

# SEVERE ASTHMA

Optimal Pathway of Care

NHS England and NHS Improvement



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## Preface Dr James Calvert

5 million people suffer from asthma in the UK and it remains responsible for 1200 deaths per year. Approximately 5% of patients have severe asthma. They suffer daily symptoms despite maximal medical therapy and are more likely to be admitted to hospital and access out of hour's emergency healthcare.

These numbers are impressive in the abstract but do not adequately describe the suffering which they represent. A patient story, shared by Nichola during a qualitative study undertaken by [Asthma UK](#) on behalf of the Severe Asthma Collaborative is provided in the introduction to this toolkit. One quote which sums up for me why designing services, that meet the needs of patients is a key responsibility for all professionals engaged in asthma care is provided below.

**"Obviously, I spent all the time in hospital. The first few times you get admitted, everybody comes to see you. But then, it gets a little bit boring and out of the way. So, friendships drift off and you fall into isolation."**

If we do not provide patients with timely access to effective therapies and the support of a multidisciplinary team that addresses their complex needs, our services cannot be considered as complete.

Development of biologic therapies for treatment of severe asthma and the national requirement to establish severe asthma networks ("Severe Asthma Services in Adults" (commissioning document A14/S/B)) presents an opportunity to improve UK asthma care. One component of this is systematic identification of variation in clinical practice. Where variation occurs clinicians and commissioners need to assure themselves that the variation is a result of patient need, not as a result of non-patient related factors such as service configuration.

Two recent national reports have identified a number of challenges to be addressed by UK clinicians and policymakers. The report "Living in limbo" [Living in limbo | Asthma UK](#) found that only 18% of people who require specialist care receive the appropriate referral and for those who fit the criteria for potentially life-saving biologic treatments only 20% receive them. The report "Slipping through the net" [slipping through the net asthma uk](#) identified a number of system issues amenable to improvement: including better sharing of data across the patient pathway and a lack of consensus on the shape of key pathways.



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## Preface Dr James Calvert

To address these challenges NHS improving value facilitated a collaborative approach to develop a consensus on areas of severe asthma care where significant variation was identified and where systematic evidence to support patient services was not readily available. The aim throughout was to provide pragmatic advice for NHS professionals to assist in the development of an "optimum patient pathway" which meets patient needs and supports responsible stewardship of NHS resources.

The ability to commission responsive services has previously suffered from a lack of consensus on how to measure quality of care. A key component of this scheme was to measure outcomes that were important to patients, that could be reported from the UK severe asthma registry. The collaborative has provided advice on this and the new measures will be incorporated into NHSE dashboards in the future. One of the greatest areas of variation in practice has been in prescribing of biologic therapies. The collaborative has designed and produced a flowchart to aid decision-making, which is incorporated in this toolkit. Another challenge, in managing long-term conditions is supporting patients to take complicated regimes of treatment whilst their ability to achieve this is impaired by the impact of their condition. To be eligible for biologics patients must be able to demonstrate that they have been taking their standard asthma care reliably. Until now there has been no consensus on how to measure adherence or how to support patients to improve adherence. This lack of clarity is a potential source of inequity in access to these important treatments. An approach to managing adherence based on available evidence and synthesis of experience of severe asthma specialist centres nationally has been provided. Finally, the heart of any severe asthma service is the MDT, where clinicians come together to make decisions in patient's best interests. Despite the importance of this function, there is little consensus on the best organisational model for structuring multi-professional working. The toolkit contains a summary of best practice from the severe asthma community.

I hope that this toolkit contains helpful resources that will provide a focus for quality improvement so that in the future the number of people who suffer in the way Nichola has so eloquently described will fall and professionals can be satisfied that the care they deliver is to the highest standard.

Over a hundred people have been involved in the production of this toolkit, including clinicians, patients and commissioners. My thanks goes to all of them and particularly to Asthma UK who provided invaluable support and encouragement throughout.

# Foreword

We welcome the Severe Asthma Toolkit. This is an exciting opportunity to support and compliment the Clinical Reference Group (CRG) work by providing key clinical guidance around a relatively rare respiratory disease severe asthma: helping to capture 'what good looks like'.

With so much of our work focussed on understanding unwarranted variation in access, to both severe asthma services and to high-cost medicines, experienced by individuals we see this toolkit as a key enabler to tackling that variation. It supplements and enhances the national service specification ([severe asthma national specification](#)), guiding commissioners through the challenges of commissioning the best severe asthma services and facilitating the delivery of the optimal care for individuals with severe asthma, ensuring consistent commissioning of high-cost medicines and robust quality data. This toolkit will help our ambition for the right patients to get the right medication at the right time.

Our thanks go to Dr James Calvert for his leadership of the Improving Value severe asthma scheme. Through him strategies were developed to address the unwarranted variation recognised by the CRG and his commitment and expertise has been key to the successful development of this toolkit.

The toolkit will fit into a constantly evolving landscape for respiratory disease reflecting the successful engagement of the project group with wider strategic parts of the system to ensure that it facilitates access to meaningful quality data and compliments the redesigned Blueteq forms, NICE Technology Appraisals and CQUIN to maximise its relevance over the coming years to the severe asthma community and as a priority area within the [NHS Long Term Plan](#).

We are pleased to have been part of this work through the project steering group, to have witnessed the collaboration and enthusiasm across the whole severe asthma community, particularly the valuable contributions from Asthma UK, that have ensured that this work was shaped by the voices and experiences of people with severe asthma.

We look forward to the continuous improvement in severe asthma care across England. Using data to demonstrate achievements will be key to ensuring sustainable long-term improvements. Already we can see the strength in the Severe Asthma community across the country as it responded to unprecedented pressures on the NHS in 2020 and worked together to deliver new models of care to support this vulnerable group of patients.



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# Foreword

The Severe Asthma Improving Value Project was established to address identified variation across England in the pathway of care and the prescribing of Biologic medication for people with severe and difficult to control asthma.

In order to do this, we established a collaborative of 54 members across England including Asthma UK, respiratory consultants, specialist nurses, pharmacists, physiotherapists, psychologists, NHS England commissioners and Improving Value Team members. At the heart of the project was the ambition to develop the optimal patient pathway to reduce variation in access and treatment, improve patient outcomes and experience, which would in turn improve the quality, effectiveness and overall efficiency of the service.

The toolkit provides national guidance for commissioners and healthcare providers and the tools and resources required to implement the optimal patient pathway, which can be applied locally to accommodate the specific requirements of your local population and geography.

The patient pathway for severe asthma is complex with patients transitioning through a variety of different healthcare settings including primary care, acute hospitals/A&Es, through to specialised asthma centres. The establishment of Integrated Care Systems and their focus on integrated pathways of care and population-based commissioning, now provides a real opportunity to look at the whole patient pathway for patients with severe asthma.

We also want to ensure that shared decision making is embedded in the patient pathway, ensuring patients are supported to make decisions that are right for them. This is a collaborative approach which brings together the expertise of the clinician on treatment options, evidence, benefits and risks, with the patient's expertise and knowledge of what's important to them, their goals, values and personal circumstances. The toolkit provides information and links on what support and training is available for commissioners and providers wanting to implement shared decision making in their services and with a growing body of evidence that this approach improves patient outcomes and experience we are keen to support this work going forward.

I would like to personally thank the collaborative members, the Respiratory Clinical Reference Group and the wider asthma community who have given their time, energy and passion to this project. I would also like to thank Dr James Calvert for his clinical leadership and vision throughout this journey. James commitment to true collaboration and co-production has enabled key stakeholders from clinical teams, Asthma UK, Academia and commissioning to work together purposefully and productively to find consensus around some of the most challenging elements of the severe asthma pathway and remain grounded in the purpose behind the scheme – to reduce unwarranted variation and improve patient outcomes, experience and safety.



**Michele Davis**

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# Introduction

The severe asthma optimal pathway of care toolkit



## Severe Asthma Scheme key objectives

All patients newly diagnosed with severe asthma will receive an MDT review of their care by a specialist asthma MDT hosted by a designated severe asthma specialist centre.

Initiation of omalizumab, benralizumab, mepolizumab, benralizumab and reslizumab (and other similar biologics yet to receive positive NICE Guidance) will only be funded if approved by a specialist MDT hosted by a commissioned severe asthma centre.

All existing patients prescribed omalizumab, mepolizumab, reslizumab or benralizumab should be reviewed to ensure ongoing prescription is appropriate and to identify patients appropriate for withdrawal from treatment, where this has not already been considered by the MDT.

All designated severe asthma specialist centres agree to implement the optimal care pathway for severe asthma.

This toolkit has been developed through consensus of the severe asthma collaborative, as part of the improving value severe asthma scheme to support the implementation of the optimal pathway of care for people affected by Severe Asthma.

This is not a top-down, one size fits all, mandated scheme, as the optimal patient pathway needs to be looked at in the context of the overall provision of asthma services at a local level. Commissioners will want to take into consideration other factors such as local patient population and healthcare landscape.

You will find the guide useful if you are a clinician, manager, administrator, commissioner or healthcare student. It contains resources and recommendations on how to deliver optimal care for patients with severe asthma at a local level. All of these have been developed through the collaborative.

We hope the information collated in this toolkit will help guide and inspire those involved in the severe asthma pathway of care to improve services for the people they care for.

# Principles Severe Asthma Optimal Pathway of Care

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## Principles

Every patient is an individual....

1. A shared decision-making approach is essential in delivering care described in the optimal pathway link to [appendices](#).
2. Assessment and management of people affected by severe asthma should be objective, non-judgemental and focussed on understanding the patient's priorities.
3. Severe asthma specialist centres are responsible for overseeing the severe asthma optimal pathway of care, which may be delivered by a number of providers in a network.
4. Every severe asthma specialist centre should be able to demonstrate that they can deliver all elements of the optimal pathway either directly or via their network.
5. The severe asthma specialist centre should consider competencies and skill mix required by the MDT to ensure effective care is delivered.
6. Best practice is achieved by a multidisciplinary approach.
7. Severe asthma specialist centres should adopt an improvement methodology that utilises data collected in the registry to demonstrate progress in improving quality of care.

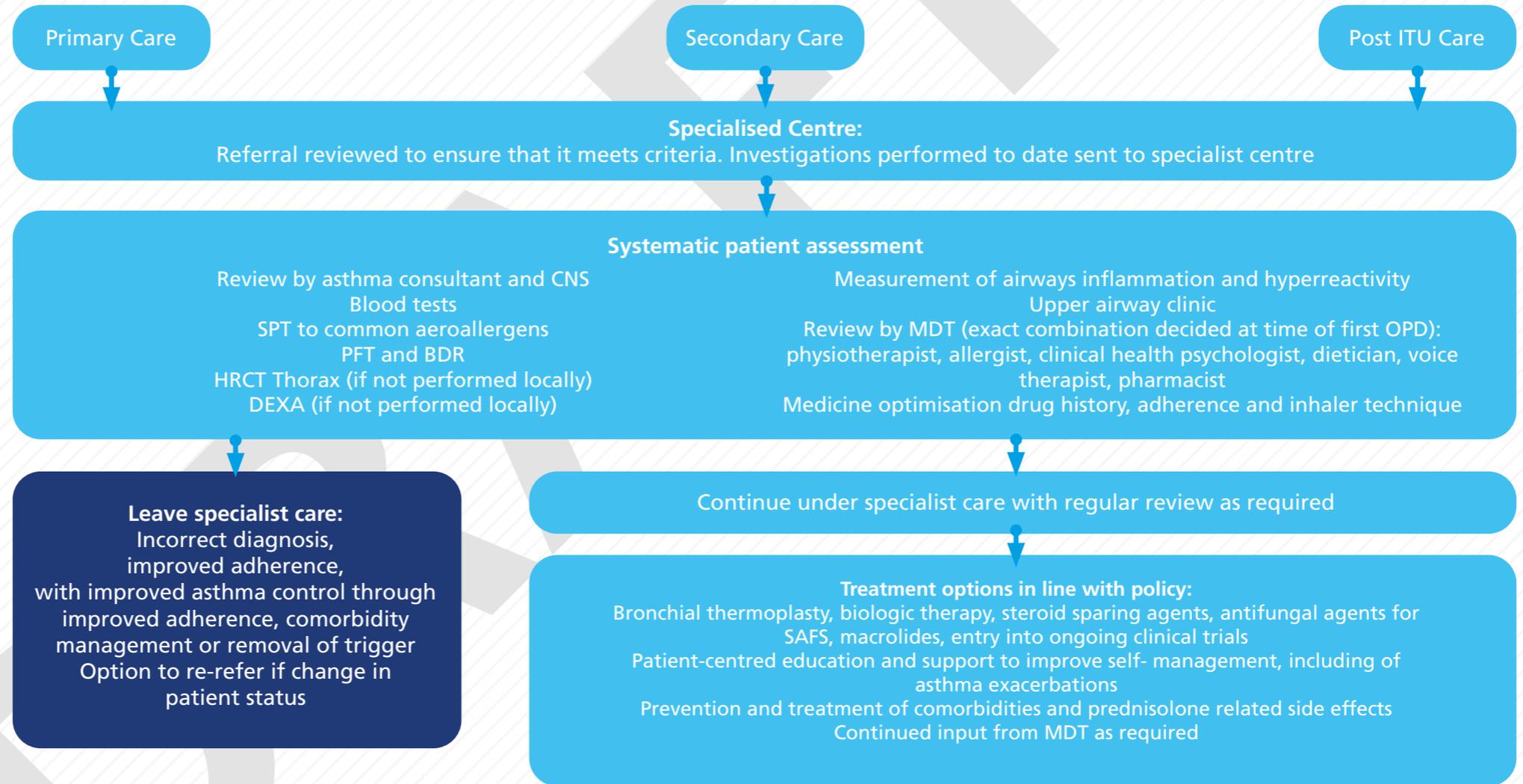


The severe asthma improving value scheme has shown the power of a collaborative approach. It has enabled development of a consensus around aspects of the severe asthma pathway and has facilitated the development of a suite of resources to enable clinical teams and commissioners to develop high quality services in partnership.

The engagement of clinicians, commissioners, healthcare charities and individual patients, facilitated the development of this toolkit. However, this is just a tool.

To make the optimal pathway for severe asthma a reality for patients a culture of continuous improvement will be needed.

# Severe Asthma toolkit in relation to **National Service Specification for Severe Asthma**



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# Nichola's Story



***"My asthma controlled everything I did. It controlled when I went to sleep, how far I'd walk. Even, too, if I ate that day. Because some days I couldn't eat, because I was too breathless. So, it dominated every aspect of my life."***

Nichola was diagnosed with asthma at the age of 21 after a bout of pneumonia and numerous chest infections. She then underwent a long process to get referred to a specialist asthma centre where a diagnosis of severe eosinophilic asthma was made. This has greatly impacted every part of her life.

***"Obviously, I spent all the time in hospital. The first few times you get admitted, everybody comes to see you. But then, it gets a little bit boring and out of the way. So, friendships drift off and fall into a bit of isolation, really."***

It was difficult to find a biologic treatment that worked for her, but Nichola found the holistic approach of her severe asthma centre was beneficial to her asthma management, wellbeing and ability to cope with life with severe asthma: including offers of support from a psychologist, dietician, physiotherapist and advice on managing her finances.

***"So, one week was nutrition. One week was physio exercises. One week was about money and things that you might be entitled to. Where to go for help and grants if you needed it. And that was really useful, because there were things that I didn't realise that I could get help with."***

Nichola found it hard to adjust to living with severe asthma and the variability of the condition.

***"I will do everything at once and completely burn myself out for about four days after. Especially if I've got my steroid, I feel like I'm invincible and I can clean the house and do this and that. And then, a few hours later, I'm ruined for the week"***

Her physiotherapist worked with her to break down tasks into manageable stages, to avoid overdoing things, Nichola can now achieve more of her goals and has regained a sense of normality. The dietician helped her with strategies to ensure that she can maintain regular nutrition; preparing food in stages, so there is always something ready if she feels too unwell to deal with cooking, as well as providing tailored recipes to help her manage her diabetes and vitamin D deficiency. The support from the psychologist enabled her to feel better in herself, deal with anxiety and talk to others about the mental toll of living with severe asthma.

Nichola has shared her story to encourage ***'all severe asthma centres to provide the support that she had because people with severe asthma need more than just medication,'***. Individuals with severe asthma need a holistic approach that considers the devastating impact severe asthma can have on every aspect of their life.



# Adherence assessment and optimisation

Medicines Adherence assessment and optimisation in relation to national service specification for severe asthma

**“Patients to have been assessed for adherence in all cases including; inhaled asthma therapy technique, measurement of blood levels of prednisolone and cortisol, review of prescription refills and FeNO suppression testing if appropriate, before being considered for injectable biologic treatments for their asthma”**

Service Specification Specialised Respiratory Services (adult) - Severe Asthma (NHSE 2017)

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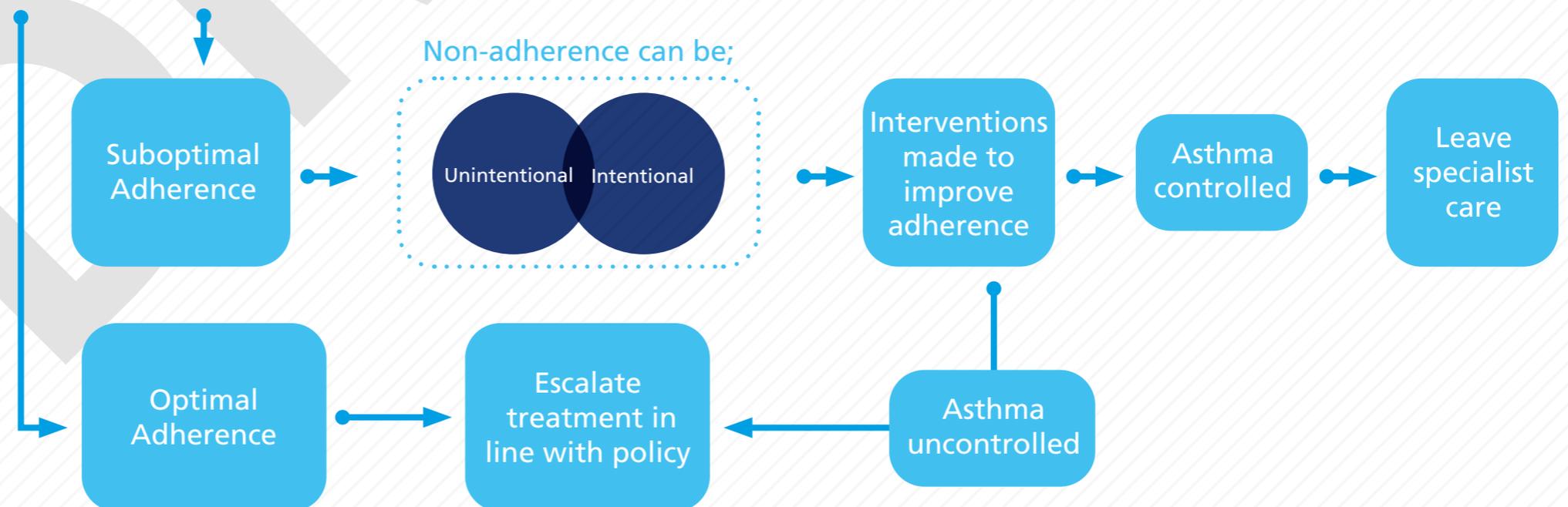
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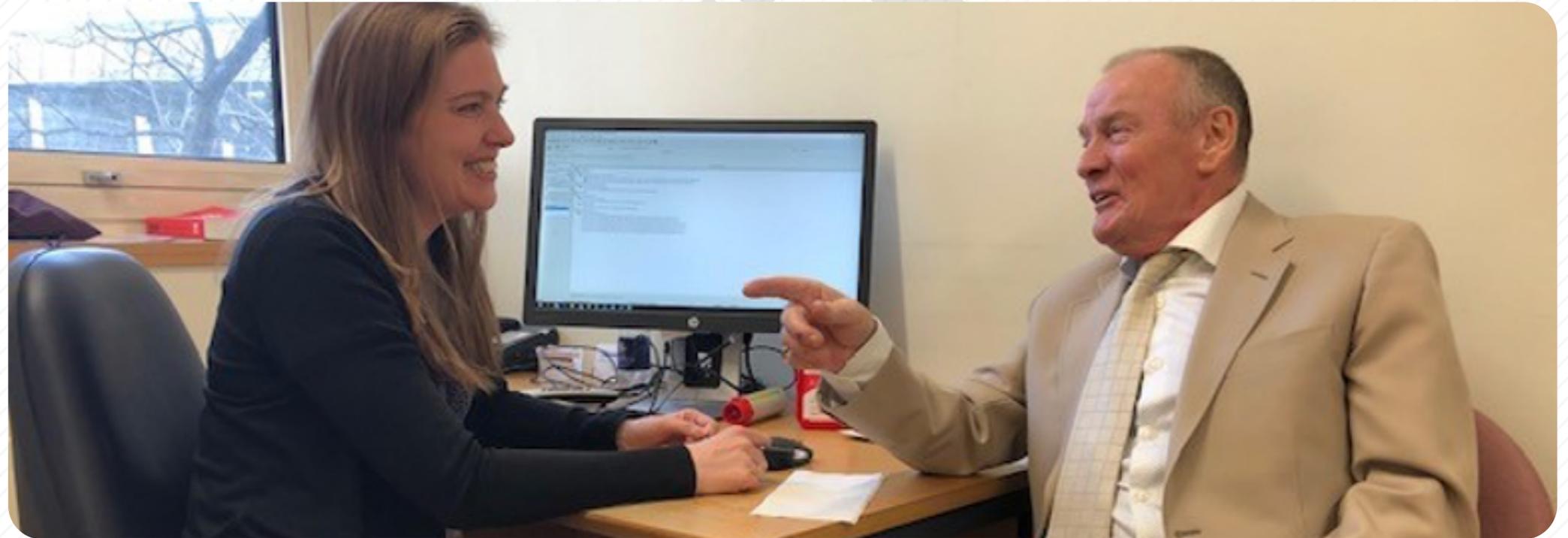
## Severe Asthma Optimal Pathway of Care Toolkit



### Adherence assesment and optimisation of tailored therapy throughout the patient pathway



# Understanding adherence in severe asthma



The optimal use of medicines in asthma alleviates symptoms, improves quality of life and reduces the frequency and severity of exacerbations. However, when adherence to treatment is suboptimal, patient outcomes are adversely affected. While appreciating its importance, prior to this work, the paucity of evidence meant there was limited consensus on how to measure adherence in asthma, and little to assist respiratory healthcare professionals in supporting patients to improve it. For these reasons, the NHS Improving Value Severe Asthma Collaborative (SAC) reviewed the evidence, then sought consensus on the following areas:

- Methods of assessing adherence
- Interventions to optimise adherence
- Adherence thresholds for eligibility for biologic therapy

Adoption of this approach across all severe asthma specialist centres will enable an equitable and consistent application of the principles of optimising adherence and will reduce unwarranted variation in the approach to identifying patients for biologic therapy.

# Understanding suboptimal medicine adherence in severe asthma



*It is acknowledged that individuals may not always be fully adherent with their treatment. There are many reasons for this which can be grouped into two main categories. The categories are not mutually exclusive; both may influence an individual's adherence to some degree.*

## **Unintentional non-adherence**

There is a willingness to follow the agreed treatment plan, but the individual is prevented from doing so by barriers considered beyond their control (practical). This includes: medication not being taken due to forgetfulness, misunderstanding dosing instructions or the inability to use their inhaler devices correctly. It may also be because the patient cannot afford the prescription charge.

## **Intentional non-adherence**

This occurs when an individual decides not to take their prescribed medication as advised. Many factors influence an individual's approach to following the clinicians' recommendations and often involves their medicines/disease beliefs and preferences.

## Measuring adherence in severe asthma



Several methods of measuring adherence are in current use. The consensus group agreed that these methods were appropriate, though in recognising their limitations and the need to individualise assessment approaches, have made suggestions to standardise their application.

An individualised assessment is essential and should include at least one of these approaches, but this list is not exhaustive. To assess medicine adherence comprehensively, such measures should be combined with an open non-judgemental discussion with the patient.

- 1 Prescription refill rates
- 2 Blood cortisol and prednisolone levels
- 3 Fractional exhaled Nitric Oxide (FeNO) suppression testing

An individualised assessment approach is recommended as these tests may not be exhaustive.

“As soon as I described my symptoms and showed my inhaler and technique and everything, it was very reassuring. Don't worry. We're going to do this and we're going to do that. We're going to do some tests.”

Patient quote 2019

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## Inhaled Corticosteroid Therapy Adherence Assessment: Prescription Refill Records

Biologic agents are approved for add-on therapy to high dose ICS (HDICS,  $\geq 1000\text{mcg/day}$  of beclomethasone dipropionate or equivalent). They should be considered after an adherence assessment of HDICS containing inhalers indicates  $\geq 75\%$  of doses intended by the prescriber are filled on prescription, with optimised inhaler technique.

Medicines Possession Ratio (MPR) is calculated using the patient's GP prescription data. For accuracy all inhaler sources should be interrogated (hospital and/or private prescription data).

The Medicines Possession Ratio MPR assumes all doses are taken appropriately. It may therefore overestimate adherence. Nonetheless a low Medicines Possession Ratio MPR is useful to confirm non-adherence.

### Calculating Medicines Possession Ratio

$$\text{MPR} (\%) = \chi \frac{\text{Number of doses prescribed (in the interval)}}{\text{Number of doses expected (in the interval)}} \times 100$$

$$\text{MPR} (\%) = \frac{10 \times 30}{12 \times 30} \times 100 = 83\%$$

An MPR calculation for the issue of 10 inhalers in a year when the expected number is 12 inhalers (where 30 is the number of doses in the prescribed device)

There are people with "severe asthma" who, despite being adherent to standard therapies, continue to need systemic steroid therapy. These people may benefit from targeted biologic therapies.

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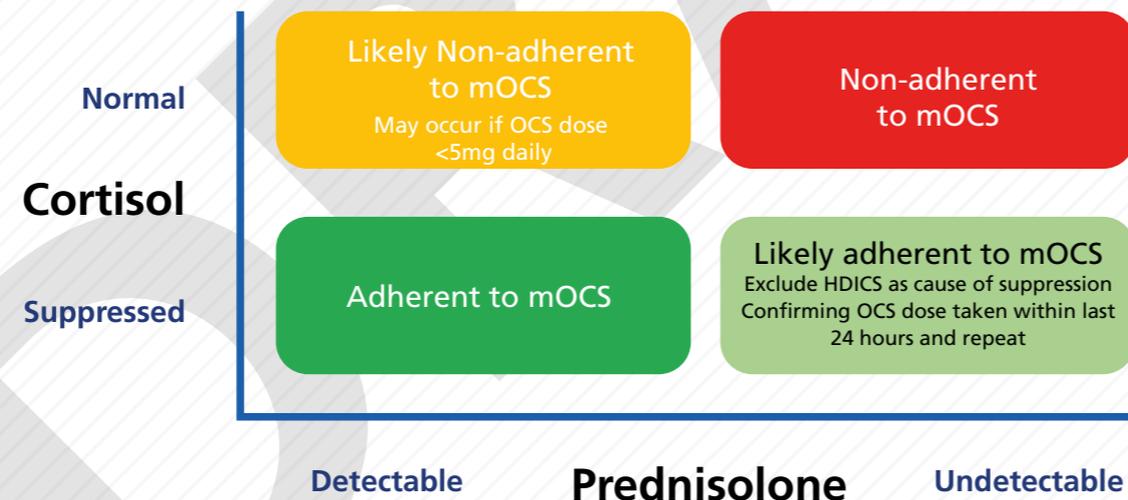
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## Oral Corticosteroid Therapy Adherence Assessment

### Assessing maintenance oral corticosteroids

In response to frequent exacerbations, some patients are prescribed maintenance oral corticosteroids (mOCS). Taken consistently over a period of weeks, synthetic glucocorticoids reduce ACTH and thus suppress cortisol production (suppression is defined as a blood cortisol  $<100\text{nmol/L}$ ). Standard cortisol assays have cross reactivity with exogenous steroids, so to minimise this, the level must be measured using

liquid chromatography combined with mass spectrometry methodology (Henzen 2000 and Ionita 2014). Measured accurately, a suppressed cortisol and a detectable prednisolone level suggests adherence or not to mOCS, but there are important exceptions to this. Figure 2. below (adapted from Mansur 2020) supports the interpretation of prednisolone and cortisol levels.



### Assessing frequency of oral corticosteroid use

When considering the number of courses of oral corticosteroids (OCS) taken, the dose, duration and frequency should be established. Where possible their timing should be considered in the context of inhaled corticosteroid (ICS) adherence i.e. whether courses of prednisolone were required in spite of optimal ICS use or potentially following a deterioration in ICS adherence. It is helpful to clarify the context of the initiation i.e. prescribed as a result of a consultation with a healthcare professional mid-exacerbation or was patient-led for example taken as a rescue pack.



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## Inhaled Corticosteroid Therapy Adherence Assessment: Fractional exhaled Nitric Oxide Suppression

Fractional exhaled Nitric Oxide (FeNO) may be raised for numerous reasons including non-adherence to prescribed high dose inhaled corticosteroid (HDICS). If a patient has a raised FeNO (>45ppb), observing them administer their HDICS (in clinic, via video-link or using "Smart" remote monitoring technology) daily for 5-7 days and concurrently measuring their FeNO can be useful to confirm ICS responsive asthma.

A reduction of  $\geq 50\%$  from baseline FeNO value suggests non-adherence to usual prescribed HDICS (McNicholl 2012).

### An illustration of a Positive FeNO Suppression Test

	Asthma clinic review	Day 1 of observed HDICS*	Day 2 of observed HDICS	Day 3 of observed HDICS	Day 4 of observed HDICS	Final day of observed HDICS
ACQ-6	2.3					1.1
FeNO (ppb)	113	82	68	46	34	33
Eosinophil count	1.1					0.2

\* 3 days after asthma clinic review



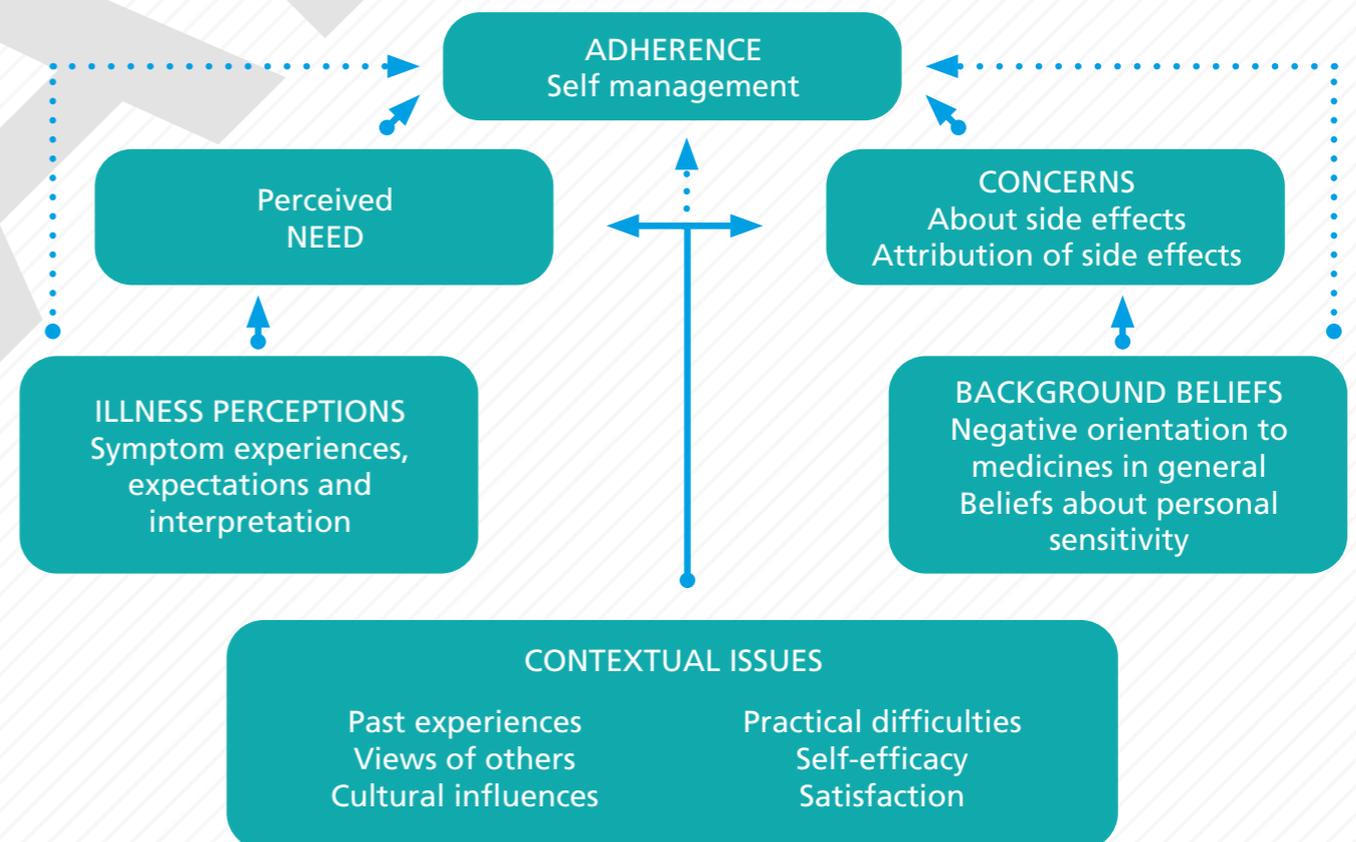
## Optimising medicine adherence

Before biologics are prescribed for an individual, the contribution of non-adherence to the severity of their disease should be assessed. It is the recommendation of the consensus group that every patient suspected to have severe asthma has their adherence measured and where necessary, they be supported to improve it for 6 months before reassessment of the need for a biologic agent. If a patient is considered high risk, defined by the collaborative as: having had an ITU admission and/or near fatal episode within the last 12 months and/or adverse psychological circumstances, we recommend that patients be supported to improve adherence for 3 months before a biologic is considered. These patients are likely to require ongoing adherence support throughout the treatment pathway. It should be made clear to patients that suboptimal adherence to an ICS on a biologic may adversely affect their outcome (d'Ancona et al 2020).

**Patient adherence to medication is influenced by a number of factors relating to how the individual judges their own need (necessity) for their treatment relative to their concerns about the medicines. This is summarised in the figure below.**

Many patients with asthma doubt their need for daily doses of ICS or have concerns about them. Doubts about the necessity of ICS often arise from the patient's beliefs about asthma. To perceive a need for treatment there must be a close link between our understanding of the problem (the illness) and the proposed solution (the treatment). Many patients with asthma simply don't see this link. The medical model defining asthma as a chronic condition that requires daily preventative medication may be at odds with their experience of asthma that is, as an episodic condition in which symptoms come and go. Hence, if their belief is 'no symptoms, no asthma', taking the ICS daily will not make sense to them.

The challenge for the health-care professional is to ascertain the patient's beliefs about asthma and its treatment. This is the starting point for tailoring the prescription and providing support to meet the needs of the individual. During a consultation, healthcare professionals can encourage the patient to understand the need for the medicine, and reduce their concerns by discussing potential adverse effects. This will lead to a better acceptance of the shared prescribing decision.



Horne, R.: Compliance, Adherence, and Concordance: Implications for Asthma Treatment. Chest. 2006;130;65-72

# How to optimise medicine adherence in severe asthma

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Seeking to understand and therefore improve medication adherence is complex. Interventions to improve adherence can be aimed at healthcare providers, patients, carers, family members, or a combination of these. The focus might be on promoting behaviour change, on developing knowledge or skills, encouraging better communication, or promoting more patient-centred decision-making. The relative importance of these determinants varies between individuals.

A systematic review of the [literature](#) pertaining to patients with severe or difficult to manage asthma, did not reveal robust evidence to advocate one particular intervention over another, however, the potential benefit in individuals who have disengaged from managing their asthma or who have been previously unsupported, is apparent.

Interventions studied as part of wider chronic disease research suggest that pharmacist-led optimisation of dosing regimens, and provision of reminders/cues for taking therapy can improve adherence. There is also significant evidence to support the use of education on self-management and optimisation of inhaler technique to improve adherence to medicines. The use of smart inhalers, digital platforms and mobile phone technology offer the opportunity to advance personalised care for asthma patients but such techniques are still relatively new. There is a need for the systematic development of evidence based interventions in people with difficult to manage asthma which allow non-adherence to be effectively managed.

When identified, medicines non-adherence can be improved. The key challenge is to empower patients to make better informed choices about medicines, instead of decisions influenced by misplaced beliefs around therapy and disease benefit and/or harm. Non-adherence should be seen as a variable behaviour: adherence rates vary not just between individuals but for the same person over time and across treatments. Continue to assess adherence, review patient's knowledge, understanding and concerns about medicines, and the patient's view of their need for medicine at regular intervals then individualise the interventions required for the person accordingly.

## NICE Medicines Adherence Guideline

<https://www.nice.org.uk/Guidance/CG76><sup>9</sup> recommends that prescribers should involve patients in treatment decisions and that a Perception and Practicalities Approach (PAPA) is adopted to support adherence.

## Case Study

### Mr D is 73 years old and was referred to the specialised severe asthma centre by his GP

He needed help with managing his 'poorly controlled asthma'. In clinic, he was found to have late onset non-atopic eosinophilic asthma. He had been taking 10mg prednisolone as maintenance therapy for 9 months. Unfortunately he had had multiple exacerbations (4 courses of prednisolone), 3 admissions to hospital in the past year and was highly symptomatic. He used reliever inhaler and nebulisers several times daily and didn't have a significant smoking history

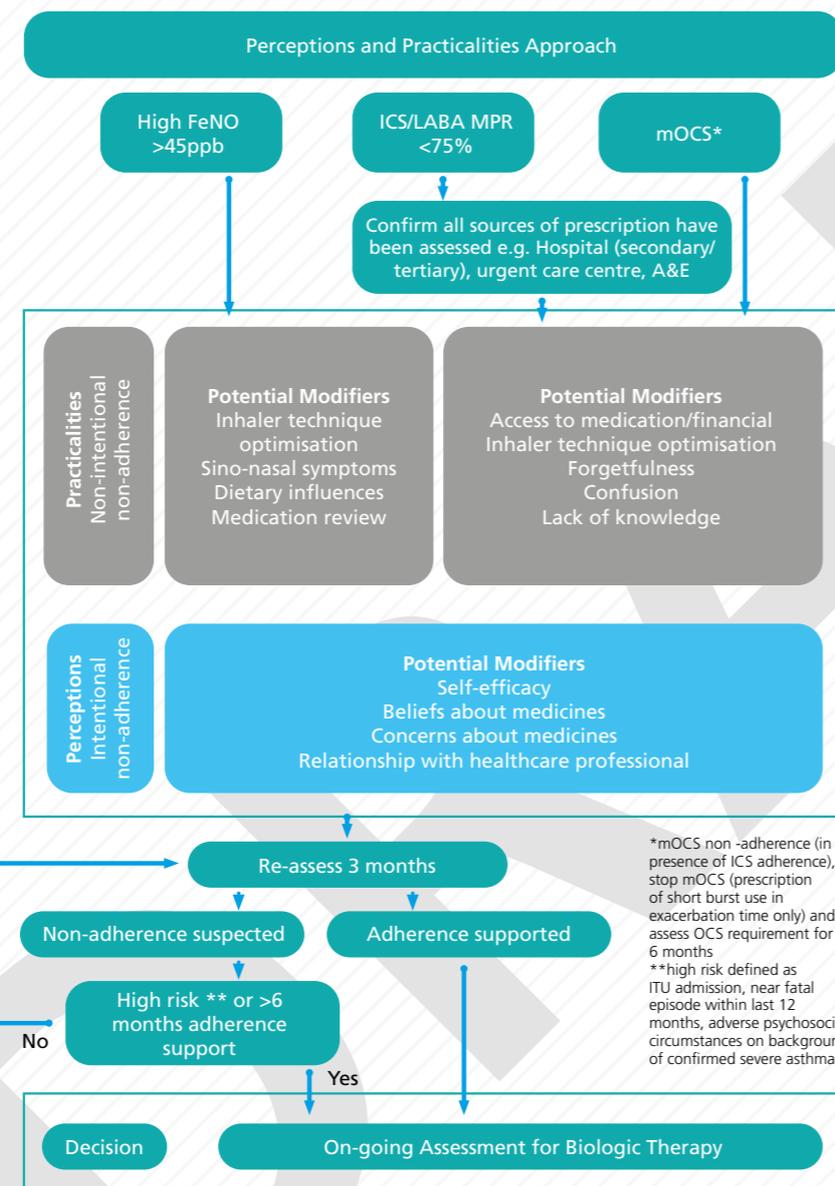
### Tests indicated

- eosinophil count was 0.50 - the highest in the previous year
- pre-mOCS was 1.50
- cortisol was suppressed at 99nmol/L
- spirometry demonstrated obstruction
- significantly reduced FEV1 of 1.7L (56% predicted).

Consultation with the pharmacist ascertained that his HDICS MPR was 83%, but that his technique was suboptimal. They provided him with coaching to improve technique, discussed the risks/benefits and scheduling of biologic therapy and he agreed to his case being discussed at the asthma Multidisciplinary Meeting the following week. He was seen again by the pharmacist 5 weeks later at which time his inhaler technique was excellent and he received his first biologic injection from the nurse specialist.

Two and a half years later Mr D no longer takes maintenance prednisolone or use his nebuliser. He has had only 2 flare ups that required a course of prednisolone. He feels 'the best he has in years' and is keeping active.

# Intervention pathway to support medicine adherence



Continue to assess adherence, review patient's knowledge, understanding and concerns about medicines, and the patient's view of their need for medicine at regular intervals and individualised to the patient.

A key challenge for the development of adherence-promoting interventions is the sheer complexity of the issue of non-adherence. In 2016, National Institute for Health and Care Excellence (NICE) published guideline CG76 Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence. After a detailed review, NICE concluded that was no definitive gold standard intervention but that much could be done to improve the quality of support delivered to individuals to improve medicine adherence.

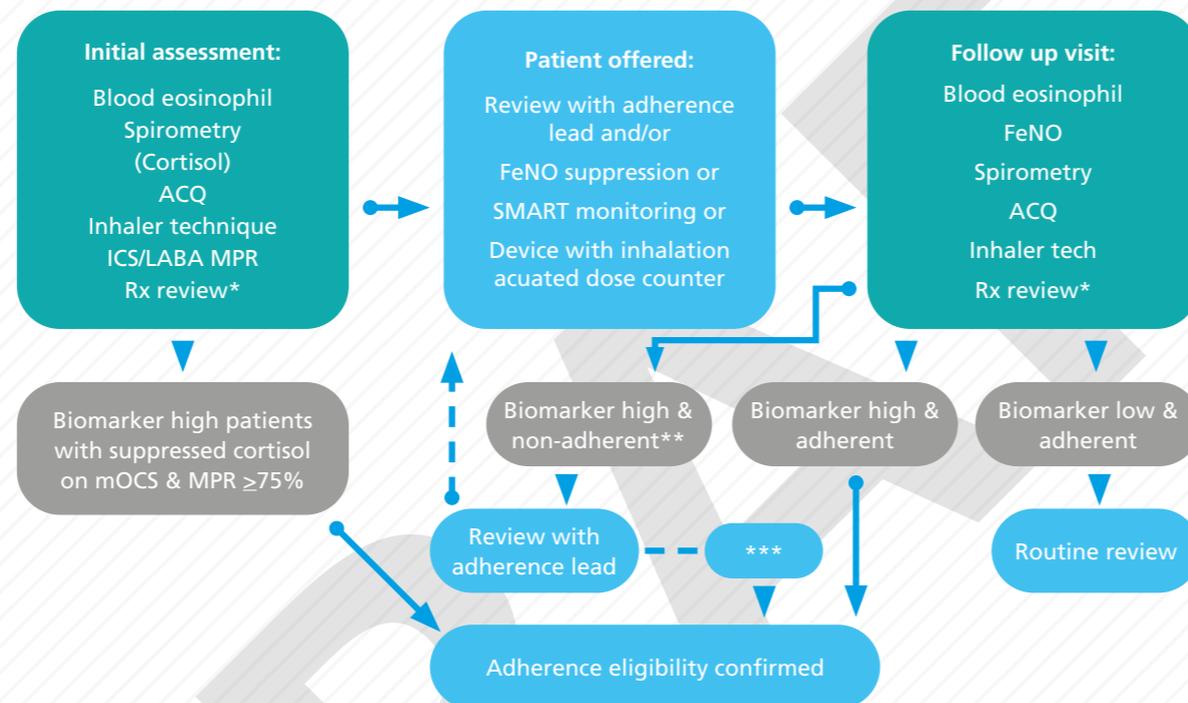
The Perceptions and Practicalities Approach (PAPA) provides a theoretical framework to understand adherence to medications based on the overlapping categories of intentional and non-intentional non-adherence. The NICE guidelines recommended the application of the PAPA advocating that addressing nonadherence should start with "an exploration of patients' perspectives of medicines and the reasons why they may not want or are unable to use them and that to understand adherence to treatment we need to consider the perceptual factors (e.g., beliefs and preferences) that influence motivation to start and continue with treatment, as well as the practical factors that influence patients' ability to adhere to the agreed treatment". Adherence interventions will be more effective if tailored to address the perceptions and practicalities underpinning individual motivation and ability of the patient to adhere.

This intervention pathway has been developed by the severe asthma consensus group to help clinical teams with understanding and supporting individuals with identified or suspected suboptimal adherence to their medicines. The pathway has drawn on the themes of the Necessity and Concerns framework and the PAPA framework to provide a pathway which relates to patients with severe asthma who have suspected non-adherence.

It is important to understand that any intervention to support medicine adherence should be considered on a case by case basis based on the findings from the techniques and methods used to assess adherence. If it is suspected that a patient is not taking their medicines, discuss with them whether this is because of beliefs and concerns or problems about the medicines (intentional non adherence) or because of practical problems (unintentional non adherence). Tailor any intervention to increase adherence to the specific difficulties with adherence the patient is experiencing. Find out what form of support the patient would prefer to increase their adherence to medicines. Together, you and your patient should consider options for support. Although adherence can be improved, no specific intervention can be recommended for all patients.

A comprehensive catalogue of adherence optimisation resources can be found [here in the Severe Asthma Toolkit resource folder](#).

# Understanding Medicine adherence in severe asthma



\* Prescription review, if indicated:

- Add LAMA, LTRA, oral antihistamine, nasal steroid and/or PPI
- Check theophylline level and advise on dosing
- [review need for therapies to treat the sequelae of prednisolone e.g. a bisphosphonate]

\*\* Response to biologic treatment may depend upon continued adherence to the ICS, so regularly reinforce the need to maintain ICS use and recheck adherence if the patient appears to be “failing” biologic therapy

\*\*\* High risk patients as defined on page 20

This algorithm should be applied to all patients being considered for biologic therapy.

Patients with a mOCS (suppressed cortisol) and HDICS (MPR >75%), can be deemed as adherent. Those with MPR ≤ 75% will require further investigation and are likely to require support with medicines optimisation.

- Where there is suboptimal adherence patients may require medicines optimisation and support to improve adherence.
- When levels of adherence meet the threshold, but biomarkers remain high and disease control is poor patients will be eligible for a trial of a biologic.

**Despite appropriate interventions, some individuals may continue to be non-adherent to their medicines, but be at such high risk of harm from poorly controlled asthma that their cases are considered exceptional. In this circumstance, where a systematic approach to improving adherence has been followed for at least 3 months, the consensus group suggests that patients may undertake a trial of a biologic medication following MDT agreement.**

**It must be remembered that the criteria to allow on-going biologic use (ie annual review) is the same for patients considered high risk and that evidence suggests that non-adherence to an ICS on biologic may affect outcome (d’Ancona et al 2020).**

## Optimising medicines in difficult-to-treat asthma

1. Complete a full drug history to confirm appropriate asthma regimens are prescribed, assess need for additional therapies (to treat asthma, its sequelae or comorbidities) and identify concomitant medicines contributing to symptoms.
2. Confirm the patients’ understanding of asthma, its treatment and the principles of self-management.
3. Assess and correct inhaler technique and where applicable, technique with nasal preparations.

## Adherence Lead

It is recommended that every Severe Asthma Specialist Centre should have a designated adherence lead responsible for medicines optimisation and delivery of targeted interventions to improve and maintain adherence.

They should be a member of the multi-disciplinary team, e.g. appropriately trained pharmacist (Horne 2006, Clifford 2006).

# Adherence assessment and optimisation in severe asthma



## Key Actions

Regular use of optimised therapies, particularly an inhaled corticosteroid, may prevent death, significant illness, and the need for high cost interventions in the 'difficult to treat' patient cohort

Systematic assessment of medication adherence is essential for effective asthma control

An 'adherence lead' should be identified in each severe asthma centre. They will support medicines optimisation through delivery of targeted interventions to improve and maintain adherence. Evidence suggests that this should be an appropriately trained pharmacist

Severe asthma specialist centres should collaborate with colleagues in primary care, secondary care and patient organisations for example Asthma UK to develop resources to educate and support individuals to get the most from their medicines

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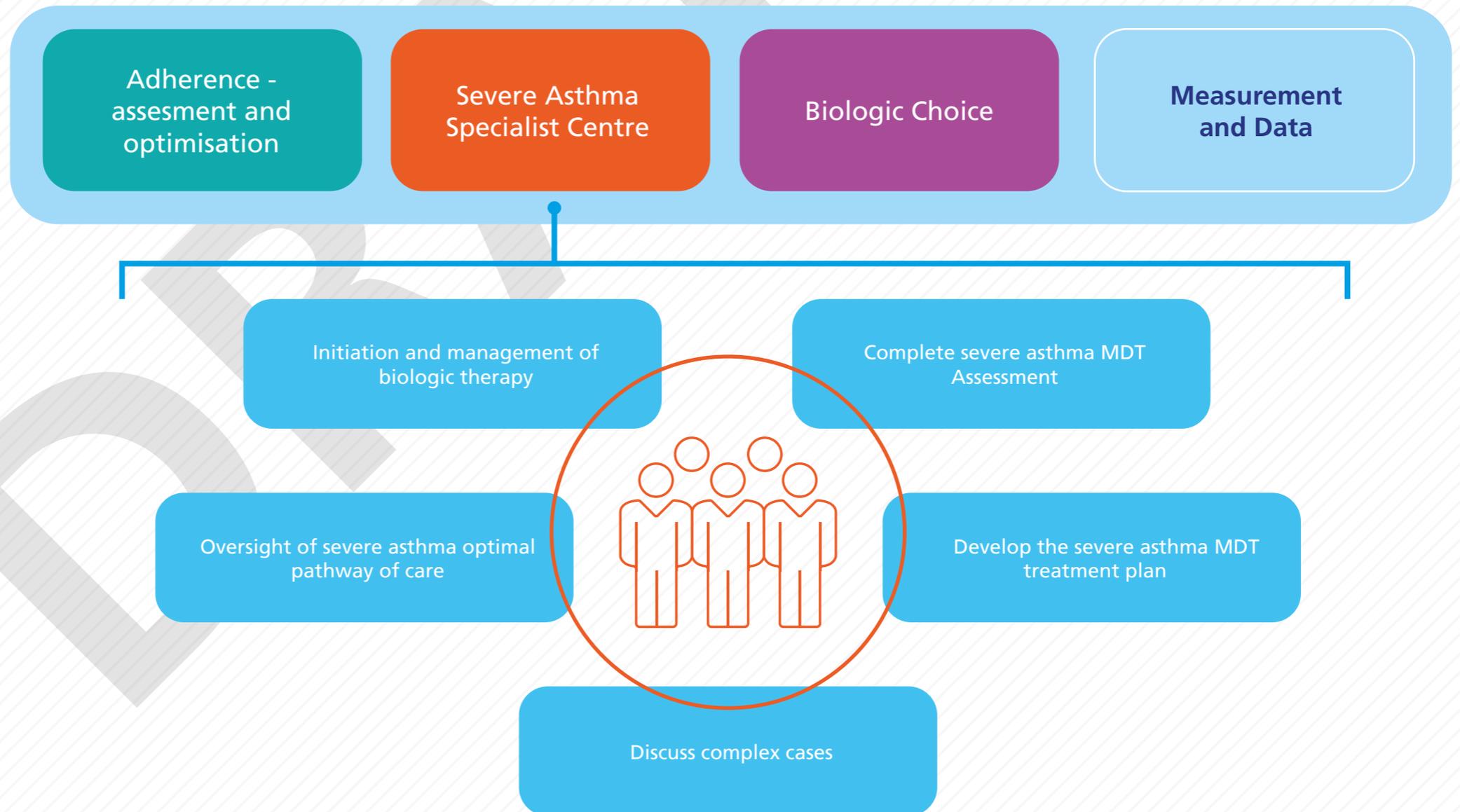
# The severe asthma specialist centre

Multidisciplinary Team Assessment and Multidisciplinary Meeting

**“Patients with severe asthma should be systematically evaluated by a dedicated multi-disciplinary service utilising a team experienced in the assessment and management of severe asthma.”**

Service Specification Specialised Respiratory Services (adult) - Severe Asthma (NHSE 2017)

## Severe Asthma Optimal Pathway of Care Toolkit



# Multidisciplinary team assessment and multidisciplinary meeting in severe asthma

The management of severe asthma should be approached as multi-professional partnership using a '[shared decision-making](#)' approach with the patient.

Understanding why a person's asthma is difficult to control can be complex and requires specialist expertise from a range of different health professionals known as a multidisciplinary team (or 'MDT'). This may include for example; doctors, nurses, physiotherapists, speech & language, pharmacists and psychologists. Systematic assessment and comprehensive, individualised management plans have been shown to improve outcomes and reduce cost of care.

The collaborative identified widespread variation in the structure of regional services and the role of MDT assessment in decision-making.

Consistency around MDT decision making and pathways of care across severe asthma specialist centres will ensure the best outcomes, consistency of experience for patients and equity in access to specialist care for individuals requiring this service, regardless of their location.

## Severe asthma specialist centres should...

- ensure the quality of holistic MDT assessment and diagnostic pathways for severe and 'difficult-to-treat' asthma.
- host the severe asthma MDT, with responsibility for each patient's pathway of care including access to biologic medicines prescribing and management.
- provide a mechanism for patient access to biologics through shared pathways between Specialist Centres and Satellite Centres across the region.



“ Every time there is something on the market ..... they have a multidisciplinary team meeting.....I get a letter saying that I have been discussed in the meeting. If there's anything I'd like to ask then ring up. So, I do feel quite included in my treatment at the severe asthma centre. ”

Patient quote

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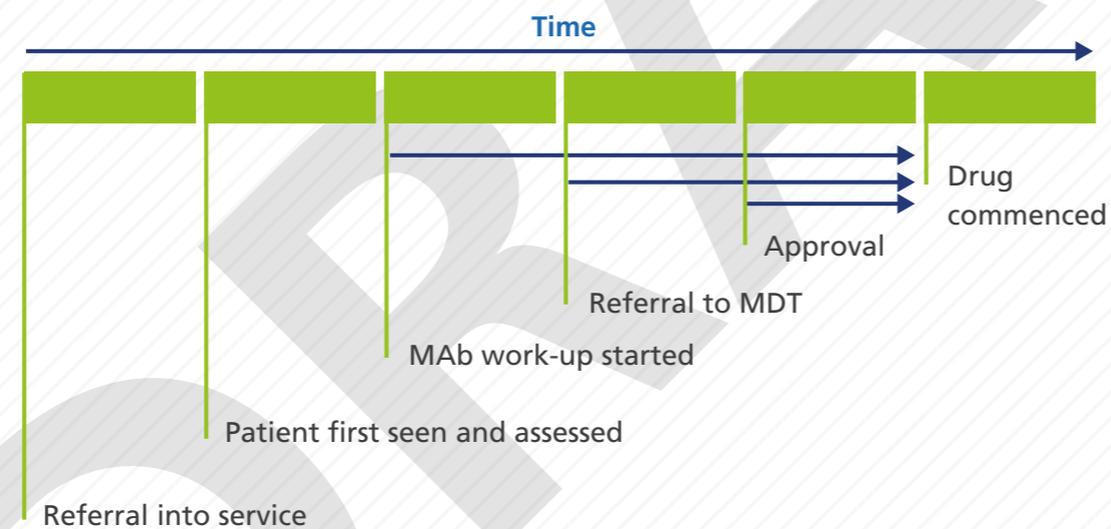
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# Multidisciplinary team assessment and multidisciplinary meeting in severe asthma

The severe asthma pathway of care can be complex, with transition through a variety of health care settings.

However, assessment and management of individuals should be undertaken in a timely manner.

The time taken to pass through each of the stages (1-6) outlined in figure below should be monitored and considered as part of a Severe Asthma Centres Annual Review. Commissioners should agree acceptable waiting times locally, where national guidance is absent.



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# Optimising regional and local MDT in severe asthma

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## Clinical Networks

The service specification outlines two types of severe asthma centre;

1. **'Specialist Centres'**; which are fully commissioned by NHSE/I to deliver severe asthma services,
2. **'Satellite Centres'** that are contracted to undertake some specialist activity and are linked to a Specialist Centre via participation in local or regional MDTs.

The designated severe asthma specialist centres, hosting the severe asthma MDT meetings, should facilitate the development of asthma networks. Learning from established national networks for trauma, stroke and cardiac disease have shown that these are enablers for:

- The development of best practice pathways of care to reduce unwarranted variation in patient care nationally.
- Improvements in patient care arising from peer support by enabling clinician to clinician discussion of highly complex cases.
- Improved data management; producing real time quality improvement metrics to enable centres to monitor changes in performance against agreed national standards.
- Improved ability of commissioners and policy makers to monitor and measure these improvements as they occur.

Improved alignment between local and regional specialist severe asthma MDTs will improve patient experience by reducing duplication of investigation and assessment. This will reduce delays in care and improve patient safety by enabling a consistent approach to prescription of biologics.

Specialist Centers should:

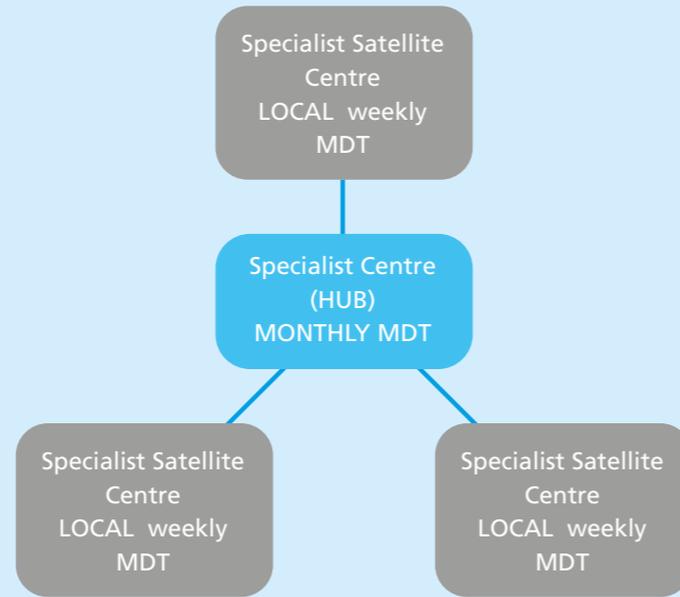
- Develop pathways to capture new ward discharges, A&E patients who may have severe asthma and patients discharged from intensive care; to improve patient experience and safety, and promote a more equitable and comprehensive referral process.
- For Trusts taking part in the RCP National Asthma Audit to establish links with teams delivering the discharge bundle to facilitate referral of appropriate patients into severe asthma services.
- Develop a training and education plan to support all members of the MDT and develop new asthma specialists in nursing, medicine and allied professionals.
- Enhance patient engagement; each region should have patient representatives or focus groups as an integral component of their service redesign process. With particular reference to areas such as homecare arrangements, how MDT decisions are relayed to patients.

“sometimes it'd be a two and a half hour journey, just for somebody to take blood, which was less than five minutes. To go back for two and a half hours. So, the fact that I can get everything done at once is not only helpful for me, but it's helpful for my family as well, and my carers. That they're not losing a full day just for a ten minute blood test. We can do everything all at once.”

Patient quote

# Options for delivery models in severe asthma

## MODEL 1 – Networked model



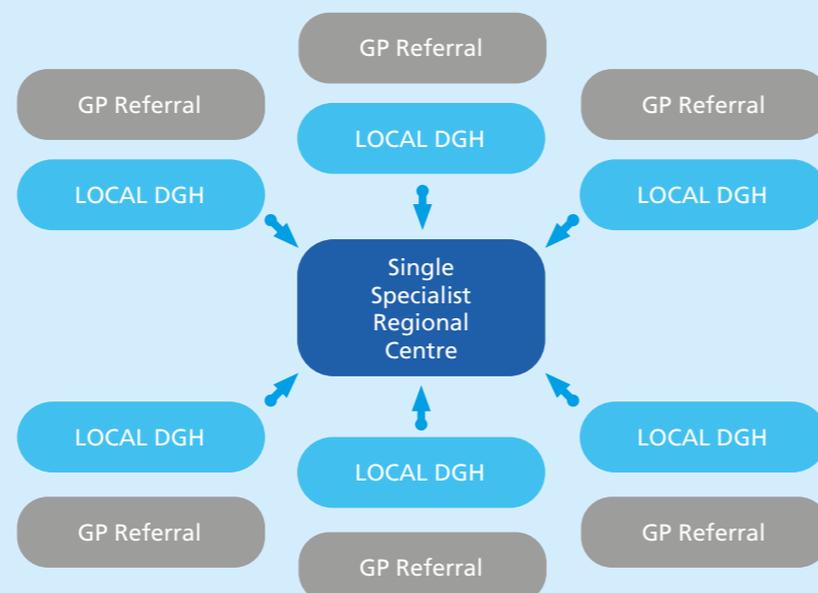
There are variety of models for delivery of the severe asthma pathway of care.

Whilst each regional model needs to be able to demonstrate delivery of all elements of the optimal pathway of care there is no 'one-size-fits-all' solution. Individual regions should adopt a model that best meets their local requirements e.g. geography and population.

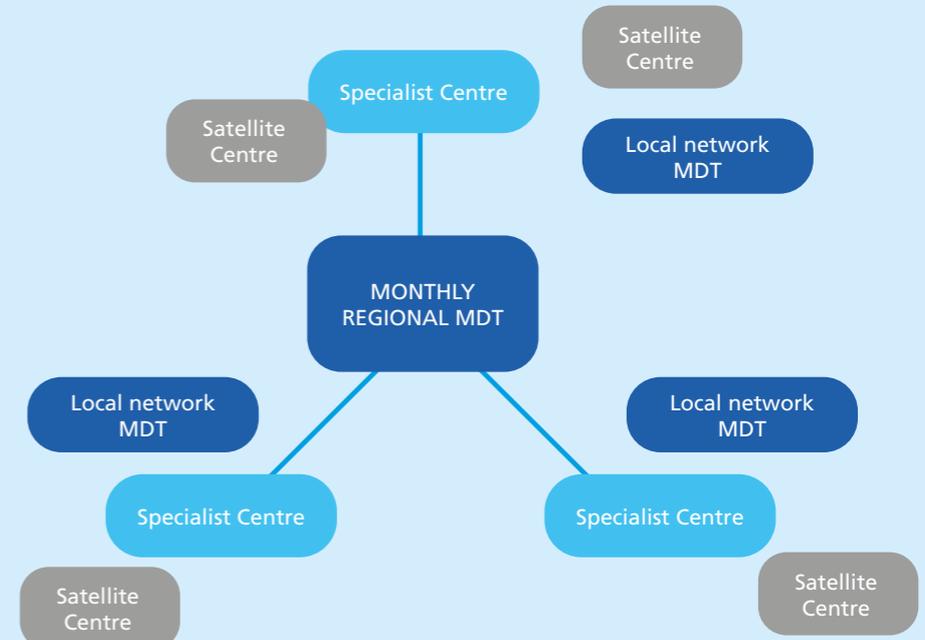
Networks try to balance care closer to home with providing the best possible specialist services. People often have to travel greater distances to be seen at a specialist centre, but with new 'home care' arrangements, much more treatment is now being delivered in people's homes.

Examples of MDT models identified by the Severe Asthma Collaborative are provided below:

## MODEL 2 - Standalone specialist centre



## MODEL 3 - Large Regional Network



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# Severe Asthma Speciality Multidisciplinary Team (MDT)



The MDT should contain Health care professionals with the necessary specialist skills and knowledge to deliver the requirements of the Severe Asthma MDT function rather than meet a checklist of designated professionals.

Establishing clarity around roles within the severe asthma specialist MDT can be a useful lever to facilitate workforce planning and developing business cases to ensure that standards of care described in the Severe Asthma Service Specification are met.

- A comprehensive skill mix directory for the severe asthma specialist MDT is provided. This has been written from the patient perspective and can be provided to patients attending Severe Asthma Centres so that they can understand the roles of professionals who they meet.
- However, it is recognised that the list is not exclusive or rigid and that it is possible for another named healthcare professional, who possesses the required competencies and experience, to undertake a specific function allocated to another professional within the MDT i.e. MDT collective competencies are more important than a list of professions in attendance at the meeting.

“ My local hospital and the specialist asthma centre don't have the same system.....Which I think is ridiculous... So, when I went from my local hospital to the severe asthma centre, I had to repeat all the tests that I've had done, because they didn't have it on their records...Well that was a lousy waste of time. ”

Patient quote

# Severe Asthma Specialist (MDT) Assessment Pathway

This facilitates a thorough clinical assessment of every patient who is accepted for review in a severe asthma specialist centre. A patient with difficult/severe asthma would be expected to have an assessment that includes;

## Access

Access to more advanced respiratory physiological testing. May include CPET; should be reported by an experienced respiratory physiologist and/or clinician, transfer factor, bronchial challenge testing.

Access to additional services including immunology, dietetics and allergy services.

Access to bronchoscopy and bronchial thermoplasty via local provision or referral route.

## Pathways

Data handling pathways. For Blueteq approvals, entry into registries, local quality dashboards, and clinical governance software (if used) for onward discussion and tracking.

Pathways for home care and biologic delivery. Biologics may be delivered as day cases, outpatient visits and/or with pathways to transition to home care services.

Pathways for transition of care from paediatric services.

## Tests

Baseline pulmonary function tests (PFTs). Typically collected by experienced respiratory physiologists, able to interpret flow volume loop quality. All centres should have access to FeNO measurement. PFTs should be reviewed within the MDT structure.

Baseline symptom control and quality of life scores. These may be offered by a range of outpatient staff and typically would be reviewed within the clinical consultation and MDT.

Collection of routine clinical phenotyping tests. To include relevant blood and/or skin prick tests.

Ability to carry out specialist tests including sputum or BAL differential cell counts and prednisolone levels

Ability to carry out specialist tests including sputum or BAL differential cell counts and prednisolone levels

## Assessment

Clinician assessment by consultant with expertise in severe asthma within a dedicated severe asthma clinic.

Specialist nurse assessment by a nurse with training and/or specific experience in the management of severe asthma.

Adherence assessment. \*- see section on adherence  
May be offered by the Adherence lead. Adherence data may be collected from local partnerships between hospital and primary care systems, by direct collection of data from GP surgeries, and/or collection records from local pharmacies, or use of smart technologies. Data should be interpreted by a member of the MDT according to a local protocol/SOP. Adherence data can be collected and collated by a trained person, who may be a pharmacist, MDT coordinator, CNS, or designated MDT data collector. In some centres, access to computer systems allows clinicians to view local prescription records before or during a consultation.

Inhaler therapy check. Performed by trained outpatient nursing teams, pharmacists, CNSs, clinicians, or respiratory physiologists.

Assessment of risks of therapies. Most patients will benefit from an assessment of their risk of fractures and bone mineral density scanning, with liaison with associated local services.

## Review

Review of radiology. Scans should be reviewed by experienced respiratory radiologist, within or prior to Clinical MDT discussions.

Review of psychological issues. Often initially identified at the first clinical consultation, patients may need assessment by a dedicated clinical psychologist. In

Specialist Centres the psychologist should be a core member of the clinical MDT, with links to psychiatry and IAPT services. Where a Satellite service does not have a clinical psychologist, clear referral pathways are required. Every effort must be made as a network to ensure equitable access to psychology services across the region.

Review of physiotherapy needs. Physiotherapists are core members of the clinical MDT but may not routinely see every patient, depending on local service configuration. All patients with severe asthma should have access to a physiotherapist with expertise in severe asthma and breathing pattern disorders.

Review of upper airway needs. All severe asthma services should have access to a dedicated upper airways service run jointly by Respiratory physicians and Speech and Language Therapists (SALT) with expertise in severe asthma and links to Ear, Nose and Throat (ENT) and voice therapy services. Where possible, SALT should be embedded within the clinical MDT.

“The experience of working with the consultant and the team up there was a genuine revelation. For the first time I had the feeling I was in the care of people, A, who cared about what they were doing. B, who had the scientific knowledge to try and get to the bottom of things.”

Patient quote

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# Severe Asthma Specialist (MDT) Assessment Pathway

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A severe asthma specialist MDT is the core decision-making body in severe asthma centres where decisions are made on initiation and cessation of high cost biologics, where patients are discussed and decisions regarding their management are made by consensus.

## Key responsibilities:

- To ensure that all patients with severe or difficult-to-treat asthma have undergone a standardised, comprehensive assessment by a multidisciplinary group of specialists.
- To gatekeep the prescribing of biologics in the region and ensure all NICE criteria have been met prior to initiation of a trial of therapy.
- To discuss continuation, or stopping of a biologic therapy after a trial of treatment.
- To discuss complex cases where further management agreed by MDT discussion and consensus is beneficial to ensure best care for patients.

Severe asthma MDTs should have in place appropriate governance structures to provide assurance on the quality of prescribing of biologics through shared pathways between specialist centres and satellite centres across the region. It is recommended the following are in place to facilitate this;

1. Set of procedures outlined in local SOPs, network agreements or other appropriate documentation; including outline of governance arrangements and accountability for decision making within the clinical MDT including quorate status.
2. Documentation of referral pathways, triage and illustrative patient journey maps. A referral triage route should be identified to ensure appropriate patients are seen within severe asthma services, making best use of resources. Local structures should be designed according to local population, considering available services, geography and transport links.
3. A documented processes for the Severe Asthma Specialist MDT meeting; including reasons for discussion and outcomes of MDT and how decisions are fed back to patients.
4. An MDT coordinator who may have the following roles:
  - a. Facilitate and co-ordinate the functions of the multidisciplinary team meetings.

- b. Establish and ensure the continuation of effective communication across the regional pathways.
  - c. Ensure all relevant data is available to the whole team for Clinical MDT meetings, including import of external scans and adherence data.
  - d. Facilitate data tracking for outcomes and quality dashboards including the National Registry.
5. A pathway for collection and evaluation of adherence data; confirmation of inhaler technique and its review as required by the MDT.
  6. The presence of, or a pathway for discussion with and evaluation by, an experienced specialised severe asthma clinical MDT team.
  7. A pathway to audit its activity and agreed targets for audit and/or quality improvement.
  8. A pathway for safe and effective delivery of biologics.
  9. A pathway for patients transitioning from the paediatric to the adult service.

Model MDT referral proformas were developed by the collaborative (which can be found [here in the Severe Asthma Toolkit resource folder](#)) aiming to establish a minimum data-set required by an MDT meeting when making decisions about the initiation and continuation of biologic therapies for severe asthma. This reflects a balance between ensuring access to all relevant information in a workable format to allow all members of the MDT to engage in the decision making process whilst avoiding the requirement for a lengthy proforma with exhaustive and repetitive detail. These proformas were developed to align with the optimal pathway of care outlined in this document and existing data capture by Severe Asthma services.

“That was quite an eye-opener... I saw physios, psychologists, cardio-therapy technicians, nurses, the whole lot, and the professor, all in one day. I mean, that was interesting. It really was helpful.”

Patient quote

## Severe Asthma Specialist Multidisciplinary Team (MTD)

Role	Description
<b>Doctor</b>	<p>Consultants working within the severe asthma services are specialists in respiratory medicine and have undertaken further training so that they have a detailed knowledge of asthma. They will work with you to find out what type of asthma you have, how this impacts your life and how you would like to manage your disease. Together you can then work out a management plan that suits you.</p> <p>Sometimes you might see doctors in training in clinic. These doctors are usually registrars and are training in respiratory medicine and asthma. They are highly trained and experienced doctors who work with the consultant team to deliver high quality care and learn more about severe asthma so they can become the consultants of the future.</p>
<b>Specialist Nurses</b>	<p>Specialist nurses working within an asthma service are specialists in respiratory nursing and often have, or are working towards, specific qualifications in the management of asthma. They are involved in every part of the assessment and treatment process from seeing you in clinic to talk about your symptoms, to defining your type of asthma and delivering your biologic therapy. In many severe asthma centres the specialist nurses will also be available for advice and support, either via telephone or a drop in service, when you have questions or problems with your asthma. <a href="#">View the competency framework</a></p>
<b>Pharmacist</b>	<p>Pharmacists working within the severe asthma service are experts in the medicines used to help treat asthma and other respiratory diseases.<sup>11</sup> They will help make sure that the medicines you are on to treat your asthma are the most effective for you and will work with you to make sure that you can use your inhalers well and your treatment suits you. Some people with asthma need support to take their treatment regularly and your pharmacist can help you with this when they see you in clinic.</p> <p>The pharmacist working in your severe asthma service will also be responsible for making sure that you are prescribed the right biologic treatment and can demonstrate that you have met, and continue to meet, the criteria for biologic treatment at each step of the treatment process.</p>
<b>Dietician</b>	<p>Dieticians are specialists in nutrition, healthy eating and weight management. They are able to support patients to eat well and make food choices that help them manage some of the symptoms that can be associated with asthma like food allergy or reflux. Sometimes this involves a change in diet or attempts to lose or gain weight and the dieticians will work with you to develop a program that suits your specific needs.</p>
<b>Psychology</b>	<p>Psychologists working within a severe asthma service are experts in assessing how respiratory disease can affect your mental health and your thoughts and actions around how you manage your asthma. Their job is to help you develop strategies to live well with asthma and feel more in control of the symptoms. They can also help you to understand and manage thoughts and feelings you experience as a result of your asthma on a day to day basis.</p>
<b>Speech and language therapy</b>	<p>Your airway extends from your nose to your lungs and people with asthma often have problems with the upper airway in addition to the changes that affect the airways in the lungs as a result of asthma. For some people problems with the upper airways can significantly influence how wheezy and breathless they feel on a day to day basis.</p> <p>Speech and language therapists are experts in assessing the upper airways, particularly the throat and vocal cords, and can help identify and manage any problems in your upper airway to alleviate your symptoms. They do this by looking directly at your vocal cords and offering exercises, advice and support that might help you manage your symptoms. Sometimes this might help reduce your need for certain asthma medications like steroids or inhalers.</p>
<b>Physiotherapist</b>	<p>Respiratory physiotherapists are able to help you take control of your asthma by helping you clear your phlegm and think about the way you breathe so that you can be in control of your symptoms. Sometimes this involves breathing retraining exercises or exercises in breathing control. They may also be able to help you with exercise or rehabilitation programs if your asthma has been bad for a long time and you are worried about getting back to exercise or finding the right exercise for you.</p>
<b>MDT Co-ordinator</b>	<p>The MDT co-ordinator is responsible for making sure that all your information is in the right place at the right time. They will make sure that all the notes and tests from your previous hospital are available for your initial appointment and will ensure that your progression through the severe asthma assessment is as smooth as possible. If you are eligible for biologic treatments then they will make sure that all your information is ready for presentation to the MDT so that a decision about treatment can be made for you as quickly as possible. You may be given the MDT co-ordinator's telephone number as a point of contact in case you have any questions during your assessment process.</p>
<b>Respiratory Physiologists</b>	<p>Respiratory physiologists support the severe asthma service by undertaking all the lung function measurements the team need to help diagnose and manage your asthma effectively. They also offer more specialist tests like exercise (CPET) or challenge testing that might be needed during the course of your severe asthma assessment. In some centres they might also support the pharmacists in demonstrating inhaler technique as part of your appointment.</p>

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## Key Actions

Assessment should be bespoke to patient needs.

Whilst not every patient will require every element of the MDT assessment to be undertaken, all services and functions should be available within each network.

All severe asthma specialist MDTs should have an MDT coordinator to improve coordination and efficiency of meetings and improve flow of information and communications across the optimal pathway.

All Severe Asthma Networks should have an agreed regional referral pathway that ensures efficient information transfer and equity in patient access.

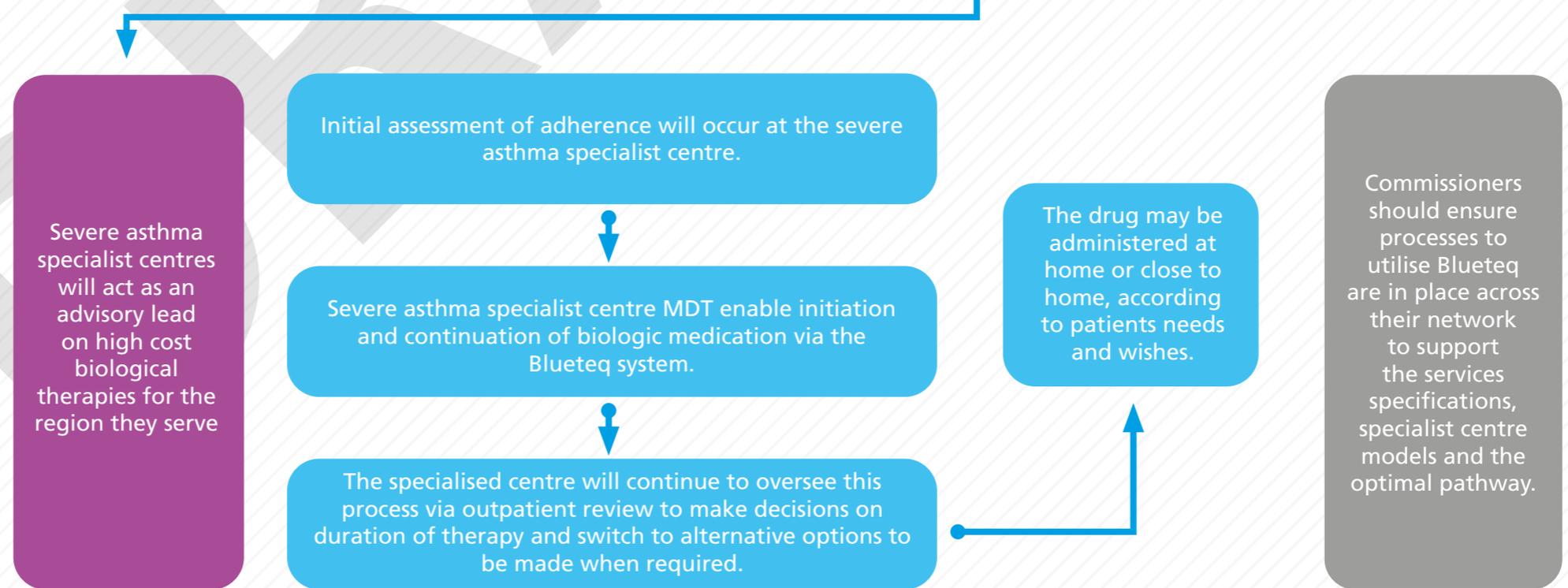
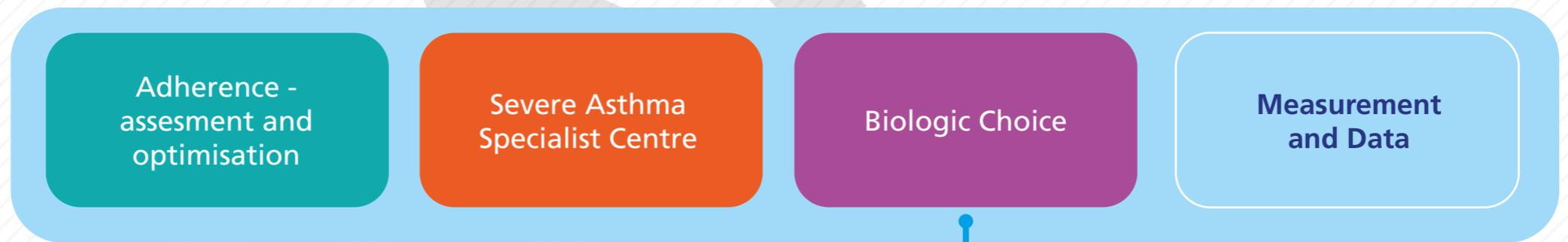
# Biologic choice in severe asthma

Understanding biologic choice in relation to national service specification for severe asthma

**“....specialist centres are to... act as clinical gatekeepers to ensure appropriate access to high cost technologies including biological agents....to prevent inappropriate use, unnecessary risk to patients and cost effective use of resources to the NHS.”**

Service Specification Specialised Respiratory Services (adult) - Severe Astma (NHSE 2017)

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# Introduction to biologic choice in severe asthma



“I just wish I had been put on this biologic a lot sooner. Because the period I was suffering, you can't explain it in words. It was really, really hard for me. It was just so depressing that sometimes you think your life is just not worth living anymore.”

Patient quote 2019

- A choice of biological agents targeting T2 pathways are approved by NICE.
- Biologics should only be prescribed by NHSE commissioned severe asthma centres.
- >50% of UK severe asthma patients are expected to be eligible for more than one biologic.
- Currently there are NO formal early stopping/ switching rules.

Licensed and National Institute of Clinical Excellence (NICE) approved medications in the UK include Omalizumab (anti-IgE), Mepolizumab (anti-IL-5), Reslizumab (anti-IL-5) and IL-5 receptor (R) targeting (Benralizumab). Dupilumab (anti-IL-4R) is currently awaiting NICE appraisal and approval.

A strong evidence base exists to support use of biologics in patients with severe asthma who meet prescribing criteria for individual products.

However, where a patient is eligible for more than one biologic there is little evidence to support evidence based differentiation between products. There is also little evidence to support decision making around switching between biologic agents where response has been suboptimal.

As a result, review of prescribing information recorded in the Severe Asthma Registry shows widespread variation in prescribing across specialist centres. This variation in practice increases the risk of detrimental variation in patient outcomes.

In the absence of a robust evidence base, the Severe Asthma Collaborative has developed a professional consensus to support biologic prescribing. In particular, the importance of including patient choice in the process is emphasised.

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# Introduction to biologic choice in severe asthma

A flow chart to support biologic prescribing was developed. This is based on published evidence where available, and by professional consensus where there is less evidence. The flow chart provides a framework for decision making to support consistency of approach across Asthma Networks.

In development of the framework, patient benefit was the primary consideration. Factors such as cost and health economic modelling were not undertaken; all NICE approved biologics were considered to be equally cost effective.

The flow chart includes all biologics that are currently NICE approved. Dupilumab – which is expected to gain future NICE approval has been included for completeness.

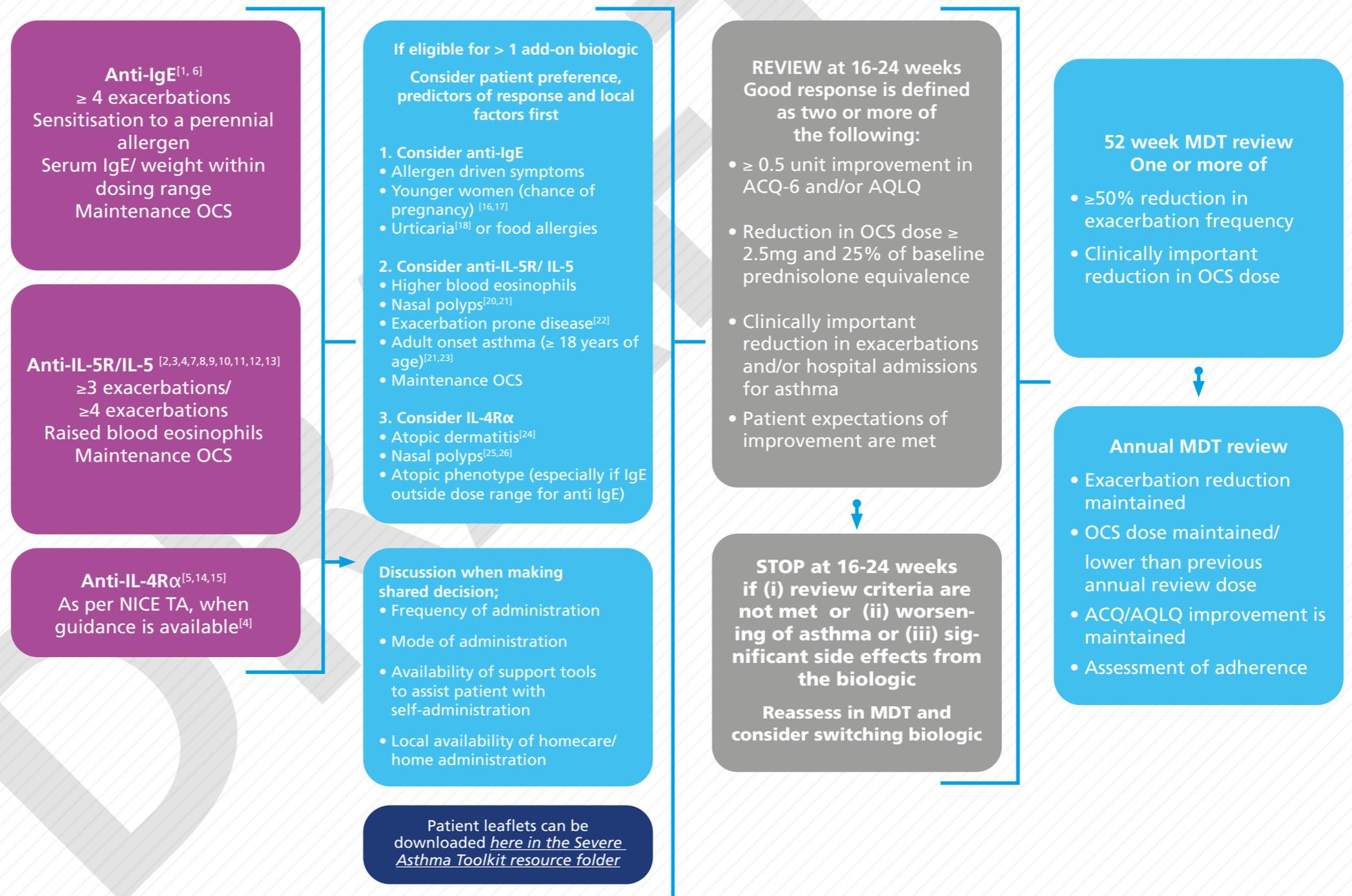
As more evidence becomes available and new drugs come to market, the national service specification should be reviewed accordingly to support prescribing of biologic therapy.

**Table of biologics for T2-high severe asthma**

Drug	Administration Route	Dosage	Eosinophils	Other criteria	FeNO
<b>Omalizumab</b>	Subcutaneous	Every 2 weeks or every 4 weeks (based on IgE and weight)	N/A	≥ 4 exacerbations in previous 12 months OR continuous OCS	N/A
<b>Mepolizumab</b>	Subcutaneous	Every 4 weeks	≥ 300 cells/ µL	≥ 4 exacerbations in previous 12 months OR continuous OCS	N/A
<b>Benralizumab</b>	Subcutaneous	Every 4 weeks for the first 3 doses, then every 8 weeks	≥ 300 cells/ µL	≥ 4 exacerbations in preceding 12 months OR continuous OCS	N/A
			≥ 400 cells/ µL	≥ 3 exacerbations in preceding 12 months	
<b>Reslizumab</b>	Intravenous	3 mg/Kg every 4 weeks	≥ 400 cells/ µL	≥ 3 exacerbations in preceding 12 months	N/A
<b>Dupilumab</b>	Subcutaneous	Every 2 weeks			

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# Biologic choice flowchart in severe asthma



Licensed and National Institute of Clinical Excellence (NICE) approved medications in the UK include Omalizumab (anti-IgE), Mepolizumab (anti-IL-5), Reslizumab (anti-IL-5) and IL-5 receptor (R) targeting (Benralizumab). Dupilumab (anti-IL-4R) is currently awaiting NICE appraisal and approval.

[Click here to view the flow chart references](#)

## The biologic pathway



“Because they say to me that I can only go a week either side of my time that I’m supposed to have my biologic medicine. I’m scared to ask what would happen if I don’t do that.”

Patient quote 2019

To facilitate shared decision making the collaborative developed two patient information leaflets. These can be downloaded [here in the Severe Asthma Toolkit resource folder](#)

A post-hoc analysis of 2 reslizumab studies developed an early response algorithm that enabled prediction at 16 weeks treatment to response to treatment at 52 weeks (App:2, Ref:19). The algorithm was based on changes in asthma control, quality of life, FEV1 and exacerbations. It was highly sensitive (>95%) but not specific (40%) when compared to the 52 weeks clinical response. More recently, evaluation of real-world experience with mepolizumab has shown that assessment of treatment response (based on reduction in exacerbations and steroid dependence) can be made at 24 weeks with sensitivity and specificity levels at >90% (App:2, Ref:29).

Refer patients to the pregnancy patient information leaflet. Omalizumab is the only biologic with reported pregnancy registry data (App:2, Ref:17), however global pregnancy exposure registries/observational studies have been established for [Mepolizumab](#), [Benralizumab](#) and [Dupilumab](#).

It should be noted that none of the anti-IL5/IL5R targeting biologics have NICE technology appraisal/approvals for nasal polyposis. Nasal

polyposis, age at diagnosis  $\geq 18$  years and FVC <65% predicted were associated with greater response to benralizumab in post hoc analyses of pivotal phase 3 trials (App:2, Ref:21). Similarly, reslizumab has been shown to produce larger reduction in exacerbations in patients with late vs early onset asthma (App:2, Ref:23) while real world data with mepolizumab has shown that older age and presence of nasal polyps are associated with responders (App:2, Ref:29).

[Dupilumab has NICE TA and approvals for atopic dermatitis with a NICE TA for nasal polyposis expected to report in July 2021] (<https://www.nice.org.uk/guidance/indevelopment/gid-ta10450/documents>)

It is recommended that severe asthma MDTs formally record the early response criteria used in practice to identify 16-week response to Omalizumab and early treatment response/failure at 16 to 24 weeks to anti-IL-5/IL-5R, anti-IL-4Ra biologics.

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# Patient information leaflet

A range of stakeholders contributed to development of the leaflets including; A quality improvement fellow, patient research ambassadors (literacy), governance teams, PAL services, Asthma UK and expert patients, the severe asthma registry steering group, together with the collaborative workstream comprising members of the MDT and commissioners.

The leaflet is designed to be adapted to incorporate local service information and corporate branding to meet local patient information governance requirements.

The collaborative engaged with EXPECT registry and a maternal medicine expert ( Prof Catherine Nelson – Piercy) to create a leaflet to support patient/clinician discussions for patients eligible for asthma biologics who hope to become pregnant. The leaflet provides information on specific biologics, FAQ and how to access additional support.

Downloadable versions of the leaflets can be found [here in the Severe Asthma Toolkit resource folder](#).

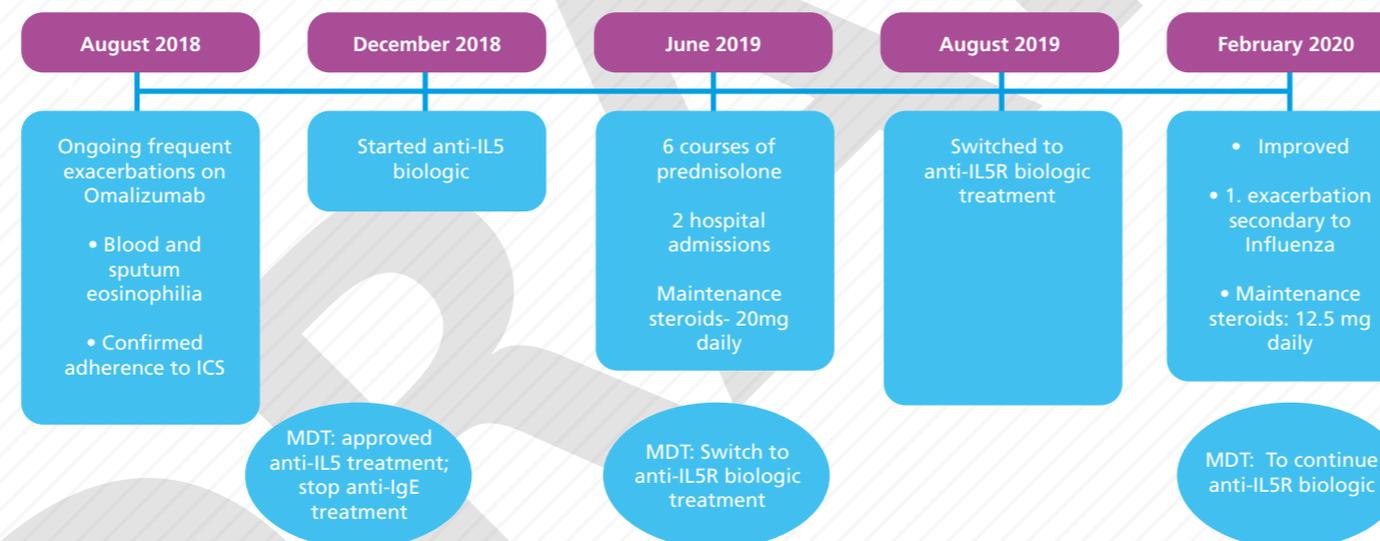


# Biologic Choice - Case Study

Philip is a 44 year old delivery driver known to have adult-onset, severe, atopic and eosinophilic asthma with co-morbid nasal polyps, breathing pattern disorder, gastroesophageal reflux disease and obstructive sleep apnoea, established on CPAP. When reviewed in clinic in August 2018 he reported 6 exacerbations requiring oral steroid treatment in the preceding 12 months, despite being on anti-IgE treatment (started 22 months ago). He was also on high dose ICS/LABA, Spiriva Respimat and Montelukast

A review of his electronic prescription records confirmed good adherence. Peripheral blood eosinophils were  $0.9 \times 10^9 / L$  and in view of his poor control he had a CT of his chest which showed mild bronchial wall thickening and sputum induction which revealed 24% sputum eosinophils. The MDT approved biologic switch to anti-IL5 biologic treatment which was started in December 2018.

## Case Study - Phillip



Over the next 6 months, despite anti-IL5 treatment he continued to have frequent exacerbations and when reviewed in June 2019 reported 2 hospital admissions due to asthma exacerbations in addition to 4 exacerbations treated in the community with oral prednisolone. During this time he had also become steroid dependent and was on 20mg of prednisolone daily. Due to the frequent courses of steroids and latterly maintenance steroids, his weight had increased as had symptoms of gastroesophageal reflux disease- he was finding this most distressing. His ACQ and AQLQ were unchanged.

The MDT approved switch to anti-IL5R biologic treatment which was started in August 2019. When reviewed in February 2020 he had only had 1 hospital admission due to an asthma exacerbation secondary to influenza infection and had managed to reduce his maintenance steroid dose down to 12.5mg daily. Both ACQ and AQLQ had improved significantly alongside reduction in symptomatic gastroesophageal reflux disease. The MDT approved continued use of the anti-IL5R biologic with a plan to review treatment response at 52 weeks.

### The case highlights the importance of:

- Early and continued review of patients on biologics.
- Considering switching biologics early i.e. after 6 months treatment if patients have failed to show a positive response.

Being mindful of the presence of co-morbidities and other clinical factors such as oral steroid dependence when choosing biologic treatment.

Reviewing response to biologics to ensure these high cost drugs are not continued in the absence of clinical response.

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# Biologic Choice

Understanding biologic choice in relation to national service specification for severe asthma



## Key Actions

Biologics should only be prescribed by severe asthma specialist centres following discussion at an MDT.

Severe asthma specialist centres should adopt the biologic prescribing guidance in order to reduce unwarranted variation, in prescribing practice.

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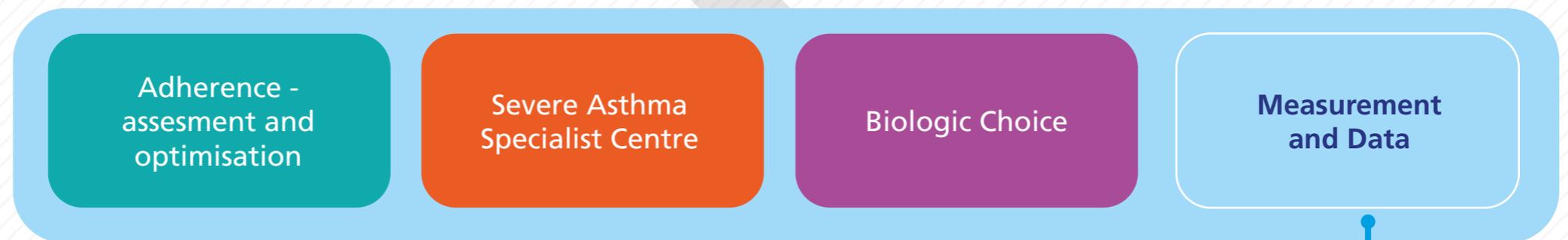
# Measurement for quality and improvement of care

Demonstrating we are providing optimal care, from both clinician and patient perspective, across networks.

**“The aims of the severe asthma service will be to improve patient outcomes...”**

Service Specification Specialised Respiratory Services (adult) - Severe Asthma (NHSE 2017)

## Severe Asthma Optimal Pathway of Care Toolkit



### QGIS metrics

<b>Metric 1</b>	Exacerbations over previous year requiring A&E attendance or hospital admission; aiming for a complete reduction
<b>Metric 2</b>	Exacerbations over previous year requiring oral corticosteroids; aiming for a reduction
<b>Metric 3</b>	Maintenance oral corticosteroid requirement; aiming for a complete reduction
<b>Metric 4</b>	Asthma control (ACQ6 score); aiming for clinically significant improvement
<b>Metric 5</b>	Asthma-related quality of life (mini-AQLQ score); aiming for clinically significant improvement

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# Measuring success of the severe asthma optimal pathway of care

Severe asthma centres are required to submit data to the severe asthma registry and to provide information to commissioners on the standard of their service as part of the national specialist commissioning framework. Centres also use Blueteq to prescribe high cost drugs and confirm that prescriptions meet prescribing guidelines. The Severe Asthma Collaborative critically examined the metrics used to assure the standard of severe asthma services to ensure that they were patient focussed and measured outcomes that were clinically meaningful. In developing the new data set the aim was to agree common tools for measuring patient experience and to ensure that reports could be generated automatically from the National Asthma Registry and could populate the specialised commissioning severe asthma quality dashboard. To ensure that centres were compared equitably statistical advice was sought to ensure that differences in case mix between centres were allowed for. The measures described were developed corroboratively by patients, clinicians and commissioners. The process by which the new data set was developed is described below.

## Consensus of the collaborative; best practice for measurement and data in the severe asthma optimal pathway of care.

High quality data is fundamental to supporting the implementation of the severe asthma optimal pathway of care. Producing a suite of standardised metrics, which can be used to support quality improvement, will enable centres to monitor their progress with delivering the optimal pathway of care. The ability to monitor these nationally will facilitate;

- the development of agreed interventions to reduce unwarranted variation in patient care.
- improvements in patient care arising from peer support enabling the sharing of expertise between healthcare professionals.

“and then I knew it was serious when I retired from my job at the age of 30, because I was spending more time as a patient than I was as a nurse.”

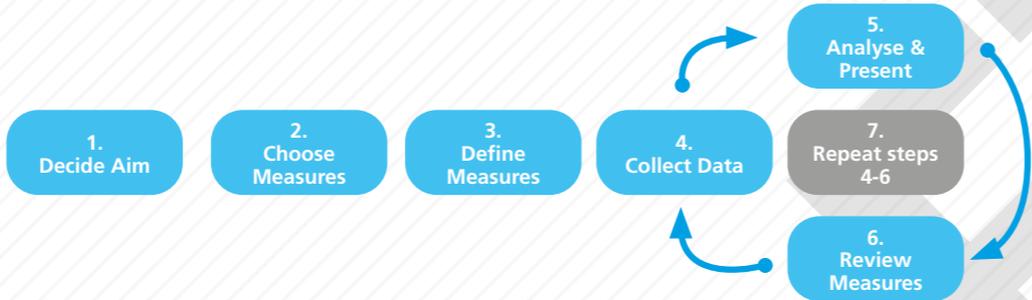
Patient quote

“Because, obviously, I wasn't living anymore. I was just existing. I had absolutely no control of my asthma.”

Patient quote



# The 7 steps to measurement for improvement



### A robust and sustainable approach to measurement

- Keep measures simple and only collect the data needed.
- Collect a few clear, unambiguous and relevant measures.
- Where possible use data collection systems and presentations that already exist.
- Minimise the burden on staff.
- Present information well and in a way that is useful to end users

**Step 1** Decide aim; The aims of the severe asthma scheme are to improve patient outcomes and patients’ experience of care. The aim of the metrics are to measure impact of implementation of the severe asthma optimal pathway on patient outcomes.

**Step 2** Choose Measures; measure the right things to identify improvements together with best practice in delivering the severe asthma optimal pathway of care, whilst demonstrating that care and treatment is tailored to the needs and preferences of patients.

A modified Delphi Process was followed asking patients, clinicians and managers to define the outcomes of care which mattered most to each group. Once the pathway outcomes were agreed metrics were selected that supported measurement of each of these outcomes using the same Delphi Process informed by a medical statistician who provided advice on the performance of the suggested measures.

### Step 3 Define measures;

- Patient defined outcomes were explored to ensure patient-centred quality improvement is the focus of the measures selected
- Measures were included to demonstrate clinically important improvements in asthma control for patients utilising biologic therapy.
- Measures were defined to record the success of asthma centres in reducing harm from systemic steroids.

### Step 4 Collect data; Determine to what extent data should be recorded to show that the optimal patient pathway is being provided.

[appendix 3.](#) Work has been undertaken with NHSE/I specialised commissioning severe asthma dashboard and with the Severe Asthma Registry to minimise the burden of data collection or changes to the specialised commissioning Dashboard of quality indicators and support engagement with the Registry, to support the recommendations of the collaborative.

**Steps 5 and 6** Analyse, present and review measures: Evaluate the changes implemented. Identify those that were successful and those less so. Metrics will be reported directly from the UK Severe Asthma Registry to avoid need for data double-entry. Data will be presented as difference from national average; focussing on reducing variation and highlighting best practice pathways. Data will be adjusted for local patient population.

**Step 7** Repeat; The collaborative have agreed a process with NHSE/I to support regular review of the data and metrics. The process included commissioners, clinicians and the Respiratory CRG. The specialised commissioning severe asthma dashboard will continue to be the mechanism for presenting metrics relating to the severe asthma optimal pathway of care.

An additional outcome from the work of the collaborative was consensus on the importance of patient engagement in the process of understanding ‘improved patient outcomes’. As well as agreeing the specific metric, a patient questionnaire was developed for use at annual review. The questionnaire can be downloaded [here in the Severe Asthma Toolkit resource folder.](#) It is recommended that this is provided to the patient before the review, to support a ‘shared decision making approach’ to delivering the optimal pathway.

# The 7 steps to measurement for improvement

## Measures:

**Metric 1;** Reduction in exacerbations over previous 12 months requiring A&E attendance or hospital admission.

**Metric 2:** Reduction in exacerbations over previous year requiring oral corticosteroids

**Metric 3:** Improvement in total maintenance oral corticosteroid requirement

**Metric 4:** Improvement in Asthma control (ACQ6 score); aiming for clinically significant improvement.

**Metric 5:** Improvement in asthma-related quality of life (mini-AQLQ score); aiming for clinically significant improvement 2021 onwards).

“ There are two key things that need to happen to really put patients at the centre of their own treatment. The first is a scientific, evidence-based approach to diagnosis and treatment, as opposed to the trial and error approach that so many of us have been used to. The second is the development and application of indicators about how patients feel that the treatments are working. Are they improving the things that really matter in their lives?

There is still a long way to go but exciting things are, at last, happening in these areas. ”

Patient statement 2019

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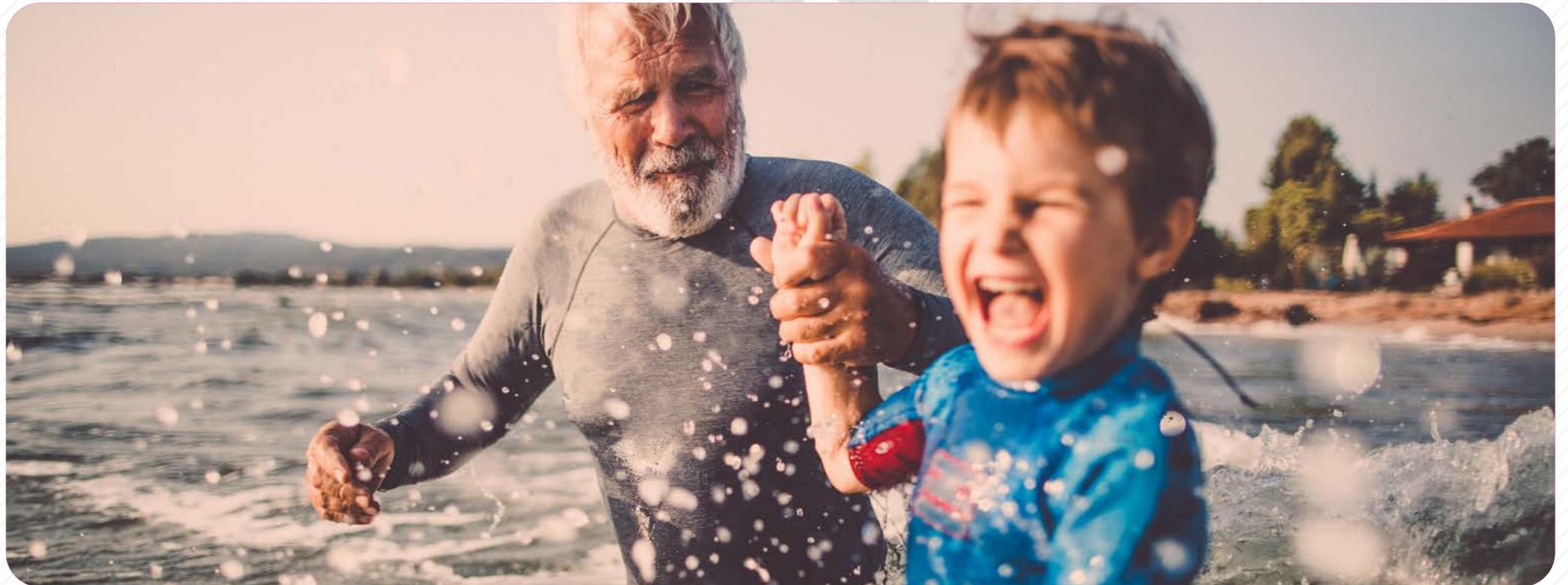
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## Measurement for quality care



### Key Actions

All severe asthma specialist centres have a responsibility to support data collection. This will ensure that the quality dashboard accurately reflects the quality of care provided by each Severe Asthma Centre.

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# The Collaborative

The Severe Asthma Improving Value Scheme (IV) was set up in 2018 to support NHSE/I specialised commissioners to understand, and where necessary, address significant unwarranted variation in the pathway of care experienced by people with difficult-to-control and severe asthma.

## Four areas of collaborative focus

Adherence - assessment and optimisation

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Good practice in multi-professional working

Measurement strategies to define high quality care

## The collaborative approach

1. Using the severe asthma national service Specification framework and a consensus approach each workstream developed a toolkit to be used by commissioners and clinicians in developing Severe Asthma Services.
2. The components and content of the toolkit were agreed over 35 teleconferences and two national workshops involving over 70 participants. The toolkit has been designed to support and guide clinical teams and commissioners to deliver the optimal pathway. It describes evidence for best practice, where this exists and a professional consensus where care is delivered without the benefit of a clear evidence base.
3. Adoption of the toolkit is suggested for regional commissioners, working through a collaborative approach locally.

Implementation of the toolkit should make it possible to reduce unwarranted variation in care to assure delivery of equitable and safe care to every individual who needs it.

## The advantages of a collaborative approach

Collaboration requires integration of activities and knowledge in a partnership of shared authority and responsibility.

Four critical elements are essential for collaborative practice in health care:

1. Coordination (working to achieve shared goals).
2. Cooperation (contributing to the team, understanding and valuing the contribution of other team members).
3. Shared decision-making (relying on negotiation, communication, openness, trust, and a respectful power balance).
4. Partnerships (open, respectful relationships cultivated over time in which all members work equitably together).

Sullivan, T. J. (1998).

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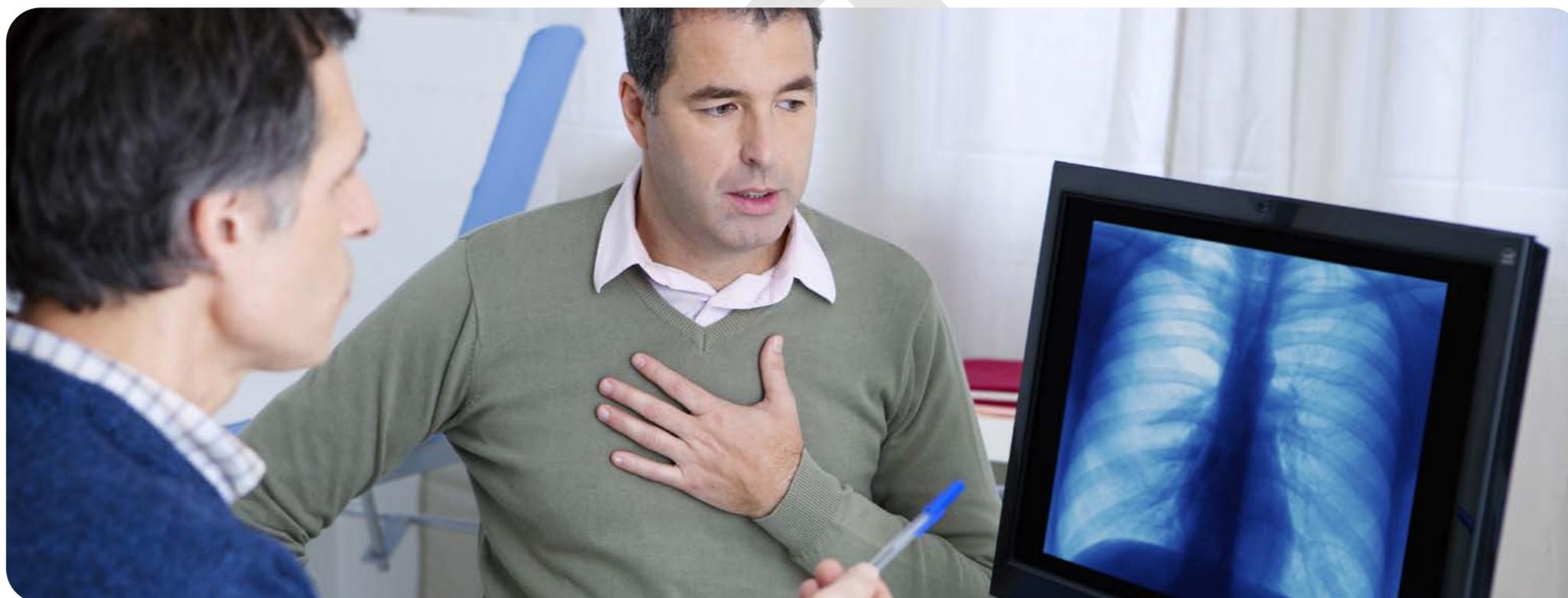
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## The benefits of the IV scheme collaborative approach



1. Developing a vision shared by clinicians, commissioners and patients for delivery of severe asthma services;
2. Developing an optimal pathway. The establishment of a network of clinical teams, working collaboratively with local and national commissioners, the NHS and the voluntary sector.
3. Building a community. Creation of a mechanism for inclusive engagement; communication in real time, knowledge exchange and sharing of resources, documents and tools to support improvement in local services pathways and MD Teams. – the futures NHS platform – <https://future.nhs.uk/connect.ti>
4. Facilitating sustainability and momentum. Alignment of the toolkit with other key national respiratory work e.g. the UK Severe Asthma Registry, Asthma UK, The NHS Long Term Plan (<https://www.longtermplan.nhs.uk/>) and Personalised Care /SDM (<https://www.england.nhs.uk/shared-decision-making/>)

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# Acknowledgements

We would like to thank the following individuals for their engagement and enthusiasm with the collaborative approach and their commitment and hard work to develop the toolkit and deliver the aspirations of the NHSE/ I IV severe asthma scheme 2018 -20.

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Simon Doe

Lynn Elsey

Joe Farrington-Douglas

Shoaib Faruqi

Nicola Green

Gemma Hayes

Liam Heaney

Leanne Jo Holmes

Robert Horne

Andy Hughes

Hannah Hylton

David Jackson

Binita Kane

Joe Kerin

Chris Lane

Jayne Longstaff

Matthew Masoli

Peter McQuitty

Andrew Menzies Gow

Graham Miller

Anna Murphy

Barry O’Neill

Paul Pfeffer

Helen Potter

Sam Prigmore

Jenny Quint

Lotte Renwick

Shakeela Riaz

Cris Roxas

Hitasha Rupani

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## Thank You

# Appendix One Shared Decision Making

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## The collaborative approach

- Ensuring shared decision-making is built into 'high value/impact' decision points along a care pathway.
- Full details of each option should be included to allow better communication with patients.

## Trained teams

- Local clinical leaders acting as champions encouraging the update of training opportunities.
- Skills for Health, Skills for Care and Health Education England [E-learning introduction to person centred approaches](#).
- Association of Medical Royal Colleges and University of Cambridge [risk communication toolkit](#).

## Prepared public

Local systems should ensure people are prepared to make decisions. Severe asthma patients will vary in their ability to engage with treatment decisions. Information should be targeted to audiences of differing health literacy and their advocates, recognising the support needed to take a more active partnership role with their care professional.

## Framework Example:

[BRAN](#): Choosing Wisely UK and Association of Medical Royal Colleges campaign to encourage individuals to ask four questions of the doctor or nurse to make better decisions together: Benefits? Risks? Alternatives? What if I do Nothing?

## Supportive systems and processes

Clinical leaders and commissioners can use tools to measure the impact of implementation and improvement. NICE routinely incorporates decision support tools into guidelines which can be used to support shared decision-making. A range of decision support resources are available through [NICE](#).

## Measurement tools

[CollaboRATE \(3 items\)](#): A patient reported measure with three brief questions completed after a consultation.

[SDM Q-9/SDM-Q-DOC](#): A nine item questionnaire completed by the individual and health care professional following a consultation. Simplified communication techniques: multiple resources are available to help clear communication between a health and care professional and the person they are caring for. These can all be found in the national health literacy toolkit, hosted on behalf of the system in England, by Health Education England.

[Shared Decision Making Summary Guide](#) published by NHS England

## Appendix Two Biological flowchart (pg 36) Reference, Evidence and NICE Technology Appraisals

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# Appendix Three Consensus approach to measurement for quality care

## Workstream Action Plan: Measurement and Data

**Aim:**

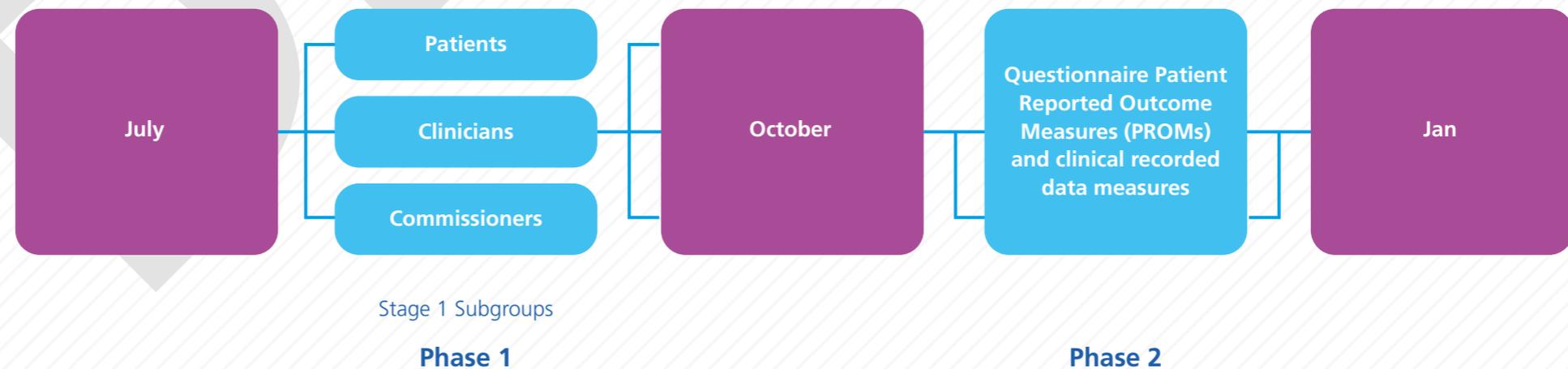
To identify what data should be measured/reported to demonstrate the effectiveness of severe asthma care and an optimal severe asthma care pathway. This should recognise the improvement in care expected with the Severe Asthma Improving Value Scheme.

This should result in identification of a collection of asthma specific outcome tools that will be adopted by all designated severe asthma centres, and a recommendations for changes to the Specialised Commissioning Dashboard of quality indicators.

## Workstream Action Plan: Measurement and Data

In broad terms what should we measure to show we are providing optimal patient care with an optimal pathway?  
Priorities for measures as viewed by:

What exact data and measurements should be recorded to show we are providing optimal patient care with an optimal pathway? In terms of:



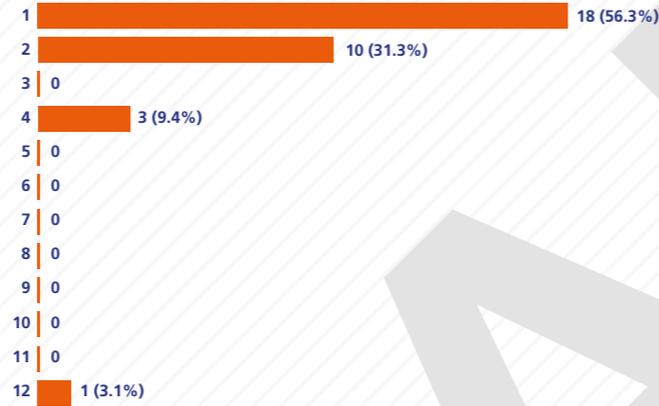
## Survey Long-List - Clinicians

	Potential Data Measures (Unranked Long-List)
1	a measure of exacerbations
2	a measure of asthma control in terms of day-to-day symptoms
3	a measure of development of long-term disease complications such as chronic airway remodeling
4	a measure of (risk of) potential complications from asthma therapy (particularly prednisolone)
5	a measure of impact of asthma on normal activities e.g. ability to work
6	a register of complications related to asthma biologics
7	a register of pregnancy outcomes in severe asthma
8	a measure of patient education for example provision of Personalised Asthma Action Plans
9	reporting of whether patients smoke / have stopped smoking / have seen smoking cessation
10	a measure of breathlessness
11	a measure of time-to-treatment and responsiveness of the patient pathway e.g. time to biologic initiation following MDM decision
12	a measure of research activity

## Survey Results - Clinicians

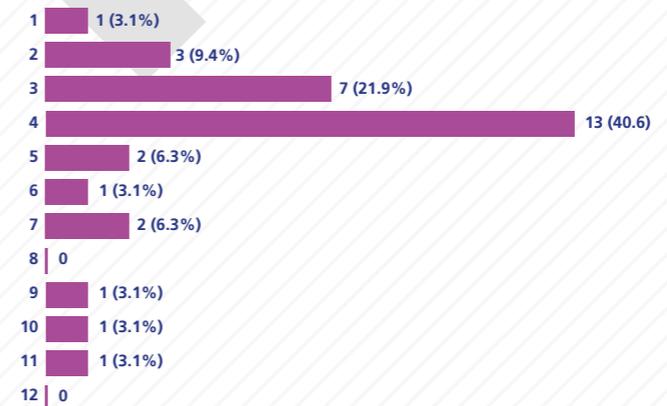
- Introduction
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- National service specification for severe asthma
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### a measure of ... exacerbations



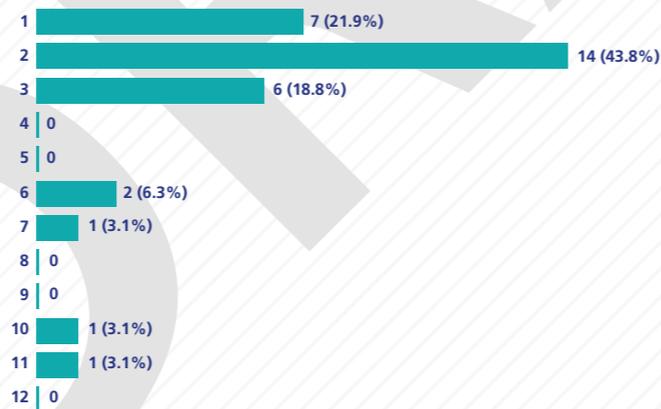
Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option).

### (risk of) complications from asthma therapy (prednisolone)



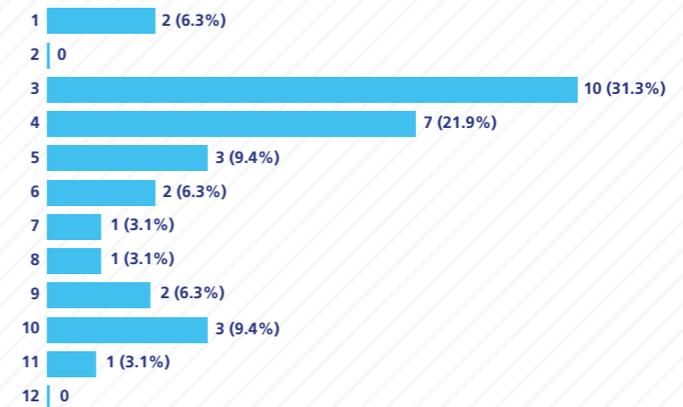
Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option).

### asthma control (day-to-day symptoms)



Multi answer: Percentage of respondents who selected each answer option (e.g. 100% would represent that all this question's respondents chose that option).

### impact of asthma on normal activities e.g. ability to work



## Survey Results - Patients

	Potential Data Measures (Unranked Long-List)
<b>1</b>	Amount of time taken off work or education due to asthma
<b>2</b>	Being kept informed about your care and treatment, and being involved in decisions about your treatment
<b>3</b>	Confidence in managing your asthma
<b>4</b>	Ease of access to treatment
<b>5</b>	Level of asthma control (day-to-day symptoms)
<b>6</b>	Number of asthma attacks
<b>7</b>	Number of courses of oral steroids
<b>8</b>	Quality of life (both during and after treatment)
<b>9</b>	Relationship with the healthcare professionals at the severe asthma centre
<b>10</b>	Your overall experience of receiving care

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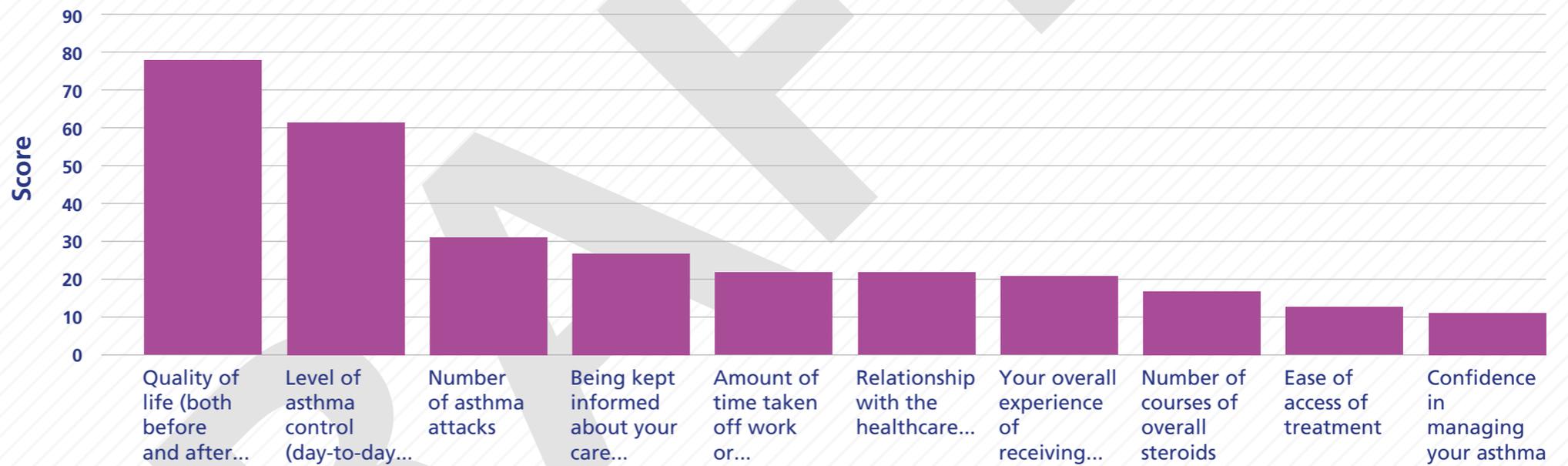
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## Survey Results - Patients

### Ranked data preferences - biologics only



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## Agreed Quality Indicator Measures (Annual Review)

**Metric 1:** Exacerbations over previous year requiring A&E attendance or hospital admission; aiming for a complete reduction.

**Metric 2:** Exacerbations over previous year requiring oral corticosteroids; aiming for a reduction.

**Metric 3:** Maintenance oral corticosteroid requirement; aiming for a complete reduction.

**Metric 4:** Asthma control (ACQ6 score); aiming for clinically significant improvement.

**Metric 5:** Asthma-related quality of life (mini-AQLQ score); aiming for clinically significant improvement (2021 onwards).

Metrics to be derived directly from the UK Severe Asthma Registry to avoid need for data double-entry.

Metrics will be presented as difference from national average to focus on reducing variation and highlighting best practice pathways; and will be adjusted for local patient population.

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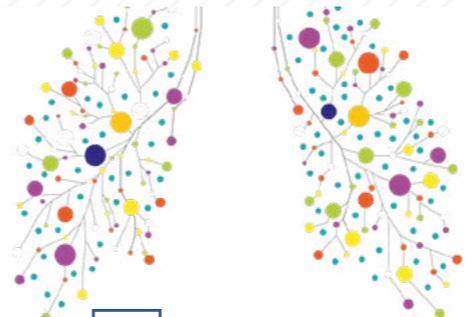
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### Severe Asthma Annual Review Patient Questionnaire



Name: \_\_\_\_\_  
Date of Birth: \_\_\_\_\_ Date Today: \_\_\_\_\_

1. How many times in the last 12 months has an asthma attack caused you to be admitted to hospital for one or more nights?

2. How many times in the last 12 months have you gone to A&E for an asthma attack but-not been admitted overnight?

3. Do you take oral steroid tablets every day to control your asthma even in between asthma attacks?

**IF YES** — How many times in the last 12 months have you had to increase the number of daily steroid tablets you have to treat an asthma attack?

**IF NO** — How many times in the last 12 months have you had a pack of oral steroid tablets for an asthma attack?

A version is available to download in the [Severe Asthma Toolkit resources folder](#)

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