education for health SUPPORTING HEALTH IMPROVEMENT

AIR and MART Regimes

A more flexible approach

AIR and MART regimes

This presentation will cover:

- The basics of AIR & MART
- The principles and rationale behind AIR & MART for asthma management
- The components and medications involved in AIR & MART therapy
- Differentiate AIR & MART from traditional asthma pharmacological approaches

www.nice.org.uk/guidance/ng245

The why

What have we seen?

The headlines

Charity warns asthma care at 'standstill' as grieving family calls for awareness

Boy, 10, died suddenly after 'feeling fine' as asthma attack deaths skyrocket by 25%

BBC NEWS

Mother makes asthma plea following daughter's sudden death

Facts and figures

- Every 10 seconds, someone has an asthma attack
- Asthma one of the most common childhood conditions, affecting 1 in 11 children
- 1 million children in the UK are receiving treatment for asthma.
- Children are less likely than adults to receive good basic asthma care – less than 25% of children with asthma have a personalised asthma action plan (PAAP)
- Outcomes worse for children, young people and adults living in deprived areas
- Air pollution is the greatest environmental threat to human health
- Low levels of good basic asthma care for children and young people • 12% of children admitted to hospital because of their asthma have been using an empty inhaler.

https://www.transformationpartners.nhs.uk/wp-content/uploads/2024/10/How-asthma-affects-children-young-peoples-quality-of-life-and-how-we-can-address-it-ALUK-2024-.pdf

Every year since 2019/20 the most deprived 10% accounted for 1 in 5 while the least deprived accounted for 1 in 20 of all childhood emergency hospital admissions • The most deprived 10% were 2.5x more likely to be admitted to hospital with an asthma exacerbation compared to the least deprived 10% of children under 5

UK Statistics

- UK asthma outcomes are among the worst in Europe:
  - Higher rates of preventable attacks
  - Higher rates of unscheduled care visits
  - Higher rates of hospital admissions
  - Higher rates of deaths
  - Higher medical costs

Levy et al,, 2014; Shah et al., 2019; Levy et al., 2021 (cited in Levey 2024)

What have we learned: change needs to happen
Asthma and Lung UK (2024)
https://www.asthmaandlung.org.uk/media/press-releases/asthma-care-crisis-charity-sounds-siren-asthma-death-toll-rises

“Asthma care is in crisis” - charity sounds the siren as asthma death toll rises

- The Asthma + Lung UK Annual Survey concluded that only a third of people with asthma received even the most basic level of care in 2022
- Released on 24th April 2024

Asthma and Lung UK (2024)

What have we learned: change needs to happen
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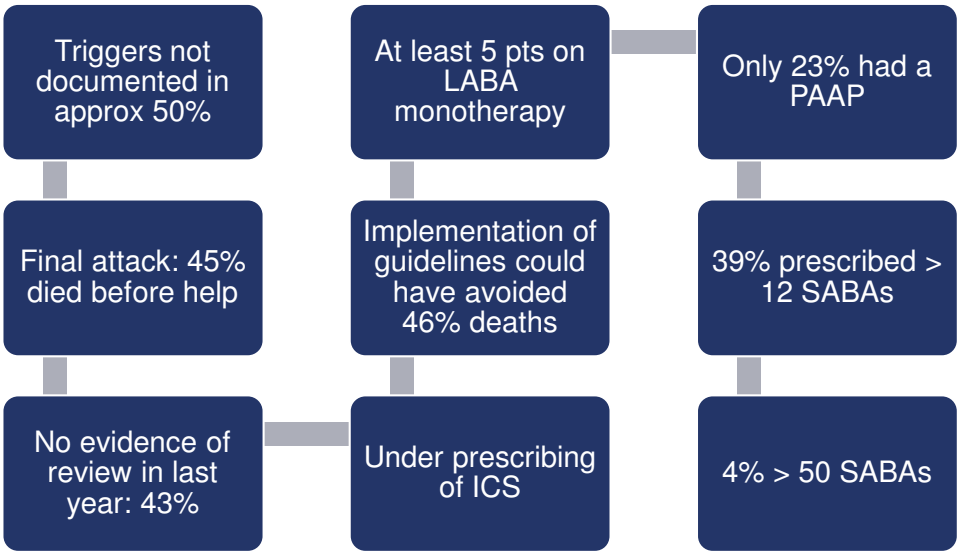
Why asthma still kills: NRAD Key Findings



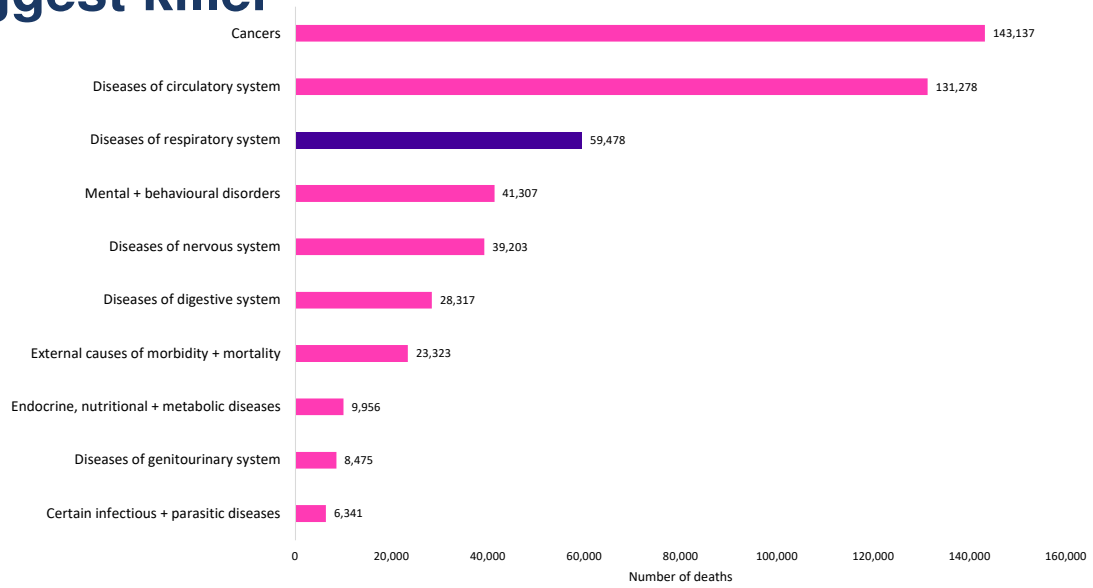
Published on World Asthma Day in 2014, attracted a lot of media attention in the UK and elsewhere in the world
The findings of the NRAD serve as a call to action for clinicians, healthcare commissioners and governments to consider potential ways forward for the future management of asthma and eradication of preventable asthma deaths

The National Review of Asthma Deaths (NRAD) was commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England, NHS Wales, the Health and Social Care Division of the Scottish Government, and the Northern Ireland Department of Health, Social Services and Public Safety (DHSSPS)

Despite the development and publication of evidence-based asthma guidelines nearly three decades ago, potentially preventable factors are repeatedly identified in studies of the care provided for patients who die from asthma The UK National Review of Asthma Deaths (NRAD), a confidential enquiry, was no exception: major preventable factors were identified in two-thirds of asthma deaths Most of these factors, such as inappropriate prescription and failure to provide patients with personal asthma action plans (PAAPs), could possibly have been prevented had asthma guidelines been implemented

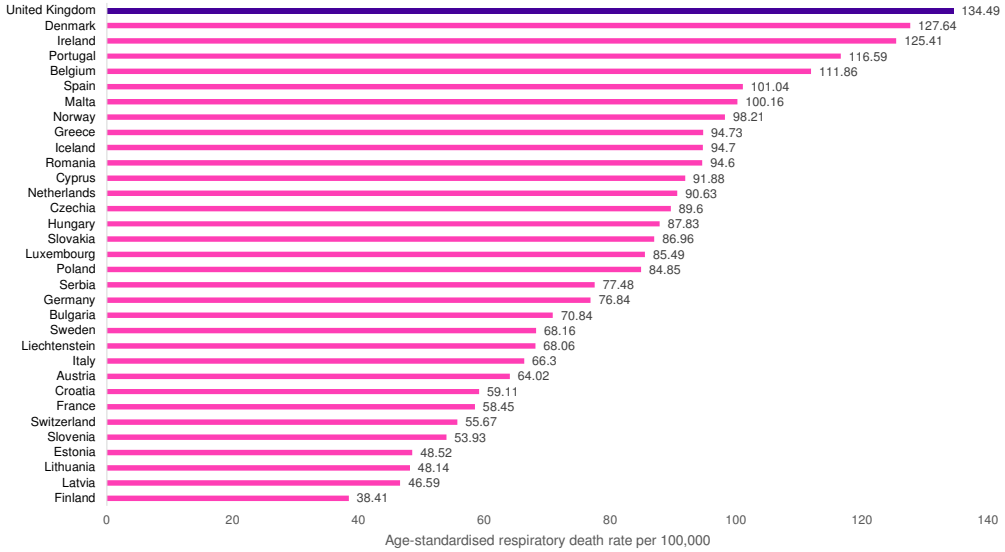
The apparent complacency with respect to asthma care, highlighted in NRAD, serves as a wake-up call for health professionals, patients and their carers to take asthma more seriously Based on the NRAD evidence, the report made 19 recommendations for change

Respiratory conditions are England's third biggest killer

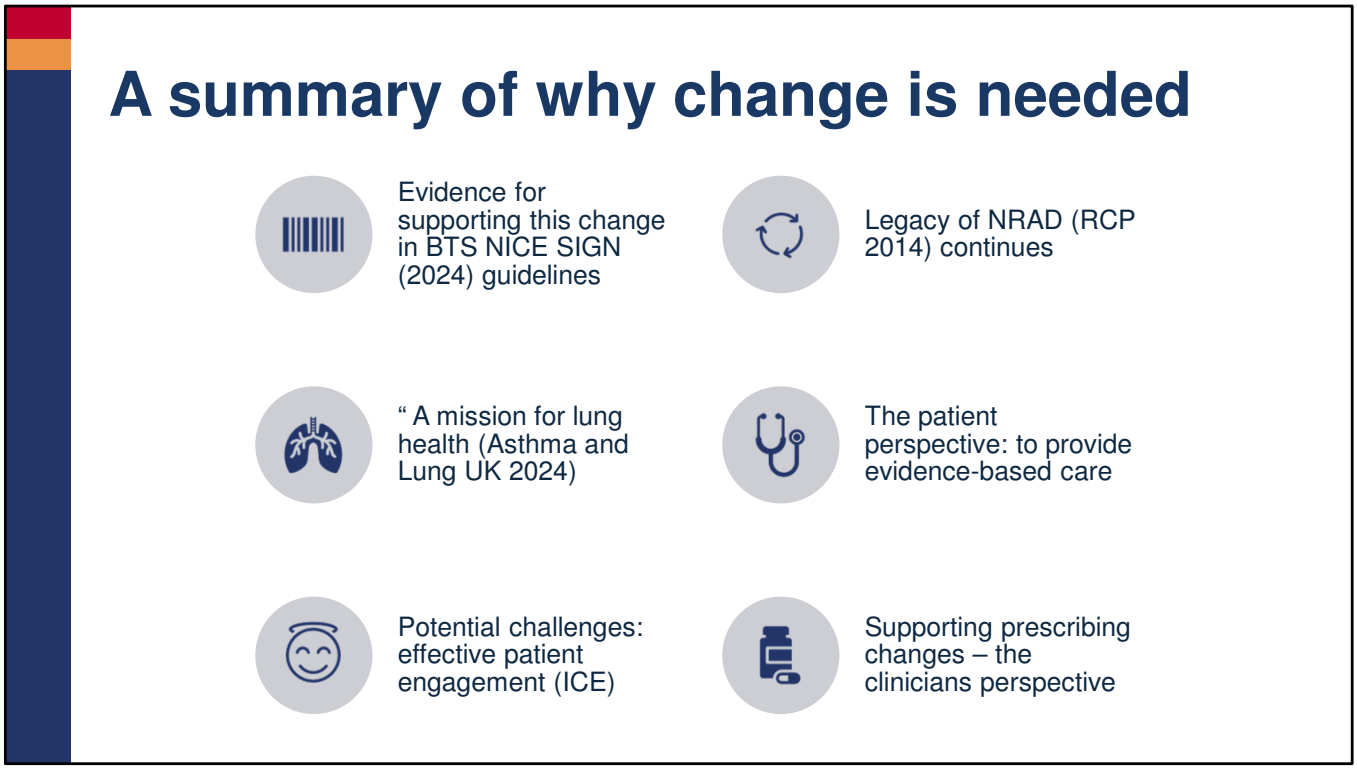


Reference: NHS England. Our ambition for respiratory disease. 2022. Accessed here.

We have the worst death rate for lung conditions in Europe



Reference: Eurostat. Causes of death – standardised death rate by region of residence 2011–2018. 2023. Accessed here



We now have the new asthma guidelines, BTS NICE and SIGN have all come together and provided an evidenced based guideline with fundamental changes to how we diagnose and manage patients with asthma.

More than a decade on, we are still living with the legacy of the NRAD confidential enquiry and the key finding in this report which demonstrated areas for improvement.

We have heard from Laura and the Asthma and Lung UK report “A Mission for lung health”. The **Government issued a rallying cry to the nation to help fix the NHS. The** Health Secretary, Wes Streeting calls on the entire nation to shape the government’s plans to overhaul the NHS **(GOV.UK 2024)**

Laura has explained how public engagement will help shape the government’s 10 Year Health Plan which will be published in spring 2025 and will be underlined by 3 big shifts in healthcare:
hospital to community
analogue to digital
sickness to prevention

We all as HCP need to be cognisant of the patient's perspective: the paradigm

shift from a blue inhaler to a combination inhaler. We must validate their concerns about “giving up” their blue inhaler.
This is achieved by exploring the patients ICE.
We must also be cognisant of our colleagues and their own health beliefs and perspective. Moving away from familiar prescribing decisions.

“If you always do what you’ve always done, you’ll always get what you’ve always got.”

(Henry Ford, n.d.)

It is time for change…

Why might poor adherence occur?

Consider:

- Misunderstanding medication.
- No perceived benefit from medication.
- Side effects from medication in particular inhaled corticosteroids (fear of side effects)
- Unable to use the device prescribed/lack of instruction
- Cost of prescription
- Under-estimation of severity
- Complex medication regimes – patients forget
- Complacency
- Inappropriate expectations of medication
- Cultural and religious reasons
- Stigmatism and attitudes

So how might AIR and MART address some of these barriers?

Why change is needed: The evidence

- Data from across the SABA Use IN Asthma (SABINA III) global programme demonstrates SABA reliever overuse is a global issue in asthma management:
  - The findings confirmed the association between SABA prescriptions and poor asthma outcomes
  - Growing evidence that SABA overuse in asthma needs to be addressed if further reductions in asthma morbidity and mortality are to be achieved
- An association between SABA prescription/possession and severe exacerbations and asthma deaths has been reported in SABINA I (UK) and II (Sweden and Italy).

Bateman et al., 2022

The SABINA III findings demonstrated that 38% of patients in 24 countries across five continents are overprescribed SABAs

The authors recognised that drivers for SABA prescribing may differ by country, but SABA overprescription results in an unnecessary burden of poor asthma symptom control and severe asthma exacerbations with their aossiated risks.

, ≥3 canisters per year. These findings extend the data from the SABINA studies in Europe.

Bateman et al (2022) Short-acting β_2-agonist prescriptions are associated with

***poor clinical outcomes of asthma: the multi-country, cross-sectional SABINA III study* European Respiratory Journal 59(5): 2101402;**
DOI: https://doi.org/10.1183/13993003.01402-2021

SABINA (SABA use IN Asthma) III forms part of the SABINA group of observational studies

Short-acting β_2-agonist prescriptions are associated with poor clinical outcomes of asthma: the multi-country, cross-sectional SABINA III study

To gain a global perspective on SABA prescriptions and associated asthma-related clinical outcomes in patients with asthma, health data across 24 countries in five continents was assessed.

GINA-defined controlled or partly controlled asthma specifies that SABA reliever use should not be >2 doses per week, which equates to <2 standard SABA canisters per year.

SABINA III assessed data from primary or specialist care to record prescribed medication(s), over-the-counter (OTC) SABA purchases and clinical outcomes in asthma patients (≥12 years old) during the past 12 months.

***Bateman et al (2022) Short-acting β_2-agonist prescriptions are associated with poor clinical outcomes of asthma: the multi-country, cross-sectional SABINA III study* European Respiratory Journal 59(5): 2101402;**
DOI: https://doi.org/10.1183/13993003.01402-2021
Henry Ford (https://www.goodreads.com/quotes/904186-if-you-always-do-what-you-ve-always-done-you-ll-always

AIR Evidence for Mild Asthma

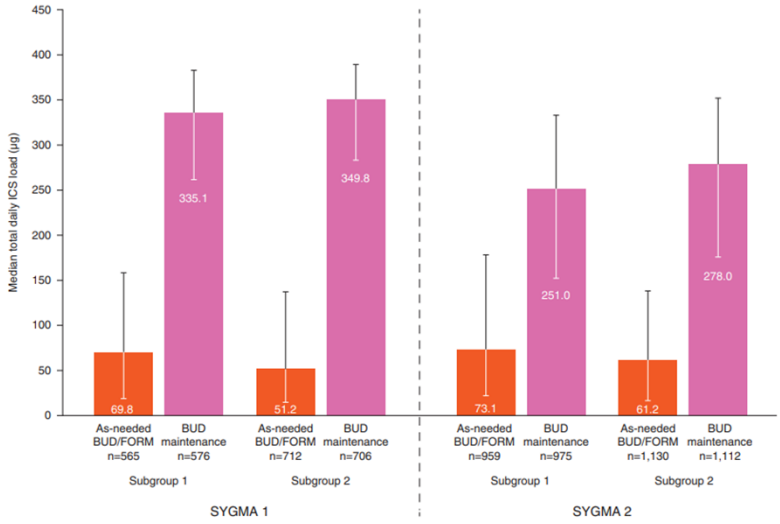
- A Cochrane meta-analysis of available trial data examined six studies from which 9657 participants contributed to the meta-analyses
- All used dry powder budesonide and formoterol as the combination inhaler.
- Authors Conclusions: fast-acting β_2-agonist (FABA) FABA/ICS as required is clinically effective in adults and adolescents with mild asthma:
  - reduced exacerbations
  - reduced hospital admissions or unscheduled healthcare visits
  - reduced exposure to oral steroids
  - FABA/ICS as required is as effective as regular ICS

Crossingham et al., 2021

In this study, formoterol was referred to as fast-acting – we will see more of this later.

Crossingham I, Turner S, Ramakrishnan S, Fries A, Gowell M, Yasmin F, Richardson R, Webb P, O'Boyle E, Hinks TSC. Combination fixed-dose β agonist and steroid inhaler as required for adults or children with mild asthma: a Cochrane systematic review. BMJ Evid Based Med. 2022 Jun;27(3):178-184. doi: 10.1136/bmjebm-2021-111764. Epub 2021 Jul 19. PMID: 34282031; PMCID: PMC9132861.
Beasley R, Bruce P, Houghton C, Hatter L The ICS/formoterol reliever therapy regimen in asthma: a review J Allergy Clin Immunol Pract 2023; 11(3): 762–772

SYGMA 1 and SYGMA 2



Median total daily ICS load, according to pre-study treatment in both SYGMA 1 and SYGMA 2.

Subgroup 1: patients uncontrolled on PRN SABA.

Subgroup 2: patients controlled on ICS or LTRA

Image courtesy of Bateman, O'Byrne, FitzGerald, et al.: As-needed Budesonide–Formoterol for Mild Asthma

The SYGMA (Symbicort Given as Needed in Mild Asthma) studies evaluated the efficacy and safety of PRN BUDESONIDE and FORMOTEROL in patients whose asthma was **uncontrolled on:**

1. PRN SABA (subgroup 1) or
2. **controlled** on ICS or leukotriene receptor antagonists (subgroup 2).

These findings suggest that, for patients with mild asthma currently receiving SABA alone, prn low-dose ICS–FORM (i.e.. AIR) should be preferred over maintenance ICS as initial controller treatment.

For patients whose asthma is controlled on maintenance low-dose ICS, prn BUD–FORM is an alternative to maintenance ICS without the need for daily treatment, and both of these options are safer than switching to SABA only

treatment.

Objectives: To assess the influence of prestudy treatment in a *post hoc* analysis of the SYGMA studies.

Evidence for MART approach

- The Maintenance and Reliever (MART) approach, with ICS-formoterol reduces the risk of severe exacerbations:
  - by 17% compared with usual care (Cates and Karner. 2013).
  - by 32% compared with the same dose of ICS-LABA (Sobieraj et al., 2018)
  - by 23% compared with a higher dose of ICS-LABA (Sobieraj et al., 2018)

What about high dose MART?

- Beasley et al (2024) acknowledged the available evidence suggests that medium dose ICS/formoterol MART has a superior efficacy/safety profile than high dose ICS/LABA plus SABA (Beasley et al 2024).

We have Cates CJ, Karner C. Combination formoterol and budesonide as MART therapy versus current best practice (including inhaled steroid maintenance), for chronic asthma in adults and children.

Cochrane Database Syst Rev. 2013 Apr 30;2013(4):CD007313. doi: 10.1002/14651858.CD007313.pub3. PMID: 23633340; PMCID: PMC10357488.

The Cates and Karmer (2013) study was to assess the efficacy and safety of budesonide and formoterol as MART compared with maintenance with ICS and any reliever therapy.

The authors' conclusions were that a single inhaler therapy has now been demonstrated to reduce exacerbations requiring oral steroids against current best

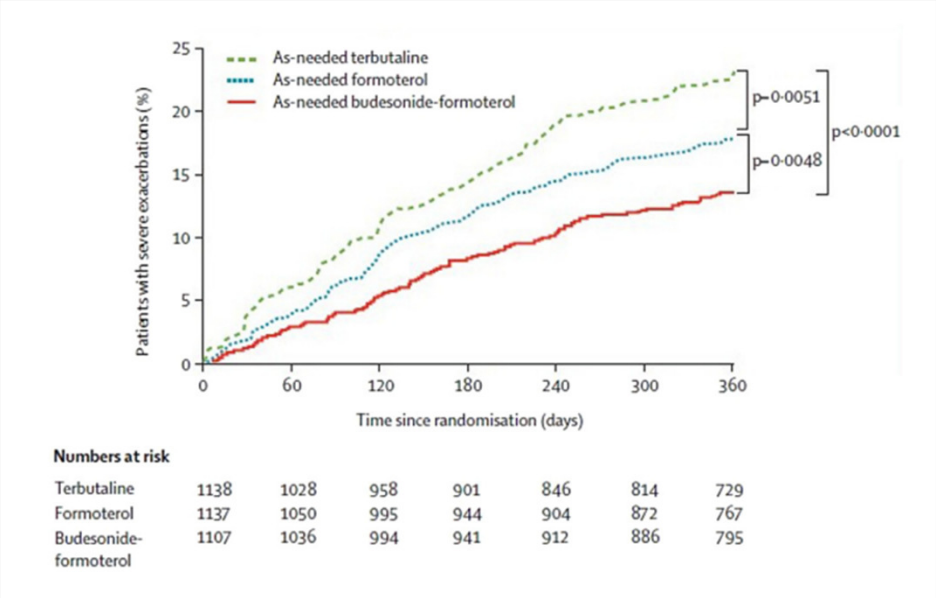
practice strategies and against a fixed higher dose of inhaled steroids.

Further support comes from Sobieraj et al (2018) Association of Inhaled Corticosteroids and Long-Acting β-Agonists as Controller and Quick Relief Therapy With Exacerbations and Symptom Control in Persistent Asthma A Systematic Review and Meta-analysis
https://jamanetwork.com/journals/jama/fullarticle/2675737

In this meta-analysis that included 22 524 patients aged 12 years or older and 341 children aged 4 to 11 years with persistent asthma, MART was associated with a significantly lower risk of asthma exacerbations compared with a higher dose of inhaled corticosteroids and LABA as controller therapy. Evidence for patients aged 4 to 11 years was limited.

Beasley et al (20240 stated This personalised medicine approach is consistent with the Global Initiative for Asthma (GINA) strategy for difficult-to-treat asthma, where MART is recommended as part of optimisation of therapy before considering high dose ICS/LABA

Beasley R, Noble J, Weatherall M. The evidence base for ICS/formoterol maintenance and reliever therapy in severe asthma. Eur Respir J. 2024 Jun 20;63(6):2400523. doi: 10.1183/13993003.00523-2024. PMID: 38901890; PMCID: PMC11187315.



Source of diagram: Rabe et al (2006): Time to first severe exacerbation in adolescents and adults taking maintenance ICS/formoterol, randomized to as-needed terbutaline, formoterol, or budesonide/formoterol reliever.

Rabe et al in (2006), published in The Lancet conducted a 12-month, double-blind, parallel-group study in 3394 patients (aged 12 years or older), in 289 centres in 20 countries, who were using inhaled steroids at study entry and symptomatic on budesonide-formoterol (160 µg and 4·5 µg, respectively), one inhalation twice daily,

The subjects were randomly assigned budesonide-formoterol maintenance therapy plus one of three alternative **as-needed medications**;

1. terbutaline
2. formoterol or combined budesonide-formoterol (160 µg and 4·5 µg).
3. The primary outcome was time to first severe exacerbation, defined as an event resulting in hospitalisation, emergency room treatment, or both, or the need for oral steroids for 3 days or more.

The results above show that maintenance plus as-needed budesonide-formoterol (otherwise known as MART) reduced the risk of severe exacerbations and events resulting in emergency room visits or hospitalisations compared with maintenance budesonide-formoterol plus either formoterol or terbutaline as needed

The combination arm is the red arm, you can see the number of patients with severe exacerbation was lower in the combination arm vs SABA or Formoterol

Rabe et al (2006) Effect of budesonide in combination with formoterol for reliever therapy in asthma exacerbations: a randomised controlled, double-blind study

https://www-sciencedirect-com.knowledge.idm.oclc.org/science/article/pii/S0140673606692842

GINA (2019) groundbreaking recommendations

- Evidence of the harmful effects of SABA use, including risk of death, has been available for decades
- Spitzer et al (1992) examined a cohort of 12,301 patients prescribed asthma medications between **1978 and 1987**:
  - an increased risk of death or near death from asthma was associated with the regular use of inhaled beta 2-agonist
- The 2019 GINA recommendations changed decades of asthma care
- GINA made groundbreaking recommendations in 2019 for the use of ICS-formoterol 'as needed' for symptoms – either alone (AIR) or MART in adolescents and adults with asthma

GINA (2019)

But AIR is not a new idea!

Spitzer WO, Suissa S, Ernst P, Horwitz RI, Habbick B, Cockcroft D, Boivin JF, McNutt M, Buist AS, Rebuck AS. The use of beta-agonists and the risk of death and near death from asthma. N Engl J Med. 1992 Feb 20;326(8):501-6. doi: 10.1056/NEJM199202203260801. PMID: 1346340.
Pavord ID, Beasley R, Agusti A, et al After asthma: redefining airways diseases Lancet 2018; 391(10118): 350–400

"The level 1 scientific evidence of the greater efficacy and safety of ICS/formoterol versus SABA reliever therapy across the range of asthma severity allows Grade A recommendations to be made for its use as the preferred reliever therapy in adults and adolescents".

Beasley et al., 2024

Beasley et al in their paper The ICS/Formoterol Reliever Therapy Regimen in Asthma: A Review.

Confirmed the rationale for ICS/formoterol therapy is based on concerns about the risks of SABA reliever therapy, and the potential benefit of titrating additional ICS through the vehicle of bronchodilator reliever use. There is a substantial evidence base extending back more than 70 years that beta2-agonist reliever therapy may lead to increased asthma severity with long-term use

Beasley R, Bruce P, Houghton C, Hatter L. The ICS/Formoterol Reliever Therapy Regimen in Asthma: A Review. J Allergy Clin Immunol Pract. 2023 Mar;11(3):762-772.e1. doi: 10.1016/j.jaip.2023.01.002. Epub 2023 Jan 10. PMID: 36639054.

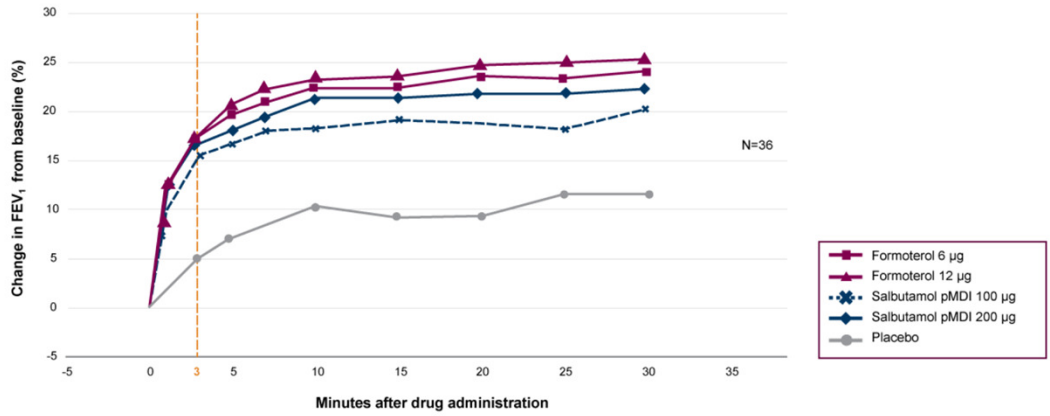
Strategies to support a patient-centred flexible approach: evidence

- Evidence of the efficacy of this approach will drive its implementation
- "Salbutamol is a selective beta$_2$-adrenoceptor agonist. At therapeutic doses it acts on the beta$_2$-adrenoceptors of bronchial muscle providing short acting (4-6 hour) bronchodilation with a fast onset (**within 5 minutes**) in reversible airways obstruction *(SPC, 2024).*
- "Formoterol is a potent selective beta2-adrenergic stimulant. It exerts a bronchodilator effect in patients with reversible airways obstruction. The effect sets in rapidly (**within 1-3 minutes**) and is **still significant 12 hours after inhalation"** *(SPC, 2022).*

Evidence to support patient decision making and choice for the onset of action of their new reliever, if reluctant to change from SABA to AIR
SPC (2024) Ventolin Evohaler 100 micrograms

SPC (2022) Formoterol Easyhaler 12 micrograms per dose inhalation powder:
https://www.medicines.org.uk/emc/product/312/smpc

Formoterol's onset of bronchodilation is similar to salbutamol's after 3 minutes



Improvement in FEV_1 is as rapid and effective with formoterol 6 or 12 µg as with salbutamol 100 or 200 µg

Adapted from Seberová E and Andersson A. Respir Med 2000;94(6):607–611.
Cited in: https://www.myastrazeneca.co.uk/symbicort/think-mart.html#

This graph illustrates the onset of action for Formoterol vs Salbutamol. For those patients reluctant to move away from SABA therapy, this slide highlights a powerful message

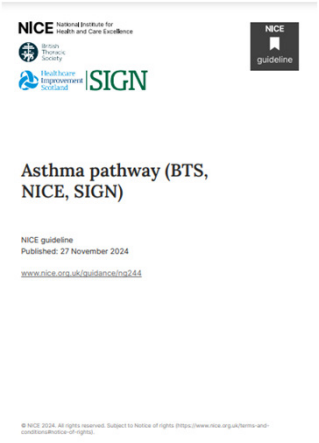
The two Formoterol arms, 6mcgs and 12 mcgs are the red arms at the top of the graph, with the change in FEV1 shown on the left

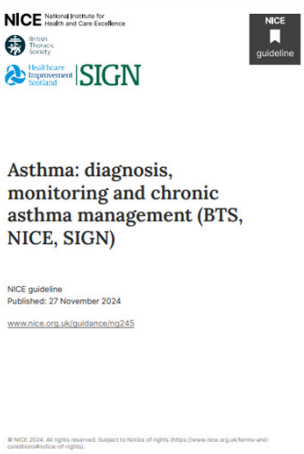
The blue lines underneath are Salbutamol either 200mcg or 200 mcg
The grey line at the bottom is a placebo.

Introducing a flexible approach to delivering person-centred care in asthma

It is time for change…

BTS/NICE/SIGN (2024); BTS/NICE/SIGN (2024); GINA (2024)





THE BTS/NICE SIGN (2024) asthma guideline is part of a new asthma pathway. The UK pathway supports health professionals in making accurate diagnoses, promoting good practice, and providing effective treatment to control the condition and prevent acute asthma attacks. It also signposts to other relevant guidance for easy reference

The new pathway includes guidance on areas that fall outside the scope of the collaborative guideline and has been informed by a short-life working group established in June 2023

This is a new collaborative guideline developed jointly by the British Thoracic Society (BTS), National Institute for Health and Care Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN).

Benefits of AIR and MART for the patient

- Potentially lower ICS dose
- Better controlled asthma
- Reduced exacerbations
- Convenient
- Simple regime
- Easy step up and step down
- One prescription charge

Prescribing considerations

The licensing of combination inhalers

SIGN: Prescribing licensed medicines out with their marketing authorisation

- Some recommendations may be for medicines prescribed out with the marketing authorisation (MA) also known as product licence
- This is known as ‘off-label’ use
- Medicines may be prescribed ‘off label’ in the following circumstances:
  - for an indication not specified within the MA
  - for administration via a different route
  - for administration of a different dose
  - for a different patient population

https://www.sign.ac.uk/using-our-guidelines/

Prescribers' professional responsibility

- Generally, 'off-label' prescribing of medicines becomes necessary if the clinical need cannot be met by licensed medicines within the MA
- Such use should be supported by appropriate evidence and experience
- "Prescribing medicines outside the conditions of their MA alters (and probably increases) the prescribers' professional responsibility and potential liability"

https://www.sign.ac.uk/using-our-guidelines/

Making decisions using NICE guidelines: off-label or unlicensed use

- People have the right to be able to make informed decisions about their care
- NICE only recommend if there is enough evidence or experience to support it
- Healthcare professionals should follow relevant professional guidance
- They should take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines
- This includes considering the contraindications, warnings, monitoring requirements and other safety recommendations for the medicine

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines#prescribing-medicines

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines#prescribing-medicines

Off-label or unlicensed use of medicines: prescribers' responsibilities (MHRA, 2014)

- HCP may have more responsibility than when they prescribe a medicine within the terms of its licence

Prescribing in a patient's best interests:

- there are clinical situations when use of unlicensed medicines or medicines outside the terms of the licence ('off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence
- all HCPs who can prescribe are subject to their individual clinical competence, the professional codes and ethics of their statutory bodies and the prescribing policies of their employers

https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities

https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities

The aim of asthma management is control of the disease

The BTS/NICE/SIGN (2024) asthma guidelines define complete control of asthma as:

- no daytime symptoms
- no night-time awakening due to asthma
- no asthma attacks
- no need for rescue medication
- no limitations on activity **including exercise**
- normal lung function (in practical terms forced expiratory volume in 1 second [FEV1] and/or peak expiratory flow [PEF] more than 80% predicted or best)
- minimal side effects from treatment

www.nice.org.uk/guidance/ng245

People with asthma should have the same quality of life and live life the same as a non asthmatic.
Asthma should not restrict their activities or affect their life choices

Consequences of poor adherence

- Estimated that up to 50% of patients have poor adherence to long term therapy (GINA 2024)
- Well documented that those with adherence rate of ≥ 80% have reduced exacerbations, reduced oral corticosteroid use and positive impacts on asthma related mortality (George and Bender, 2019)
- If this is the case, why do we think patients' adherence is so poor?

Take a few moments to think about your own patient population. Why do you think they may have poor adherence?

1. Global Initiative for Asthma. Full report 2024. Available at: https://ginasthma.org/2024-report/
2. George and Bender (2019) New insights to improve treatment adherence in asthma and COPD 2019. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6681064/ Accessed July 2021

Important to look at adherence. Non adherence rates are high with people on long term therapy
No adherence can be intentional non adherence or intentional no adherence.
Non adherence can be multifactoral

Why do asthma patients have poor asthma control?

- Poor at perceiving changes in their airways
- Poor inhaler technique
- Treatment adherence
- Poor prescription pick-up rates
- Overuse of SABA inhalers
- Need for an increased dose of inhaled corticosteroid (ICS)
- Ongoing triggers/occupational element
- Anxiety and depression, relationships and social networks
- Comorbidities

www.nice.org.uk/guidance/ng245

Poor asthma control is usually multifactorial
It is not always necessary to step up treatment to gain good control.
Any other non-pharmacological factors should be addressed prior to stepping up treatment

How can healthcare professionals identify and improve poor adherence?

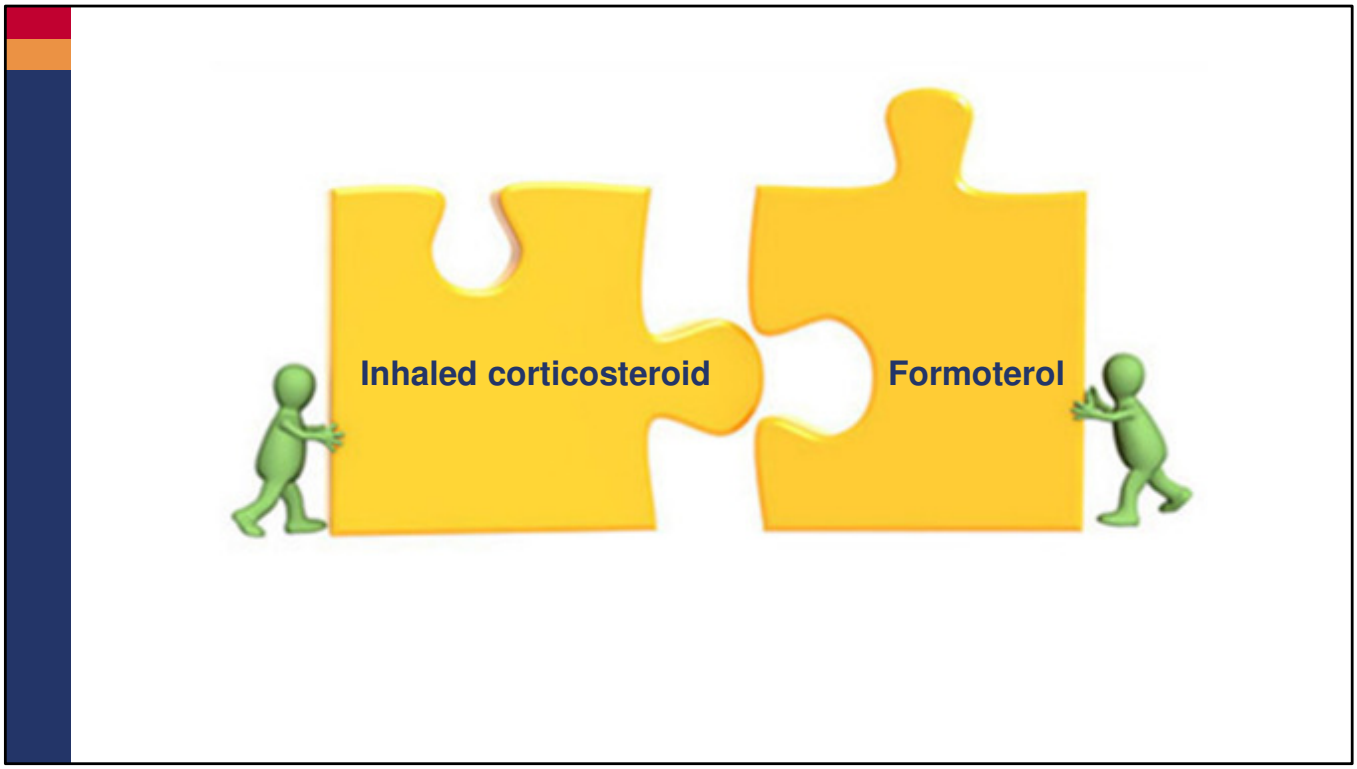
- Ask empathetic questions
- Check medication usage
- Explain what asthma is and how it is treated
- Offer realistic expectations from medications; give clear instruction on how and when to use
- Check inhaler technique at every opportunity
- Ensure the patient has medication that they can and are prepared to take
- Discuss pre-payment prescription options
- Chase follow up appointments of those that miss appointments - could you offer a telephone or video consultation instead?

It is important that you build a relationship with your patient.
Your own attitude and beliefs can affect the way you conduct you consultation.
Your own prejudice regarding how your patient looks and behaves can also affect how you approach and treat your patient.
Consider why your patients miss their review, is the appointment at an inconveient time, do they feel the review is valuable? Are they included in the decision making process?

AIR, low dose MART, and medium dose MART Pharmacological management of asthma

(BTS/NICE/SIGN, 2024)

These are the only inhalers currently licenced for AIR therapy



How do these treatments work - combination of ICS and LABA!
and moving on to why in the next slides

Pharmacological treatment options*

***for young people and adults aged >12**

- SABA-free pathways are preferential (to reduce risks associated with SABA overuse)
- The SABA free options include anti-inflammatory reliever (AIR) and maintenance and reliever therapy (MART) which both use a combination of ICS/formoterol
- Only certain ICS/formoterol inhalers are licensed for reliever therapy
- **None should be prescribed SABA only!**

BTS/NICE/SIGN, 2024

Do not prescribe a SABA (blue inhaler) to people **of any age** with asthma **without a concomitant prescription of an ICS**.

The emphasis for management now focuses on SABA-free pathway, introduced with AIR and MART regimes.

BTS/NICE/SIGN (2024)

Initial management of newly diagnosed asthma in people aged 12+

- In November 2024, only three budesonide/formoterol inhalers were licensed for anti-inflammatory reliever therapy (AIR) in mild asthma.
- The use of any other ICS/formoterol inhalers would therefore be off-label.
- The current evidence supporting the use of budesonide/formoterol is based on the use of a dry powder inhaler.

BTS/NICE/SIGN (2024)

For more information re: prescribing off-label:
NICE information on prescribing medicines: Making decisions using NICE guidelines
SIGN using our guidelines: Statement of intent
NMC Standards for Prescribers. The standards that set out how nurses and midwives can achieve prescriber status
RPS Prescribing Practice safely and confidently with our practical guidance, resources and support

What is AIR therapy?

- A single inhaler for as needed use in asthma
- A simple and effective evidence-based approach to asthma management: ICS-formoterol reliever therapy

Symbicort 200/6: **Mild asthma, reliever therapy for Symbicort 200/6 Turbohaler®**
By inhalation of powder
Child 12–17 years1 puff as required for relief of symptoms, increased if necessary up to 6 puffs as required, max 8 puffs per day; up to 12 puffs daily can be used for a limited time but medical assessment is recommended
Adult1 puff as required for relief of symptoms, increased if necessary up to 6 puffs as required, max 8 puffs per day; up to 12 puffs daily can be used for a limited time but medical assessment is recommended

DuoResp
®
Spiromax®160/45 reliever therapy: Taken as needed in response to symptoms

***DuoResp® Spiromax® 160/45 reliever therapy*:** Taken as needed in response to symptoms The recommended use as a reliver therapy should take into consideration the frequency of need In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used *Adults and adolescents (12 years and older)*: Patients should take 1 inhalation as needed in response to symptoms If symptoms persist after a few minutes, an additional inhalation should be taken

Not more than 6 inhalations should be taken on any single occasion If a patient finds the treatment less effective or experiences progressive deterioration of symptoms despite taking DuoResp Spiromax as needed the patient should seek medical attention as soon as possible A total daily dose of up to 12 inhalations could be used for a limited period
Let us have a look at these “flexible” treatment regimes for asthma

WockAIR is also indicated as reliever therapy for adults and adolescents (12 years and older) with mild asthma *Recommended doses:*
Adults and adolescents (12 years and older): Patients should take 1 inhalation as needed in response to symptoms If symptoms persist after a few minutes, an additional inhalation should be taken Not more than 6 inhalations should be taken on any single occasion
NB: Show **For Symbicort 100/6 Turbohaler® NOT licenced in AIR MART only**

Use of AIR

"Complacency with asthma, and entrenched overprescribing and overreliance on SABAs persists in the UK.

Despite the known morbidity and mortality risks associated with regular and/or excessive use of SABAs, most countries have failed to implement the alternative evidence-based AIR approach recommended by GINA"

Levy et al., 2024

An excellent paper published by Levy et al (2024) which recognised the UK asthma outcomes are among the worst in Europe, more detail coming later

Levy ML, Beasley R, Bostock B, Capstick TG, Crooks MG, Fleming L, Freeman D, Marsh V, Rupani H, Whittamore A, Barnes PJ, Bush A. A simple and effective evidence-based approach to asthma management: ICS-formoterol reliever therapy. Br J Gen Pract. 2024 Jan 25;74(739):86-89. doi: 10.3399/bjgp24X736353. PMID: 38272684; PMCID: PMC10824346.

When to choose AIR?

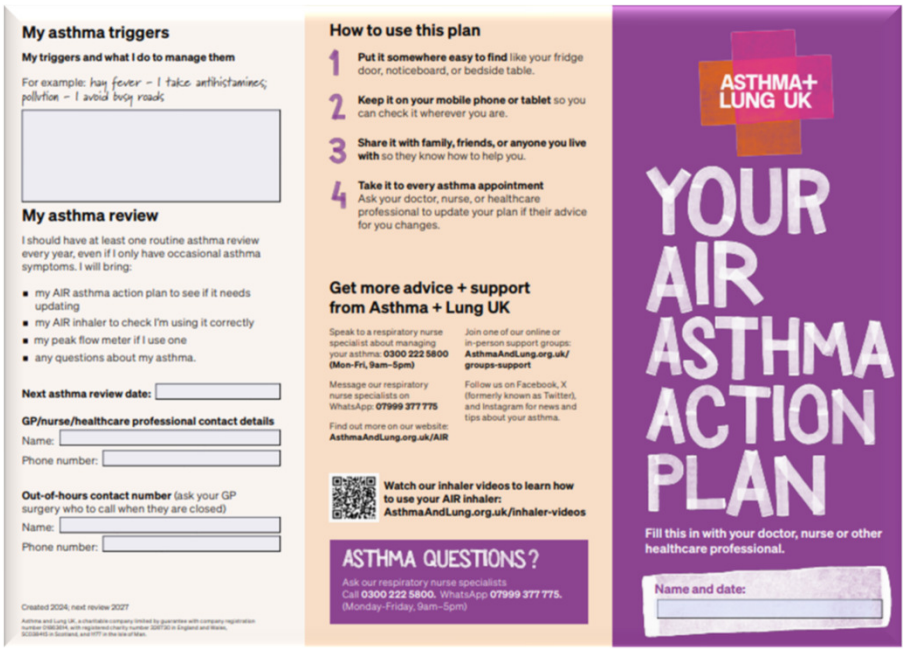
- Offer a **low-dose** ICS/formoterol combination inhaler to be taken as needed for symptom relief (**as-needed AIR therapy**) to people aged 12+ **with newly diagnosed asthma**

- If the person needing asthma treatment presents highly symptomatic, for example, **regular nocturnal waking or with a severe exacerbation, start treatment with low-dose MART** (maintenance and reliever therapy) in addition to treating the acute symptoms as indicated (a course of oral steroids may be needed)

(BTS/NICE/SIGN, 2024)

Prescribing example AIR: Check current BNF

- Take one puff as needed
- Take up to a maximum of 8 puffs throughout the day
- Review if needing regularly (most days) – step up to MART?
- Seek urgent medical advice if needing 8 or more puffs in a day even if feeling better
- If AIR inhaler is not working or not lasting 4hrs –> asthma attack
  - Call 999
  - One puff -> wait 1-3 minutes -> no improvement -> one puff
  - Repeat up to 6 puffs
  - If no improvement after 10 minutes and ambulance has not arrived repeat cycle
- AIR regimes should be SABA free



My asthma triggers

My triggers and what I do to manage them

For example: hay fever – I take antihistamines; pollution – I avoid busy roads

My asthma review

I should have at least one routine asthma review every year, even if I only have occasional asthma symptoms. I will bring:

- my AIR asthma action plan to see if it needs updating
- my AIR inhaler to check I'm using it correctly
- my peak flow meter if I use one
- any questions about my asthma.

Next asthma review date:

GP/nurse/healthcare professional contact details

Name:

Phone number:

Out-of-hours contact number (ask your GP surgery who to call when they are closed)

Name:

Phone number:

Created 2024; next review 2027

Asthma and Lung UK, a charitable company limited by guarantee with company registration number 01863834, with registered charity number 326730 in England and Wales, SC038445 in Scotland, and 1177 in the Isle of Man.

How to use this plan

1. **Put it somewhere easy to find** like your fridge door, noticeboard, or bedside table.
2. **Keep it on your mobile phone or tablet** so you can check it wherever you are.
3. **Share it with family, friends, or anyone you live with** so they know how to help you.
4. **Take it to every asthma appointment** Ask your doctor, nurse, or healthcare professional to update your plan if their advice for you changes.

Get more advice + support from Asthma + Lung UK

Speak to a respiratory nurse specialist about managing your asthma: **0300 222 5800 (Mon-Fri, 9am–5pm)**

Join one of our online or in-person support groups: **AsthmaAndLung.org.uk/groups-support**

Message our respiratory nurse specialists on WhatsApp: **07999 377 775**

Follow us on Facebook, X (formerly known as Twitter), and Instagram for news and tips about your asthma.

Find out more on our website: **AsthmaAndLung.org.uk/AIR**

Watch our inhaler videos to learn how to use your AIR inhaler: AsthmaAndLung.org.uk/inhaler-videos

ASTHMA QUESTIONS?

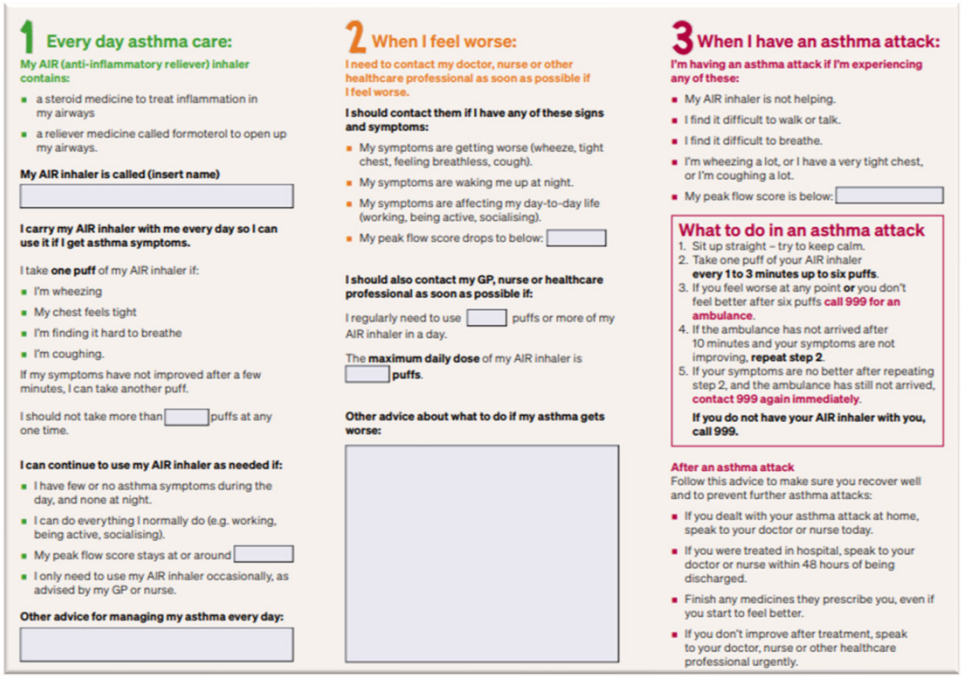
Ask our respiratory nurse specialists Call **0300 222 5800.** WhatsApp **07999 377 775.** (Monday–Friday, 9am–5pm)

ASTHMA+ LUNG UK

YOUR AIR ASTHMA ACTION PLAN

Fill this in with your doctor, nurse or other healthcare professional.

Name and date:



1 Every day asthma care:

My AIR (anti-inflammatory reliever) inhaler contains:

- a steroid medicine to treat inflammation in my airways
- a reliever medicine called formoterol to open up my airways.

My AIR inhaler is called (insert name)

I carry my AIR inhaler with me every day so I can use it if I get asthma symptoms.

I take **one puff** of my AIR inhaler if:

- I'm wheezing
- My chest feels tight
- I'm finding it hard to breathe
- I'm coughing.

If my symptoms have not improved after a few minutes, I can take another puff.

I should not take more than [ ] puffs at any one time.

I can continue to use my AIR inhaler as needed if:

- I have few or no asthma symptoms during the day, and none at night.
- I can do everything I normally do (e.g. working, being active, socialising).
- My peak flow score stays at or around [ ]
- I only need to use my AIR inhaler occasionally, as advised by my GP or nurse.

Other advice for managing my asthma every day:

2 When I feel worse:

I need to contact my doctor, nurse or other healthcare professional as soon as possible if I feel worse.

I should contact them if I have any of these signs and symptoms:

- My symptoms are getting worse (wheeze, tight chest, feeling breathless, cough).
- My symptoms are waking me up at night.
- My symptoms are affecting my day-to-day life (working, being active, socialising).
- My peak flow score drops to below: [ ]

I should also contact my GP, nurse or healthcare professional as soon as possible if:

I regularly need to use [ ] puffs or more of my AIR inhaler in a day.

The **maximum daily dose** of my AIR inhaler is [ ] **puffs**.

Other advice about what to do if my asthma gets worse:

3 When I have an asthma attack:

I'm having an asthma attack if I'm experiencing any of these:

- My AIR inhaler is not helping.
- I find it difficult to walk or talk.
- I find it difficult to breathe.
- I'm wheezing a lot, or I have a very tight chest, or I'm coughing a lot.
- My peak flow score is below: [ ]

What to do in an asthma attack

1. Sit up straight – try to keep calm.
2. Take one puff of your AIR inhaler **every 1 to 3 minutes up to six puffs**.
3. If you feel worse at any point **or** you don't feel better after six puffs **call 999 for an ambulance**.
4. If the ambulance has not arrived after 10 minutes and your symptoms are not improving, **repeat step 2**.
5. If your symptoms are no better after repeating step 2, and the ambulance has still not arrived, **contact 999 again immediately**.

If you do not have your AIR inhaler with you, call 999.

After an asthma attack

Follow this advice to make sure you recover well and to prevent further asthma attacks:

- If you dealt with your asthma attack at home, speak to your doctor or nurse today.
- If you were treated in hospital, speak to your doctor or nurse within 48 hours of being discharged.
- Finish any medicines they prescribe you, even if you start to feel better.
- If you don't improve after treatment, speak to your doctor, nurse or other healthcare professional urgently.

Case Studies

AIR

Akash

- Akash is 26 years old.
- Occupation: accountant.
- Never smoked.
- He currently uses his Blue inhaler pre-exercise, or if he get a viral cold.
- FeNO = 9 (low)
- Akash's ACT score is 23, down slightly as he may use his blue inhaler when he plays squash twice a week.
- Social History: lives in newly furnished apartment, no mould.

We will come back to Akash later.

5-19
Your asthma symptoms may not be well controlled

20-25
Your asthma symptoms may be well controlled

No matter what your score is, share the results with your healthcare provider

Pharmacological treatment options*

***for young people and adults aged >12**

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- The SABA free options include anti-inflammatory reliever (AIR) and maintenance and reliever therapy (MART) which both use a combination of ICS/formoterol
- Only certain ICS/formoterol inhalers are licensed for reliever therapy
- **None should be prescribed SABA only!**

BTS/NICE/SIGN, 2024

Do not prescribe a SABA (blue inhaler) to people **of any age** with asthma **without a concomitant prescription of an ICS**.

The emphasis for management now focuses on SABA-free pathway, introduced with AIR and MART regimes.

BTS/NICE/SIGN (2024)

Akash

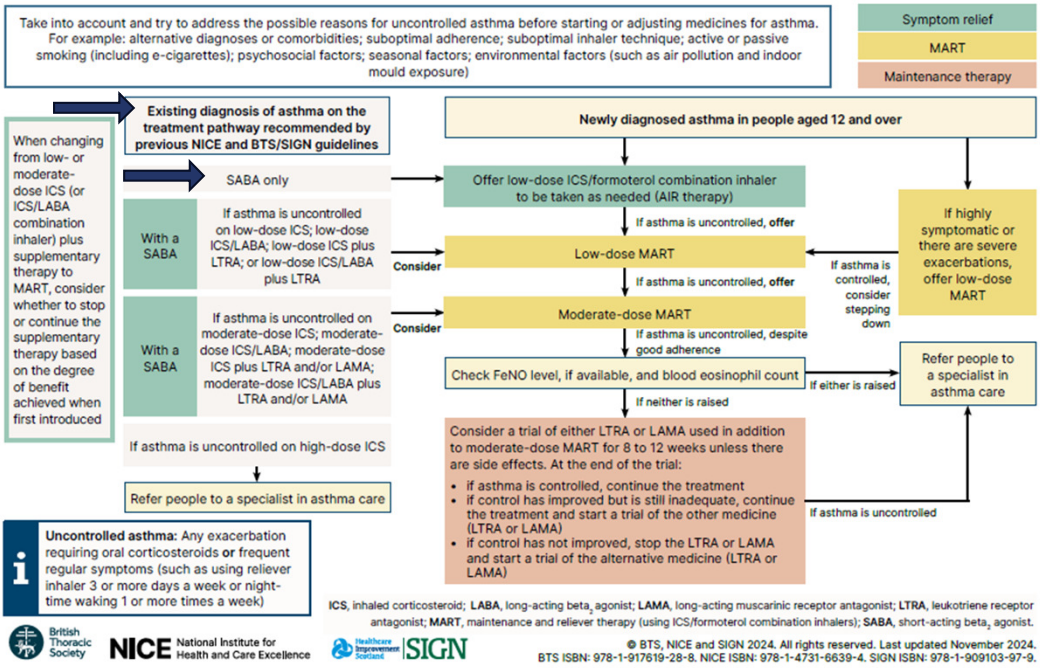
- AIR therapy was agreed:

1. Control good
2. FeNO = low

- BTS NICE SIGN (2024) define uncontrolled asthma:
  - Any exacerbation requiring oral corticosteroids or
  - frequent regular symptoms such as using reliever inhaler 3 or more days a week or
  - night-time waking 1 or more times a week

Algorithm C: Pharmacological management of asthma in people aged 12 years and over

BTS, NICE and SIGN guideline on asthma



BTS ISBN: 978-1-917619-28-8. NICE ISBN: 978-1-4731-6639-4. SIGN ISBN: 978-1-909103-97-9.

Initial management of newly diagnosed asthma in people aged 12+

- In November 2024, only three budesonide/formoterol inhalers were licensed for anti-inflammatory reliever therapy (AIR) in mild asthma.
- The use of any other ICS/formoterol inhalers would therefore be off-label.
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Anja

- Anja is 42 years old.
- Occupation: works in the school as head of science.
- Never smoked.
- Pets: 1 cat.
- FeNO = 30 (intermediate)
- Anja's ACT score is 18, use of blue inhaler.
- Lives in a town in middle of England.
- Currently using Clenil 200mcg 1p bd. Medication history shows poor adherence with

When to choose MART

- If the person needing asthma treatment presents highly symptomatic, for example, **regular nocturnal waking or with a severe exacerbation, start treatment with low-dose MART** in addition to treating the acute symptoms as indicated (a course of oral steroids may be needed)
- Low Dose MART: the terms low-dose MART and moderate-dose MART refer to the dosage of the maintenance component of MART
- Offer moderate-dose MART to people aged 12+ with asthma that is not controlled on low-dose MART

BTS/NICE/SIGN (2024)

Prescribing Example MART:

- Take one puff twice daily and take one puff as needed
- Take up to a maximum of 8 puffs throughout the day
- Review if needing extra doses 3+ times a week -> step up to medium dose MART?
- Seek urgent medical advice if needing 8 or more puffs in a day even if feeling better
- If MART not working or not lasting 4hrs –> attack
  - Call 999
  - One puff -> wait 1-3 minutes -> no improvement -> one puff
  - Repeat up to 6 puffs
  - If no improvement after 10 minutes and ambulance has not arrived repeat cycle
  - People using MART do not normally need a SABA

BTS/NICE/SIGN (2024)

People 12+ not controlled on moderate-dose MART despite good adherence:

- Check FeNO level if available, and blood eosinophil count. If either is raised, **refer to a specialist in asthma care**
- If neither FeNO or eosinophil count is raised, consider a trial of either a leukotriene receptor antagonist (LTRA) or a long-acting muscarinic receptor antagonist (LAMA) used **in addition to moderate-dose MART**

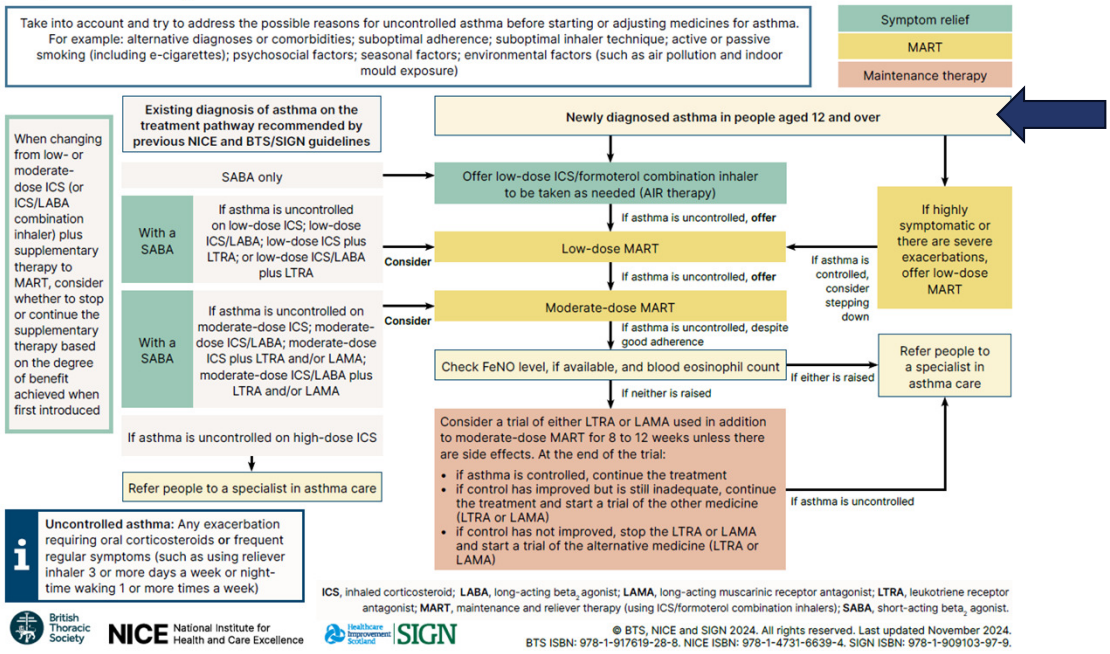
BTS/NICE/SIGN (2024)

Benefits of AIR and MART for the patient

- Potentially lower ICS dose
- Better controlled asthma
- Reduced exacerbations
- Convenient
- Simple regime
- Easy step up and step down
- One prescription charge

Algorithm C: Pharmacological management of asthma in people aged 12 years and over

BTS, NICE and SIGN guideline on asthma



ICS, inhaled corticosteroid; **LABA**, long-acting beta$_2$ agonist; **LAMA**, long-acting muscarinic receptor antagonist; **LTRA**, leukotriene receptor antagonist; **MART**, maintenance and reliever therapy (using ICS/formoterol combination inhalers); **SABA**, short-acting beta$_2$ agonist.

British Thoracic Society | NICE National Institute for Health and Care Excellence | Healthcare Improvement Scotland SIGN

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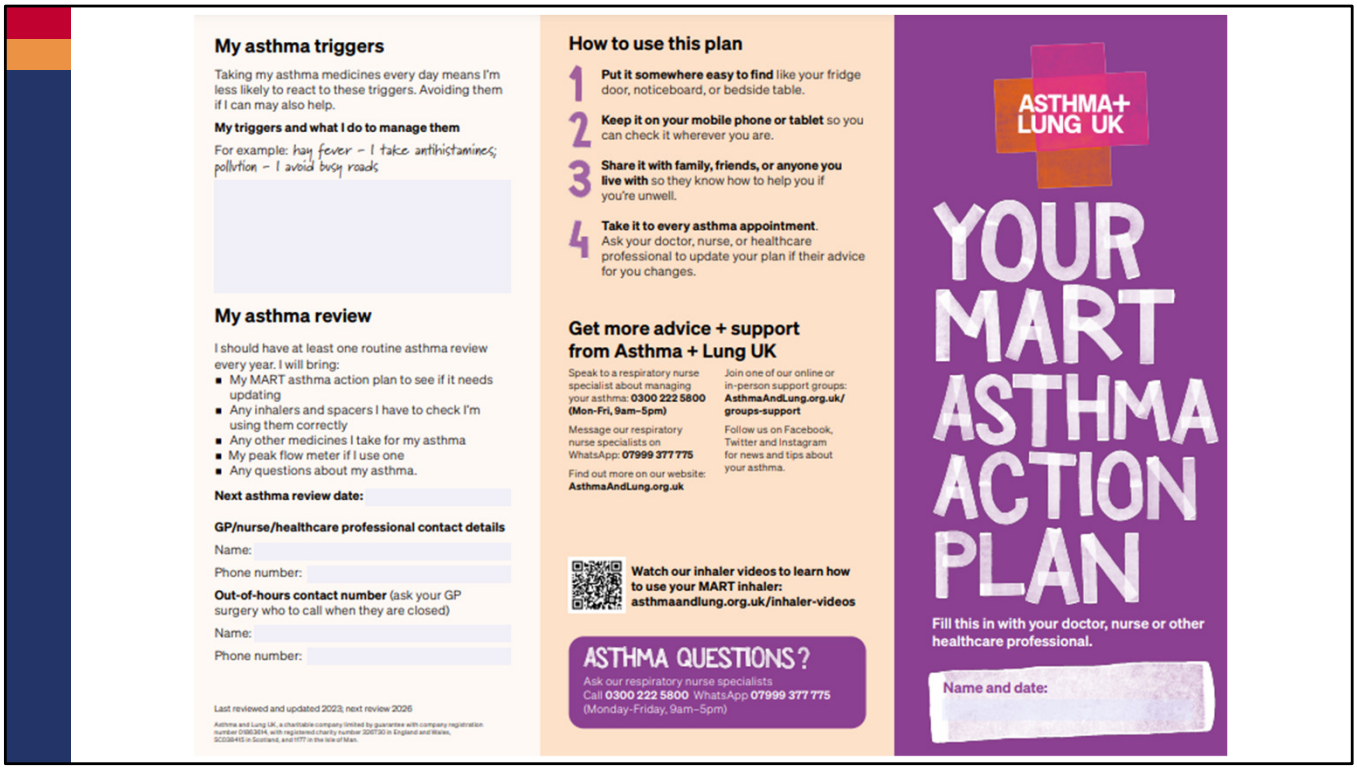

My asthma triggers

Taking my asthma medicines every day means I'm less likely to react to these triggers. Avoiding them if I can may also help.

My triggers and what I do to manage them

For example: *hay fever – I take antihistamines; pollution – I avoid busy roads*

My asthma review

I should have at least one routine asthma review every year. I will bring:

- My MART asthma action plan to see if it needs updating
- Any inhalers and spacers I have to check I'm using them correctly
- Any other medicines I take for my asthma
- My peak flow meter if I use one
- Any questions about my asthma.

Next asthma review date:

GP/nurse/healthcare professional contact details

Name:

Phone number:

Out-of-hours contact number (ask your GP surgery who to call when they are closed)

Name:

Phone number:

Last reviewed and updated 2023; next review 2026

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3. **Share it with family, friends, or anyone you live with** so they know how to help you if you're unwell.
4. **Take it to every asthma appointment**. Ask your doctor, nurse, or healthcare professional to update your plan if their advice for you changes.

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Message our respiratory nurse specialists on WhatsApp: **07999 377 775**

Find out more on our website: **AsthmaAndLung.org.uk**

Join one of our online or in-person support groups: **AsthmaAndLung.org.uk/groups-support**

Follow us on Facebook, Twitter and Instagram for news and tips about your asthma.

Watch our inhaler videos to learn how to use your MART inhaler: asthmaandlung.org.uk/inhaler-videos

ASTHMA QUESTIONS?

Ask our respiratory nurse specialists
Call **0300 222 5800** WhatsApp **07999 377 775**
(Monday-Friday, 9am–5pm)

ASTHMA+ LUNG UK

YOUR MART ASTHMA ACTION PLAN

Fill this in with your doctor, nurse or other healthcare professional.

Name and date:

1 Every day asthma care:

With this daily routine:

- I should have few or no asthma symptoms during the day and none at night (wheeze, tight chest, feeling breathless, cough).
- I should be able to do everything I normally do in my day-to-day life (working, being active, socialising).
- My personal best peak flow score is:

  Date taken

My Maintenance and Reliever Therapy (MART) inhaler is called (insert name):

I need to take my MART inhaler every day even when I feel well.

I take puff(s) in the morning

and puff(s) at night.

I use my MART inhaler as my reliever inhaler if I get asthma symptoms.

I take one puff of my MART inhaler if:

- I'm wheezing
- My chest feels tight
- I'm finding it hard to breathe
- I'm coughing.

I can take up to a **maximum** of puffs a day (including my morning and night puffs).

Other medicines and devices (for example, spacer, peak flow meter) I use for my asthma every day:

2 When I feel worse:

My asthma is getting worse if I'm experiencing any of these:

- My symptoms are getting worse (wheeze, tight chest, feeling breathless, cough).
- My symptoms are waking me up at night.
- My symptoms are affecting my day-to-day life (working, being active, socialising).
- My peak flow score drops to below:

If my asthma gets worse:
I can continue to take **one** puff of my MART inhaler as needed to deal with my asthma symptoms, up to a **maximum** of puffs a day (including my morning and night puffs).

URGENT! Contact your doctor, nurse or other healthcare professional if:

- You need to use the **maximum** daily dose of your MART inhaler and your symptoms are not improving **or**
- You're regularly using extra doses of your MART inhaler most days for weeks (as advised by your healthcare professional) **or**
- You're worried about your asthma.

Other advice from my doctor, asthma nurse or healthcare professional about what to do if my asthma is worse:

3 When I have an asthma attack:

I'm having an asthma attack if I'm experiencing any of these:

- My MART inhaler is not helping.
- I find it difficult to walk or talk.
- I find it difficult to breathe.
- I'm wheezing a lot, or I have a very tight chest, or I'm coughing a lot.
- My peak flow score is below:

What to do in an asthma attack

1. Sit up straight – try to keep calm.
2. Take one puff of your MART inhaler **every 1 to 3 minutes up to six puffs**.
3. If you feel worse at any point **or** you don't feel better after six puffs **call 999 for an ambulance**.
4. If the ambulance has not arrived after 10 minutes and your symptoms are not improving, **repeat step 2**.
5. If your symptoms are no better after repeating step 2, and the ambulance has still not arrived, **contact 999 again immediately**.

After an asthma attack

Follow this advice to make sure you recover well and to prevent further asthma attacks:

- If you dealt with your asthma attack at home, see your doctor or nurse today.
- If you were treated in hospital, see your doctor or nurse within 48 hours of being discharged.
- Finish any medicines they prescribe you, even if you start to feel better.
- If you don't improve after treatment, see your doctor, nurse or other healthcare professional urgently.

If you don't have your MART inhaler with you and need to use a blue reliever inhaler, take one dose every 30–60 seconds up to a maximum of 10 puffs and call 999 for an ambulance.

Anti Inflammatory Reliever (AIR) (GINA 2024)

- AIR reduces the risk of severe exacerbations compared with regimes that use SABA as a reliever
- Similar symptom control and lung function
- Treatment regime is simpler with patients using a single medication for reliever and for maintenance treatment (if prescribed) across all treatment steps
- With AIR approach, patient at any treatment step uses ICS-formoterol in single inhaler for symptoms relief
- STEPS 1-2: AIR
- STEPS 3-5: MART

In **2019**, the Global Initiative for Asthma (**GINA**) made ground-breaking recommendations to change the way asthma had been managed for the previous 50 years with the Anti Inflammatory Reliever (AIR) therapy regime.

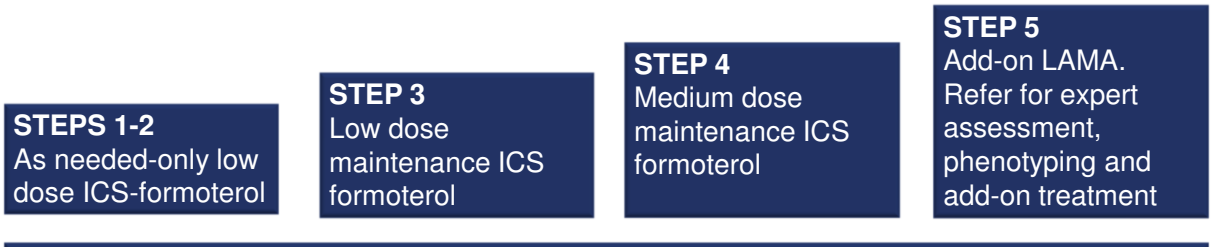
GINA (2024) adults and adolescents

GINA (2024) offers a Preferred Track approach to the pharmacological management of asthma.

Within the preferred track are steps to consider the therapeutic options.

The key differences between the two treatment tracks **are the medications that are used for symptoms relief**.

GINA 2024: Track 1 (Preferred) treatment Steps 1-4.adults and adolescents



Reliever: as-needed low-dose ICS-formoterol

Track 1: preferred controller and reliever using ICS-formoterol as AIR with or without maintenance ICS-formoterol, reduces risk of exacerbations compared with SABA reliever

A simpler regimen with single medication across treatment steps

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Company Registration Number: 03090774
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