concordant medications. Together, these introduce barriers for health professionals to prescribe, and patients to take, guidelines-concordant medications. (It was noted that ICS-formoterol inhalers are much less expensive in Australia than some countries and for this PBS should be commended).

Every person with asthma needs to have an inhaler for quick relief of asthma symptoms. Stakeholders envision reducing overuse of SABA relievers by increasing equitable access to and use of guideline-concordant combination ICS-formoterol medications. Changes to PBS regulations and pricing would support healthcare practitioners and adults and adolescents with asthma in following updated international guidelines for asthma management and prioritising ICS-formoterol medication regimens (AIR and MART), including via DPI, where suitable; review of Australian guidelines is currently underway.

Recommendation 5a: Monitor and limit access to SABA for safety.

Develop a strategic plan to support this transition by limiting (via regulatory approaches) opportunities to purchase unsafe quantities of SABA, either over-the-counter or via multi-repeat scripts, given the evidence linking SABA overuse to the risk of severe asthma exacerbations and death.

Immediate priority

- Invite stakeholders from all relevant authorities, peak bodies, asthma care experts, and consumer representatives to work with implementation experts and form a SABA working group to explore safe ways to implement evidence-based guidelines and reduce overuse of SABA.
- Limit the quantity and number of repeats for SABA on standard prescriptions. If symptoms are causing someone with asthma to seek more SABA inhalers, this should prompt a medical review. For example, an authority script could be required if a patient needs more than 2 SABA inhalers in 3 months.

Sustained implementation and scaling

Develop a 3-year coordinated strategy to decrease over-the-counter access to SABA while retaining emergency access. Supporting initiatives to be considered include:

- establish a mechanism for monitoring over-the-counter SABA purchases, with a trigger when, for example, more than two devices have been purchased by a consumer within 12 months, prompting the pharmacist to offer a discussion on the value of seeking an asthma review to optimise control
- establish a mechanism for pharmacists to seek consent and communicate with consumers and their health practitioners regarding the need to have an asthma review
- consider limiting the number of over-the-counter SABA purchases per year (note that this initiative would need to be supported by mechanisms for consumers to access clinician support and guideline-concordant medications and devices equitably)
- if SABA inhalers remain available over-the-counter, consider 'down-scheduling' other medications and devices to be available over-the-counter (for example, guideline-aligned ICS-formoterol medications for AIR and MART regimens, (including via DPI devices)) †

Measure of success

Evidence from the proposed data dashboard (**Goal 1**) of reductions in the quantity of SABA prescriptions and over-the-counter purchases and improvements in the rates of guideline-concordant prescribing and other disease control metrics.

<u>Recommendation 5b: Ensure equitable access to other guideline-concordant medications and low-carbon devices</u>

'We need safe and affordable access to alternatives. You cannot remove or restrict something without providing an equivalent or lower cost alternative, with safeguards.' (Stakeholder, Workshop. 1).

Immediate priority

- Establish a working group of asthma treatment experts, industry and government representatives to explore the following actions further and develop an implementation plan:
- Cost of medications and devices- Work with the relevant authorities to review the current cost of guidelineconcordant medications and low-carbon devices to consumers with and without concession cards.
- Range of medications and devices to meet different consumer needs- Work with the relevant authorities to increase access to a broader range of asthma medications with lower greenhouse gas emissions in the Australian PBS formulary and broader market (e.g., alternative competitively priced ICS / formoterol devices for use in AIR and MART treatment regimens, and a DPI option for Salbutamol).
- Reconsider current prescribing barriers to access Work with PBS/PBAC to review prescribing criteria for
 guideline-concordant medications and DPI (for example, currently, prescribing of DPI ICS-formoterol to
 children age 6–11 is available to paediatricians but not GPs, and only if the patient has failed to respond to
 fluticasone propionate-salmeterol, (which cannot be used for AIR/MART regimens)).

Sustained implementation and scaling

- Develop recommendations to the Pharmaceutical Benefits Advisory Committee for the above PBS changes
- Establish a requirement for environmental product declaration (EPD) from pharmaceutical manufacturers of inhaler medications

Measures of success

Improved equitable access to guideline-concordant, low-carbon asthma devices and medications in Australia

Goal 6 - Support research to implement and evaluate high-quality sustainable 3,2,6 asthma care

Current state and future vision

While the interventions recommended for **Goals 1–5** are grounded in existing evidence and expert consensus and some can be initiated promptly, further research is essential to optimise their implementation and ensure the most effective approaches for improving asthma care in Australia. There are some established potential funding mechanisms via NHMRC and MRFF. Further investment is required in this area to supplement Australia's existing asthma research expertise.

Through rigorous mixed-methods research, the asthma care sector will better understand the lived experiences of Australians with asthma and, therefore, the factors that influence effective disease management. Research that matters will inform the development of the actions listed in Goals 1-5, particularly targeted educational interventions and personalised action plans, ultimately improving the quality of life and health outcomes for individuals with asthma.

Recommendation 6: Support mixed methods research to inform this co-benefits-oriented implementation

- Expand the capacity for Australian qualitative research into the experiences of people with asthma, prescribers, nurses and pharmacists in accessing and incorporating evidence-informed, high-quality, lowemissions asthma care, to inform recommendations for improving the models of care for people with asthma
- Informed by the above, quantitative data monitoring should be developed regarding measures that matter to consumers and providers as well as indicators demonstrating progress towards the program's co-benefit aims (see Goal 1)

Immediate priority

Engage representative organisations, key stakeholders and academic partners to map the knowledge gaps regarding the experience of people with asthma in accessing high-quality care. Consider how this qualitative data will be augmented by quantitative asthma care metrics from the dashboard (see Goal 1).

Sustained implementation and scaling

- Generate and publish research findings. Relevant methodologies could include:
 - qualitative and semi-quantitative research to monitor patient and healthcare professional knowledge, attitudes and behaviours.
 - longitudinal cohort studies and behaviour change models to understand consumer experiences and decision-making regarding asthma management and medication usage over time
 - participatory co-design to inform innovation in the manufacture of devices in Australia, including people with asthma with diverse needs (for example, children and adults with frailty and people with a physical disability)†

Measure of success

Research capacity is strengthened by involving government, stakeholder, and academic partnerships, with the necessary resources and mechanisms to undertake contextually appropriate qualitative and quantitative data collection, monitoring, and analysis. This data cycle would inform an adaptive, data-driven implementation of consistent national asthma guidelines and supporting resources to improve person-centred, evidence-informed practice in Australia.

3.2.7 Goal 7 – Reduce greenhouse gas emissions by minimising residual hydrofluorocarbon leakage from discarded asthma inhalers

Current state and future vision

Most inhalers are currently disposed of in domestic rubbish, and residual propellant leaks into the atmosphere. Stakeholders envision the establishment of an effective nationwide program for collecting and appropriately disposing of pMDIs with the destruction of unused propellant. (Note: DPIs and SMIs can be either recycled as per product labelling and local recycling capacity or disposed of in domestic waste. For COPD, some mist inhaler devices are being designed to be refilled).

Recommendation 7: Establish an effective nationwide program for collecting and appropriately disposing of pMDIs with the destruction of unused propellant.

To develop a feasible implementation plan, a working group involving <u>Return Unwanted Medicines</u>, state and territory departments, pharmaceutical companies, recycling and gas destruction companies, and other stakeholders must be established. Some initial action recommendations are included below.

Immediate priorities

- Form a working group and develop an implementation plan informed by insights from previous programs with similar aims in Australia and overseas.
- Consider program funding options such as building the cost of pMDI recovery and HFC destruction into the sales cost of devices as a levy.
- Consider offering incentives (such as a discount on subsequent devices) to people returning their used pMDI to the pharmacy or recycling site.

Sustained implementation and scaling

- Recruit pharmacies (and possibly other locations such as supermarkets) for a nationwide pilot program for responsible disposal of asthma devices and medications.
- Evaluate the program and publish the findings.

Measures of success

- Positive consumer feedback regarding the usability of the program.
- Establishment of an academic partnership to monitor the number and type of inhalers collected for disposal
 and destruction, their residual propellant (for example, partially or fully used) and estimated reduction in
 greenhouse gas emissions.

Goal 8 - Support governments in developing a 'health in all policies' approach to 3.2.8 reducing the modifiable inducers and triggers of asthma

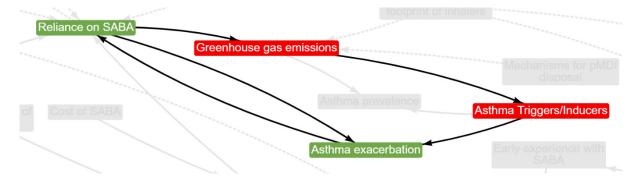


Figure 5. Asthma trigger causal loop diagram

(For details on how to read a visual systems map, refer to Appendix B.)

Current state and future vision

As shown in Figure 5, stakeholders emphasised that reducing SABA use reduces greenhouse gas emissions, both directly from inhalers and indirectly from reduced healthcare resource utilisation. This reduces asthma triggers related to global warming. Reducing global warming (caused mainly by fossil fuel combustion) would decrease the prevalence of asthma by reducing its inducers and decrease the incidence of asthma attacks by reducing triggers and aggravators. This would ultimately lead to lower SABA consumption and greenhouse gas emissions.

Objective 4 of the National Health and Climate Strategy is to adopt a 'Health in all policies' approach through 'whole-of-government action', 'promoting the health co-benefits of emissions reductions across society and adaptation action beyond the health system to protect health and wellbeing'.

Collaborative efforts across sectors would prioritise air quality and a healthy environment for all Australians. This approach would focus on identifying and addressing the root causes of poor air quality, ensuring that air quality is a critical consideration in transport and energy policy and urban planning. Research and data would inform effective public health policies.

Recommendation 8: Implement a 'Health in all policies' approach to reducing the triggers of asthma, particularly related to air quality and climate change

Immediate priorities

- Undertake more representative and comprehensive system-oriented stakeholder mapping, particularly with industry (particularly mining, energy, transport) and government representatives, focusing on understanding the barriers to and opportunities for improving air quality and reducing asthma incidence in Australia
- Synthesise existing research and best practices to identify proven interventions that reduce air pollution across relevant industries, considering their feasibility and scalability in an Australian context
- Engage affected communities to understand their priorities and concerns regarding air quality and wellbeing
- Conduct rigorous cost-benefit analyses to evaluate the short- and long-term health and economic benefits of measures to reduce asthma triggers, providing robust evidence to support policy decisions

Sustained implementation and scaling

- Use the information and evidence drawn from stakeholder system mapping, needs assessment, and community engagement exercises to advocate for high-impact changes to improve air quality in Australia
- Develop and implement policies and regulations to reduce asthma incidence and prevalence, focusing on controlling and reducing contributing factors to poor air quality¹
- Conduct education and awareness campaigns regarding the common asthma triggers (for example, traffic pollution, smog, bushfire smoke, wood heaters, gas appliances, and pollens (including thunderstorm.asthma risk forecasting)[†]
- Incentivise households, schools and workplaces to transition from gas and other inefficient and polluting means of heating and cooking (particularly gas cooktops and indoor gas and wood heaters) to electrical appliances to mitigate household asthma triggers †

(† Action from Roundtable 1, not developed in Roundtable 2 due to time constraints.)

Measures of success

- · Comprehensive monitoring and reporting are established for air quality
- Effective, high-impact policy developed and implemented to reduce the avoidable triggers of exacerbations for people with asthma

4. PROGRESSING THE ROADMAP

Representatives from 50 stakeholder organisations in Australia came together to develop a roadmap with the intention of both improving the quality of asthma care provided to 1 in 9 Australians, and significantly decreasing the carbon footprint associated with this care.

The Australian Sustainable Asthma Care Roadmap (the Roadmap) is the result of a collaboration between 50 key stakeholder organisations. The vision for the Roadmap is to improve the lives of people living with asthma, with emissions reduction as a co-benefit outcome. Eight ambitious goals, underpinned by actionable recommendations to all system stakeholders and government (federal, state and territory), provide a clear roadmap to transition asthma care in Australia to a higher quality and more environmentally sustainable model. The actions provided below are intended to progress the Roadmap goals and recommendations into a comprehensive implementation strategy and plan.

Action 1: Establish a collaborative body to develop a detailed implementation plan

To initiate this process, a stakeholder body would be formed, consisting of stakeholders who contributed to the roundtables and other identified groups. It would establish a committee to foster communication and ensure a collaborative and efficient process. The body would partner with relevent government departments to develop a comprehensive implementation plan for the Roadmap goals and recommendations. Leadership from peak bodies, including strong consumer representation, is important to this process. Funding could be sourced from government (federal, state and territory), research grants and philanthropic contributions.

Action 2: Undertake a detailed economic evaluation to assess the likely return on investment

Concurrent with the step above, stakeholders and governments should prioritise undertaking an economic evaluation of the costs and potential savings for the health sector and broader community in making a transition to high-value care, including assessment of the associated social, health and environmental benefits.

This economic evaluation will provide estimates of the potential expenditure required to fund a national implementation of the Roadmap's goals for guideline-concordant, low-carbon care, while also detailing the potential return on investment and identifying opportunities to reduce ongoing health system costs and improve efficiency.

Action 3: Provide governance and resources to deliver a collaborative national sustainable asthma implementation plan

Once the implementation plan and economic evaluation have been developed, a governance framework can then be established to define reporting lines, roles and responsibilities. This framework would consider relationships between stakeholder organisations, government bodies, the community and healthcare sector (including primary, secondary and tertiary; public and private).

Funding and resources will be required to deliver a collaborative national implementation plan and to realise the health, environmental and economic benefits. Effective implementation will require continued collaboration between consumers, the asthma care sector (including Roadmap stakeholders), governments, and regulatory bodies. A partnership approach would build on the Roadmap's momentum and consensus for change. It would also facilitate targeted investment in key initiatives, which is critical to achieving the shared goals of improving the quality of care and the wellbeing of all Australians with asthma, while reducing the associated greenhouse emissions.

Appendix A Roundtable participating organisations

Fifty roundtable stakeholder organisations represented

Consumer representatives

- Asthma Australia Consumer Advisory Council
- Consumer Health Forum

Peak asthma and respiratory health organisations

- Asthma Australia
- Asthma Foundation Northern Territory
- Asthma Western Australia
- Global Allergy and Airways Patient Platform
- Global Initiative for Asthma
- Lung Foundation Australia
- National Asthma Council Australia
- Thoracic Society of Australia and New Zealand

Other peak bodies

- Australian Chronic Disease Prevention Alliance
- Pharmaceutical Society of Australia
- Return Unwanted Medications
- United Nations Medical and Technical Options Committee- Ozone Secretariat

Peak climate and health bodies

- Climate and Health Alliance
- Doctors for Environment Australia

Health professional organisations and associations

- Australian Chronic Disease Prevention Alliance
- Australian College of Nurse Practitioners
- Australian Primary Health Care Nurses Association
- Royal Australian College of General Practitioners
- Royal Australian College of Physicians
- Royal Children's Hospital / (Paediatric Improvement Collaborative)

Government departments and health services

- ACT Health and Canberra Health Services
- Australian Commission on Safety and Quality in Health Care
- Department of Health, Northern Territory
- Department of Health, Victoria
- Department of Health, Western Australia / Sustainable Development Unit
- Federal Department of Climate Change, Energy, the Environment and Water
- NSW Health (Northern Sydney Local Health District Nth Syd LHD)- Net Zero Resp Health

- SA Health
- Safer Care Victoria
- Tasmanian Health Service

Research institutions

- Child Health Research Centre, (University of Queensland)
- Curtin University
- Deakin University
- Macquarie University
- Melbourne University- (Climate Futures)
- Monash University Health and Climate Initiative
- Murdoch Children's Research Institute
- Planet Futures, (Deakin University)
- Telethon Kids Institute
- University of Canberra (Healthy Environments and Lives 'HEAL' National Research Network)
- UTAS Menzies Institute for Medical Research
- University of Western Australia
- Wiser Healthcare
- Woolcock Institute of Medical Research

Pharmaceutical companies

- Astra Zeneca
- Chiesi
- GSK
- Orion Parma

Apologies

- Asthma Centre for Research Excellence
- Australian College of Nursing
- Australian Medical Association
- · Chief Medical Officer, Australia
- Climate Risk and Net Zero Unit (NSW Health)
- Department of Health, ACT
- Department of Health, Queensland
- Future of Asthma Research Group
- Medications Australia
- South Eastern Sydney Local Health District
- Pharmaceutical Benefits Advisory Committee
- · Pharmacy Guild of Australia
- Public Health Association of Australasia
- Therapeutic Goods Administration
- Viatris
- Victorian Health Promotion Foundation

Appendix B How to read a visual systems map

Solid and dotted line connections

The connections between each of the variables or 'factors' within the systems show how they influence each other. The connections are either represented by a solid line denoting a positive relationship (where they increase or decrease together) or a 'dotted line' denoting a negative relationship (where one increases, the other decreases, or vice versa)

Reinforcing and balancing loops

Within the systems map, we also see feedback loops, which represent core components of the system where 'factors' operate together in their closed system within a broader system. The two main types of feedback loops are reinforcing and balancing loops. A reinforcing feedback loop is when elements in a system reinforce more of the same. A simple example of this is seen in the systems map, where the increasing use of SABA as a method of asthma management causes an increase in asthma exacerbations, which in turn causes an increase in use of SABA and so on unless another factor influences a change within the feedback loop.

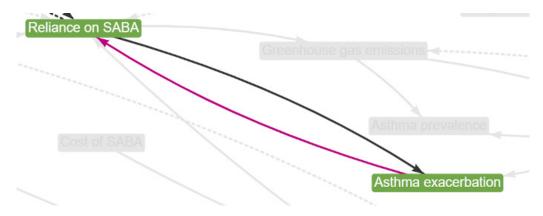


Figure 6. Example of a reinforcing loop within a systems map

In contrast, a balancing feedback loop within a system is where an increase in the behavior of one factor has the opposite effect on the factor it is influencing (i.e., where one increases, the other decreases), which Figure 6 demonstrates. In this reinforcing loop, we see a relationship where an increase in disease/symptom control has a flow-on effect of decreasing use of SABA, and with reducing use of SABA, we see an increase in disease/ symptom control.

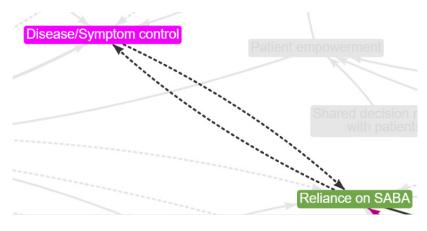


Figure 7. Example of a balancing loop within a visual systems map

Appendix C Supplementary Figures S1, S2, S3 from 'Comparing DPI and pMDI efficacy and safety for management of asthma and COPD'

Figure S1 – Comparison of Forced Expiratory Volume in 1 second (FEV1) with medications delivered by DPI or SMI vs pMDI in patients with COPD*

Study or Subgroup	MD	SE	Weight	Mean difference IV, Random, 95% CI	Mean difference IV, Random, 95% CI
Barnes 2013	19	12.453433	0.7%	19.00 [-5.41 , 43.41]	
Bateman 2001	-3	4.336734694	5.8%	-3.00 [-11.50 , 5.50]	+
Bernstein 2011	1.7	5.615516	3.5%	1.70 [-9.31 , 12.71]	+
Bodzenta-Lukaszyk 2012	-6.2	6.729799	2.4%	-6.20 [-19.39 , 6.99]	- +
Bracamonte 2005	-0.9	3.176995	10.8%	-0.90 [-7.13 , 5.33]	+
Bronsky 1987	6.1	18.787855	0.3%	6.10 [-30.72 , 42.92]	
Busse 2008	4.34	3.255331	10.3%	4.34 [-2.04 , 10.72]	-
Dusser 2005	0.88	5.477442	3.6%	0.88 [-9.86 , 11.62]	+
Kanniess 2015	-1.84	2.488904	17.6%	-1.84 [-6.72 , 3.04]	4
Koskela 2000	4	6.297133	2.7%	4.00 [-8.34 , 16.34]	+
Lundback 1993	16	14.091446	0.5%	16.00 [-11.62 , 43.62]	+
Lundback 1994	3	15.045714	0.5%	3.00 [-26.49 , 32.49]	
Morice 2007	2.8	3.903061224	7.1%	2.80 [-4.85 , 10.45]	+
Papi 2007	-0.49	6.357142857	2.7%	-0.49 [-12.95 , 11.97]	+
Papi 2012	-2.26	6.448829	2.6%	-2.26 [-14.90 , 10.38]	+
Poukkula 1998	8	11.98979592	0.8%	8.00 [-15.50 , 31.50]	
Reichel 2001	-1.7	5.81037	3.2%	-1.70 [-13.09 , 9.69]	+
Srichana 2016	14.2	42.132145	0.1%	14.20 [-68.38 , 96.78]	
Stradling 2000	0.5	3.520408163	8.8%	0.50 [-6.40 , 7.40]	+
Van Noord 2001	-6	8.247333	1.6%	-6.00 [-22.16 , 10.16]	
Von Berg 2004	-3	13.858161	0.6%	-3.00 [-30.16 , 24.16]	
Wardlaw 2004	-7.5	11.628144	0.8%	-7.50 [-30.29 , 15.29]	
Wolfe 2000	3	11.313708	0.9%	3.00 [-19.17 , 25.17]	
Zheng 2023	5.41	2.980051	12.3%	5.41 [-0.43 , 11.25]	•
Total (95% CI)			100.0%	0.86 [-1.19 , 2.90]	
Heterogeneity: Tau ² = 0.00;	Chi ² = 13	.00, df = 23 (P	= 0.95); I	2 = 0%	
Test for overall effect: Z = 0	.82 (P = 0	.41)			-100 -50 0 50 100
Test for subgroup difference	es: Not ap	plicable			Favours MDI Favours non-MDI

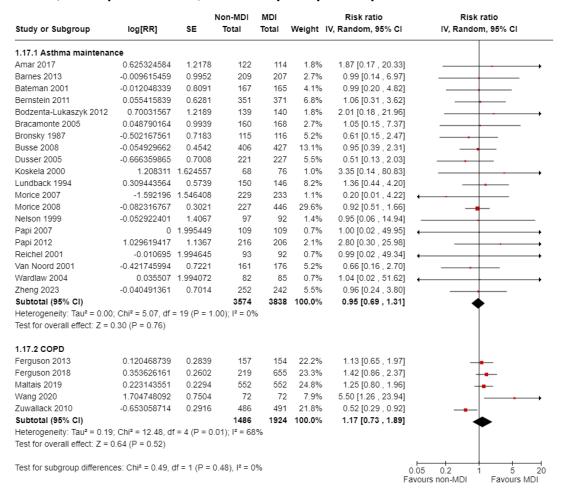
^{*}Studies assessed medications from the same medication classes, at comparable doses, delivered by non-pMDI (DPI or SMI) or pMDI. The variable reported in most studies was trough FEV1.

Figure S2 – Adverse Events in Asthma and COPD, in studies comparing medications from the same classes, at comparable doses, delivered by non-pMDI vs pMDI inhalers*

Study or Subgroup	log[RR]	SE	Non-MDI Total	MDI Total	Weight	Risk ratio IV, Random, 95% CI	Risk ratio IV, Random, 95% CI
1.16.1 Asthma maintenar							
		0.1601	122	11.1	2.20/	0.00 (0.50, 4.40)	
Amar 2017	-0.218645486	0.1621		114	2.3%		
Barnes 2013	-0.186961936	0.5978	216	215			
Bateman 2001	0.135109306	0.1033	167	165			<u> </u>
Bodzenta-Lukaszyk 2012	-0.102030802	0.2421	139	140			
Bracamonte 2005	-0.012394124	0.1113	213	215			+
Bronsky 1987	-0.359066717	0.2769	115	116			
Busse 2008	-0.049452505	0.0566	406	427			†
Dusser 2005	-0.117106864	0.1153	221	227	4.5%		+
Koskela 2000	-0.175890666	0.1471	68	76			-
Lundback 1993	-0.134379702	0.1076	198	193			-
Lundback 1994	-0.027028672	0.1943	150	146			+
Morice 2007	-0.04152405	0.1441	229	233			+
Morice 2008	0.03501994	0.0456	227	446			•
Nelson 1999	0.064860634	0.112	97	92			+
Papi 2007	0.182321557	0.3223	109	109		1.20 [0.64 , 2.26]	
Papi 2012	-0.073611817	0.2323	216	206	1.1%	0.93 [0.59 , 1.46]	-
Reichel 2001	-0.119024501	0.1805	93	92	1.8%	0.89 [0.62 , 1.26]	+
Srichana 2016	0	1.3744	18	18	0.0%	1.00 [0.07 , 14.79]	
Stradling 2000	-0.00174	0.340117488	98	106	0.5%	1.00 [0.51 , 1.94]	
Van Noord 2001	-0.163755711	0.1116	161	176	4.8%	0.85 [0.68 , 1.06]	-
Zheng 2023	-0.023962059	0.0918	252	242	7.1%	0.98 [0.82 , 1.17]	+
Subtotal (95% CI)			3515	3754	100.0%	0.97 [0.93 , 1.02]	•
Heterogeneity: Tau ² = 0.00	; Chi ² = 13.03, df =	= 20 (P = 0.88	B); I ² = 0%				1
Test for overall effect: Z = 1	1.16 (P = 0.24)						
1.16.2 COPD							
Ferguson 2013	-0.046444192	0.0724	157	154	17.6%	0.95 [0.83 , 1.10]	4
Ferguson 2018	0.023619464	0.0754	219	655	16.9%	1.02 [0.88 , 1.19]	.
Kilfeather 2004	0.065363103	0.0877	224	220	14.3%		-
Koser 2010	0.088553397	0.14	126	126	7.5%	1.09 [0.83 , 1.44]	_
Maltais 2019	0.092893747	0.0695	552	552	18.4%		<u> </u>
Nang 2020	0.318453731	0.1619	72	72			
Zuwallack 2010	-0.124421381	0.0659	486	491			
Subtotal (95% CI)		2.2300	1836		100.0%		1
Heterogeneity: Tau ² = 0.01	· Chi² = 10.57 df =	6 (P = 0.10)					Ĭ
Test for overall effect: Z = 0		2 (1 0.10)	,, , ,,,,,,				
Fest for subgroup difference	es: Chi² = 1.11, df	= 1 (P = 0.29	9), I² = 9.6%			0	05 0.2 1 5

^{*}Studies were at least 4 weeks' duration.

Figure S3 – Serious Adverse Events in Asthma and COPD in studies comparing medications from the same classes, at comparable doses, delivered by non-pMDI vs pMDI inhalers*



^{*}Studies were at least 4 weeks' duration

Appendix D Estimating the footprint of hydrofluorocarbon (HFC) propellant in Australia

Australian pharmaceutical Industry supplied data snapshot

- Total Inhaler sales in Australia ~24-26 million
- SABA sales 15 to 16 million
- SABA percentage of total 61% to 63%
- Total pMDI 80% of total inhaler sales
- Preventer / Combination pMDI 41% to 52% of Preventers (Use 46.5%)
- SABA pMDI 98% are pMDI
- Over-the-counter SABA (no script) Estimated at 55% of total SABA sales

MCTOC data

https://ozone.unep.org/system/files/documents/MCTOC-Assessment-Report-2022.pdf

- "The market data for inhaler units sold worldwide indicates approximately 60% were pMDIs, 32% were DPIs, and the remaining 8% were either SMIs or nebulised liquids. These percentages have changed little over the past decade."
- Based on knowledge about DPI raw material inputs, one industry estimate puts the number of DPIs manufactured worldwide at 450 million annually."
- Approximately 800–825 million HFC pMDIs (assuming a global weighted average fill weight: 14.61 g/ HFC-134a pMDI and 11.38 g/HFC-227ea pMDI) are currently manufactured annually worldwide, using approximately 10,700 tonnes HFCs (~10,100 tonnes HFC-134a; ~600 tonnes HFC-227ea) in 2021.
- Therefore Global weighted average for 227ea is 5.6%

UK / NHS data

- 'In 2015, the sector in England emitted 26.6 Mt of GHG emissions (Sustainable Development Unit, 2016), contributing 7% to **England's annual emissions of 370 Mt CO2 eq.** (NAEI, 2018). Currently, 57% of GHG emissions (15.2 Mt CO2 eq.) from healthcare in England are related to procurement (Sustainable Development Unit, 2016). Of this, 24% (3.6 Mt CO2 eq.) is from pharmaceuticals. Pressurised metered-dose inhalers (pMDIs) are the largest single contributors to the pharmaceutical-related GHG emissions (Sustainable Development Unit, 2016)'{Jeswani, 2019`, Nov #18}
- 'The data for the latter were obtained from the NHS in England, Scotland, Wales and NI (Table 5). As can be seen in Fig. 8, the annual GWP of inhalers amounts to 1.34 Mt CO₂ eq. Considering that the total GHG emissions of the NHS in England and Scotland are 26.6 Mt CO₂ eq./yr (Sustainable Development Unit, 2016) and 2.63 Mt CO₂ eq./yr (NHS Scotland, 2009), respectively, the inhalers account for around 4.3% of the NHS emissions in England and Scotland. The contribution of inhalers to the UK's GHG emissions is around 0.3%. Although this percentage appears to be small, it is equivalent to the annual GHG emissions from 610,000 diesel cars in the UK.² The annual use of inhalers in the UK generates GHG emissions equivalent to 1.34 Mt CO₂ eq., largely due to the HFC-134a inhalers.'
- Replacing all pMDIs with DPIs (S-2) would achieve even higher reductions (94–96%) for GWP. (So pMDI footprint is 1.27 Mt CO₂ in the UK)

Calculations based on Aus industry and MCTOC data

- Adjusting for fill weight 14.61g/134 pMDI, 11.38g/HFC227. (Ratio of 1.28 times more inhaler units per tonne of 227ea vs 134a)
- Therefore the percentage of 227 inhalers increases to 7.2% of global pMDI inhaler market
- Apply Global % of 227/134 pMDIs to the Aus market for preventers
- Preventers Use 9.4 million inhalers
 - Est 46.5% of preventers are pMDI =4.37 million

- 7.2% of 4.37 million use HFC-227ea = 315000 inhalers
 - Using 35kg footrprint/inhaler = 11,025 tonne footprint from HFC-227ea preventer pMDI
- \circ 82.8% of 4.37 = 4.06 million 134a pMDI preventer inhalers
 - Using estimate of ~15kg median footprint per HFC-134 pMDI preventer = 113,680 tonne footprint from 135 preventers
- Total preventer pMDI footprint ~ 124,705 tonnes CO_{2e} /yr
- SABA 15.5 million all 135a ~ (Using 28kg/device) = 434,000 ton CO_{2e} /yr
- Total Aus pMDI inhaler footprint of 547,680 tonnes ~550,000 tonnes/yr HFC inhaler footprint

Notes re potential error- All data are estimates. Highest impact potential error in the calculation is the mean CO₂ per 134a inhaler of 15kg. We would need to know the complete breakdown of all devices sold in Australia, with HFC fil weights and footprints to accurately calculate.

Comparative calculations based on extrapolation of UK data

- Aus population is 26 million UK is 67 million = 38% of UK
- Aust prevalence- 11% (AIHW). UK asthma prevalence is 8% Ratio is 1.38
- Thus, based on UK data extrapolation, we expect Aus footprint (adjusting for higher incidence) to be 1.27 Mt \times 0.38 \times 1.38 \sim 665,000 Tonnes

Estimating equivalence for illustration purposes- Using 550-665 Tonnes...

If we use a median figure of 612,500 tonnes, for illustrative purposes, this is equivalent to the footprint of approximately –

- 350,000 cars driving 12,000 km/year (using 146.5g/km (NTC 2022),
- or the emissions of 45,000 households (based on 13.5 tonnes mean emissions/2.5 person household in Australia (Greenfleet).
- the sequestration potential of 28- 60 million eucalyptus trees (the latter likely being a better estimate), to absorb the equivalent CO₂ each year (based on 10-22 kg/tree/year EcoTree, EEA, OneTreePlanted).

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