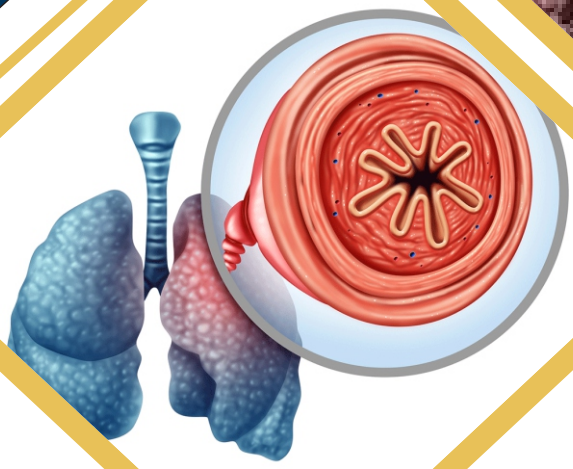

Chronic Obstructive Pulmonary Disease (COPD) and Asthma CME Module

National Program for Prevention and Control of Non-Communicable Diseases

ACKNOWLEDGMENTS

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MESSAGE

Shri Brajesh Pathak
Honorable Deputy Chief Minster
Honorable Minister of Medical
Health and Family Welfare Department
Government of Uttar Pradesh

Bronchial asthma and Chronic Obstructive Pulmonary Disease (COPD) are obstructive pulmonary diseases that affected millions of people in India. These two illnesses have many similarities and many differences which may sometimes confuse therapists in the diagnostics and management of these diseases which affect more and more people every year worldwide. Although asthma and COPD have many similarities, they also have many differences. COPD is not asthma. Asthma is not COPD.

Considering the above stated facts, module on asthma and COPD is a minimum standard practice to be offered in a facility. Through this, medical officers in Uttar Pradesh, will be exposed to much needed training, thus ensuring that management asthma and COPD is crucial and this could be achieved through staggered approaches.

I wish the team of State Institute of Health & Family Welfare, Uttar Pradesh and subject matter experts to continue developing such module on asthma and COPD for the medical officers in health services that ultimately benefit their community.

(Brajesh Pathak)

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MESSAGE

Shri Mayankeshwar Sharan Singh
Hon'ble State Minister
Medical Health and Family
Welfare Department
Government of Uttar Pradesh

Uttar Pradesh state is moving towards achieving the Goal 3 of the Sustainable Development Goals "ensuring healthy lives and promoting well-being for all at all ages- by 2030, reduce by one third premature mortality from non-communicable disease through prevention and treatment and promote mental health and wellbeing."

In this, Chronic obstructive pulmonary disease (COPD) is a growing healthcare problem that is expected to worsen as the population ages. It is a poorly reversible disease of the lungs that is one of the major causes of morbidity and mortality. In order to further strengthen the medical officers, it helps in understanding a range of diagnostic and management, this module for officers in medical services in Uttar Pradesh is one of the good interventions in states growth.

I am happy that the team at State Institute of Health & Family Welfare, Uttar Pradesh along with the experts from the field, have come up with such an intensified and detailed manual for medical officers in Uttar Pradesh.

I wish team at SIHFW success in their endeavors of aiding an improved medical service intervention through such module on asthma and COPD.

(Mayankeshwar Sharan Singh)

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FOREWORD

Shri Partha Sarthi Sen Sharma, I.A.S
Principal Secretary
Department of Medical,
Health & Family Welfare
Government of Uttar Pradesh

In 2015, nearly 3.2 million global deaths were reported due to COPD with an increase of 11.6% in deaths due to COPD as compared to 1990. Globally in 2015, 63.9 million disability-adjusted life years (DALYs), which is defined as the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability, were reported due to COPD. This represented 2.6% of the entire global burden of disease.

Along with disability-adjusted life years, COPD also affects the health-related quality of life of COPD patients. Among COPD patients, quality of life deteriorates with the progression of disease due to a decline in lung function, worsening symptoms, and presence of risk factors, which leads to gradual impairment of physical performance.

Besides disease burden, COPD contributes to the economic burden in terms of direct and indirect costs related to disease management. Working-age group (18–65 years) patients with COPD have higher direct and indirect costs and were more resource-intensive. Previous evidence revealed an overall prevalence of COPD in low- and middle-income countries was 9.2%. Meta-analysis estimates found the prevalence of COPD among patients 30 years and older was 10.6 in LMICs.

The global burden of disease study for India reported the prevalence of COPD increased from 3.3% (28.1 million cases) in 1990 to 4.4% (55.3 million cases) in 2016. In India, COPD is the second most leading cause of DALYs with the 36% average change in the number of DALYs from 1990 to 2016. The rate of DALYs per case due to COPD was 1.7 times higher than the global average in 2016.

Research studies from India suggest the economic impact in terms of direct and indirect cost is on the higher side and is associated with absenteeism at the job for a significant duration of time. A study conducted on COPD patients in Uttar Pradesh reported that 56.5% of patients were nonsmokers, indicating the major role of second-hand smoke and other risk factors.

Considering the complexity and economic impact of COPD across population, this module on Asthma & COPD for Medical Officers in Provincial Health & Medical Services in Uttar Pradesh becomes exceedingly important not only from medical intervention perspective but it will also indirectly uplift the economic status of the state.

I congratulate the faculties of State Institute of Health & Family Welfare, Uttar Pradesh and subject matter experts for developing an impactful module that will enhance the capacity of Medical officers in managing cases of Asthma & COPD at their PHCs/CHCs.

(Partha Sarthi Sen Sharma)

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MESSAGE

Dr. Brijesh Rathor
Director General
Medical and Health Services
Uttar Pradesh

Chronic obstructive lung disease is a lung disease characterized by lung airflow limitation and can be from exposure to harmful substances. It is a common cause of death worldwide. To avoid the high morbidity and mortality associated with this condition, it must be diagnosed and treated promptly. Chronic inflammation causes airway narrowing and decreased lung recoil. The disease often presents with symptoms of cough, dyspnea, and sputum production. Symptoms can range from being asymptomatic to respiratory failure.

This module focuses on the evaluation and treatment of chronic obstructive pulmonary disease (COPD) and highlights the role of the professional team in evaluating and managing patients with this condition. It deals with Identify the etiology, epidemiology, pathophysiology; recall, analyze, and select appropriate history, physical, evaluation andavailableoptionsfor treatment and management.

Considering the above stated facts, asthma and COPD module, State Institute of Health & Family Welfare, Uttar Pradesh with the help of subject matter experts has provided a comprehensive, coherent and insightful module for pharmacist.

I wish the team of State Institute of Health & Family Welfare, Uttar Pradesh and subject matter experts for such a commendable job.

(Dr. Brijesh Rathor)

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MESSAGE

Dr. Shailesh Kumar Srivastav
Director General Family Welfare
Directorate of Family Welfare
Uttar Pradesh

The number of COPD cases in India was a staggering 55.3 million in 2016 and is the second common cause of deaths due to NCD. Evidence from India suggested the COPD prevalence increases with age and exponentially after 30 years of age. The estimated prevalence of COPD ranged from 0.1% to 0.9% between the age group of 5 years to 29 years while the incidence ranged from 1.6% to 28.3% in population above 30 years of age.

The prevalence of COPD varies across different regions and states of India. While the COPD prevalence in Bangaluru was reported to be 4.36%, evidence from Delhi reported a prevalence of 10% whereas the prevalence in Kerala was reported to be 6.19% among the general population. Empirical data further reported the prevalence of Chronic Bronchitis (CB) was 3.5% in population above 35 years.

Risk factors for COPD include smoking, use of cooking fuel, biomass fuel and firewood, outdoor air pollution, increasing age, occupation, gender, pulmonary impairment after tuberculosis and socio-economic status among many others. Older age, lower socio-economic status, level of education, poor knowledge about smoking consequences, and rural areas were found to be associated with smoking. Pooled evidence from multiple studies showed the risk of COPD is higher with lower socio-economic status, air pollution, and exposure to environmental or occupation tobacco/dust.

Considering the above stated facts, this module on Asthma & COPD for Medical Officers in Provincial Health & Medical Services in Uttar Pradesh, developed by the faculties of State Institute of Health & Family Welfare, Uttar Pradesh with the help of Subject Matter Experts, has provided a comprehensive, coherent and insightful module for Medical Officers thus equipping them with the required necessary knowledge for successful management of cases of Asthma & COPD at their respective health facilities.

I congratulate the best to the faculties of State Institute of Health & Family Welfare, Uttar Pradesh and subject matter experts for such a commendable job.

(Dr. Shailesh Kumar Srivastava)

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MESSAGE

Dr. Narendra Agrawal
Director General-Training
Medical and Health Services
Uttar Pradesh

The CHCs are required to deliver specialised health care services to the rural people, in the absence of which they would be forced to spend a lot of time and money in availing themselves of such services in the urban areas. To enable CHCs to discharge this responsibility, the CHCs were envisaged to be equipped with medical specialists, para medical staff and complementary infrastructure.

The utilisation of the services of CHCs depends primarily on the quality of services rendered by them. Other factors that may have a bearing on the utilization rate are the distance and location of the CHCs. Longer distance and inconvenient location can adversely affect utilisation.

The quality of services rendered by CHCs is influenced by the availability of medical and para medical staff, and the availability and functionality of the infrastructure as proposed in the guidelines. The infrastructure includes all the physical facilities, viz; the building/rooms, operation threatre / labour room, arrangements for uninterrupted supply of water/electricity, medical equipments, pathology laboratories and the like.

Availability of medicines is yet another factor that could influence the utilisation of CHCs as referral centres. Non-availability of medicines in CHCs would also have a bearing on the cost of health care services for the poor.

Keeping the above facts in mind, State Institute of Health & Family Welfare, Uttar Pradesh with the help of Subject Matter Experts has developed an extensive and up to date module on Management of CHC for Medical Officers in Provincial Health & Medical Services in Uttar Pradesh, State Institute of Health & Family Welfare, Uttar Pradesh, that deals with all the underlying nuances and provides a comprehensive, coherent and insightful module for Medical Officers.

I applaud the faculties of State Institute of Health & Family Welfare, Uttar Pradesh and subject matter experts for such a commendable job.

(Dr. Narendra Agrawal)

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ACKNOWLEDGMENT

Dr. Rajaganapathy R, I.A.S
Director
State Institute of Health & Family Welfare, UP
Government of Uttar Pradesh

Chronic respiratory diseases account for 4% of all diseases and 8.3% of chronic diseases worldwide and India shares a large part of the global disease burden. The various data sources point toward the increasing chronic respiratory disease burden in India. The worldwide prevalence of asthma is 1-18% of the population in different countries whereas the prevalence of asthma in children and adults in India is at least 2%.

In India, asthma is seen equally in both urban and rural populations. The major risk factors associated with asthma include allergies, pollution, advancing age, smoking, household/environmental tobacco smoke exposure, use of unclean cooking fuels.

Chronic Obstructive Pulmonary disease is a heterogeneous lung condition characterized by chronic respiratory symptoms due to airway abnormalities that cause progressive persistent airflow obstruction. Rigorous estimates of the current prevalence of COPD in India indicate that prevalence may vary from 3% to 8%. The age-specific prevalence of COPD increases rapidly after the age of 30 years, with a greater increase in men than in women, reaching the highest prevalence among men in the 80 years or older age group (37.8%) and among women in the 75-79 years age group (19.7%).

The epidemiological report for India cites air pollution as the leading risk factor for COPD in 2016, more responsible than smoking for the COPD burden. It reports that, in India, there is increased association between chronic respiratory diseases like COPD and non-smoking related factors, such as outdoor air pollution from particulate matter, indoor air pollution from biomass fuels, occupational exposure to crop dust, dust from mines, chemicals, poor socio-economic status, poor nutrition, overcrowding, and residence in urban slums.

In the light of these above stated facts, it is imperative the skills and knowledge of Medical Officers in Provincial Health & Medical Services in Uttar Pradesh is up to par to tackle the challenges posed by Asthma & COPD in the state. This module on Management module on Asthma & COPD for Medical Officers in Provincial Health & Medical Services in Uttar Pradesh, defines and facilitates the treatment protocols and treatment regimen for managing cases of Asthma & COPD.

I acknowledge the sincere efforts made by the faculties of State Institute of Health & Family Welfare, Uttar Pradesh and by Dr. Surya Kant, Professor & HOD, Department of Respiratory Medicine, King George's Medical University, Uttar Pradesh, Lucknow & Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, Uttar Pradesh, Lucknow in developing such a comprehensive, coherent and insightful module for Medical Officers.

(Dr. Rajaganapathy R.)

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CONTENTS

Disclaimer :

The treatment of COPD & Asthma patients are as per the state government and/or institution policies and as per the experience of the treating physician. These guidelines are indicative and are brought out to facilitate the treating physician. The latest scientific knowledge must be keptin mind for treatment and management of any patient.

List of Abbreviation

AFB	Acid- Fast Bacilli
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
BWM	Biomedical Waste Management
CBAC	Community Based Assessment Checklist
CHC	Community Health Center
CKD	Chronic Kidney Diseases
COPD	Chronic Obstructive Pulmonary Disease
CPHC	Comprehensive Primary Health Care
CRD	Chronic Respiratory Diseases
CT	Computed Tomography
CVD	Cardiovascular disease
DALYs	Disability-adjusted life years
DH	District Hospital
DHS	District Health Society
DM	Diabetes Mellitus
DPI	Dry powder inhaler
EAG	Empowered Action Group
ECG	Electrocardiogram
FEV	Forced Expiratory Volume
FVC	Forced Vital Capacity
GOLD	Global initiative for Chronic Obstructive Lung Disease
HWC	Health and Wellness Center
ICMR	Indian Council of Medical Research
ICS	Inhaled Corticosteroids

IMV	Invasive Mechanical Ventilation
KFT	Kidney Function test
LABA	Long-acting beta agonist
LAMA	Long-acting anti-muscarinic agents
LFT	Liver function test
LLN	Lower Limit of Normal
mMRC scale	Modified Medical Research Council scale
MO	Medical Officer
MRI	Magnetic Resonance Imaging
NHM	National Health Mission
NIV	Non-invasive Mechanical ventilation
NPCDCS	National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke
NPHCE	National Programme for Health Care of Elderly
NSAIDs	Nonsteroidal anti-inflammatory drugs
NTCP	National Tobacco Control Programme
PEF	Peak Expiratory Flow
PEFR	Peak Expiratory Flow Rate
PFM	Peak Flow Meter
PHC	Primary Health Center
PMUY	Pradhan Mantri Ujjwala Yojana
SABA	Short acting beta agonist
SAMA	Short acting antimuscarinic agent
SHS	State Health Society
SpO2	Saturation of peripheral oxygen
USG	Ultrasonography

Chapter 1
Introduction
Chronic Respiratory Diseases (CRD)

Chapter 1

Introduction

Chronic Respiratory Diseases(CRD)

- Burden of disease: Global
- Burden of disease: India
- Integration of the CRD services with focus on continuum of care
- About the guidelines: What and for whom?
- Lifestyle Modification and Risk reduction for Chronic Respiratory Diseases
- Risk Reduction
- Diagnosis and Management

1.1 Burden of disease: Global and India:

According to the latest Global Burden of Disease Report (2019), there are an estimated 212 million cases of COPD and 262 million cases of Asthma in the world, making them one of the most common chronic diseases in the world. COPD is the third leading cause of death in the world, accounting for a total of 74 million disability-adjusted life years (DALYs), while Asthma ranks more than 20 in the world for death and causes 21 million DALYs.

In India, there are an estimated 37.8 million cases of COPD, contributing to 17.8% of the global burden. India ranks number two in the world regarding the global burden of COPD. COPD is the Second leading cause of death and DALYs in India, and in terms of absolute numbers, India ranks No. 2 in the world for COPD deaths as well as DALYs. Although India contributes to 17.8% of the global burden of COPD, it contributes to a disproportionate 27.3% of the global COPD deaths and 28.5% to the global COPD DALYs, indicating mismanagement of COPD in India. There is a wide heterogeneity in the burden of COPD between different states in India, with Uttar Pradesh, Bihar, West Bengal, and Rajasthan having the highest burden. Tobacco smoking contributes to only 20-25% of the national COPD burden, while air pollution (household and outdoor)contributes to over 50% of the national COPD burden.

Sharma R, Shahi VK, Khanduri S, Goyal A, Chaudhary S, Rana RK, et al. Effect of Ayurveda intervention, lifestyle modification and Yoga in prediabetic and type 2 diabetes under the National Programme for Prevention and Control of Cancer, diabetes, cardiovascular diseases and Stroke (NPCDCS)-AYUSH integration project. Ayu 2019;40:8–15

In India, there are an estimated 34.3 million cases of Asthma, contributing to 13% of the global burden. India ranks number 1 in the world for the total number of Asthma cases, first in the world for the total DALYs and first in the world for total Asthma deaths. Although India contributes to only 13% of the global Asthma burden, it contributes to disproportionate 43% of the worldwide Asthma deaths, indicating that Asthma remains very poorly managed in India. These findings are supported by the Asthma Insights and Management (AIM) Study, in which India was one of the 20 countries that participated. India had the greatest number of Asthma patients reporting both daytime and nighttime symptoms, the greatest number of people reporting school or work absenteeism and the worst quality of life. None of the 400 randomly selected Asthmatics from 8 cities and towns in India had good Asthma control.

The National Commission on Macroeconomics and Health was set up to study various diseases and their burden on the country's health care system in 2001, and the COPD burden they estimated and projected was an eye opener for clinicians and policymakers alike. The economic loss of COPD and Asthma estimated for India is now Rs. 60,000 Crore, assuming no specific government intervention and no substantial change in the practice of treating COPD have been made in the last decade. However, if the medical community adhered to standardized treatment guidelines in the previous decades, this cost was estimated to reduce drastically to one-fifth (1/5) for the same year.

Many people suffer from these ailments for years and die prematurely from it or its complications. This has a major long-term implication in terms of increasing burden to the patient, family, community, and eventually health care system and economy. Patient access to diagnostic and management facilities, disease-state education, drug therapies and non-pharmacological interventions (e.g., pulmonary rehabilitation) must be improved. Considering the rising burden of chronic respiratory diseases, prevention and management guidelines for COPD and Asthma have been included under the National Program for Prevention and Control of CVD, diabetes, cancers, and Stroke (NPCDCS)

1.2 Integration of the CRD services with a focus on continuum of care

The NPCDCS has been integrated into the NHM framework to optimise scarce resources and ensure the sustainability of flawless services. Sharing the NHM financial, administrative, and institutionalised structure, e.g., NCD (Non-Communicable Disease) Flexi pool, State Health Society (SHS), District Health Society (DHS), rationalisation of human resources, etc., all have become crucial programme strategies for NPCDCS implementation.

For creating awareness, early detection, management, appropriate referral and continuumof care, the care for COPD and Asthma patients under the NHM needs to be streamlined with Ayushman Bharat, including integration with Comprehensive Primary Health Care (CPHC), National Tobacco Control Programme (NTCP), National TB Elimination Programme (NTEP) and National Programme for Health Care of Elderly (NPHCE).

Primary Health Centers supported by outreach services, Mobile Medical Units, healthcamps, home visits and community-based interaction will provide a seamless continuumof care that ensures the principles of equity, quality, universality and no financial hardship[2].

1.3 About the guidelines: What and for whom?

Guidelines are primarily to be used by the programme managers and medical officers for prevention, early detection, and management of COPD and Asthma patients under the public health system. The guidelines also briefly mention the roles and responsibilities of the supporting staff, e.g., ANM and ASHA workers, in preventing and detecting COPD and Asthma. The guidelines also state the epidemiology, risk factors, classification/staging of COPD and Asthma, and drug interactions.

These guidelines will help medical officers' decision-making capacity for early diagnosis and management of COPD and asthma at the primary healthcare level. Still, they would also enhance the skills of the health care staffat Sub Health Centre, e.g., Community Health Officer (CHO), ANM, and ASHA, in screening andreferring suspected cases of COPD andAsthma.

These guidelines would enable the states to put in place the necessary elements, i.e., human resources, drugs, equipment, and diagnostics required at various healthcare levels for delivering the continuum of care for COPD and Asthma patients.

Reference: *[2] Operational Guidelines: Ayushman Bharat - Comprehensive Primary Health Care through Health and Wellness Centres, Ministry of Health and Family Welfare, Government of India.*

1.4 Risk Factors for Chronic Respiratory Diseases:

Modifiable Risk factors	Biological Risk Factors	Non modifiable risk Factors
• Tobacco use • Indoor air pollution • Outdoor air pollution • Allergens • Occupational agents • Unhealthy diet (both undernutrition and overnutrition) • Physical Inactivity • Secondhand smoke • Smoking during pregnancy	• Overweight /Obesity • Impaired Pulmonary Function • Allergic sensitization • Recurrent respiratory tract infections during childhood • Tuberculosis infection	• Age • Hereditary

1.5 Lifestyle Modification and Risk Reduction for Chronic Respiratory Diseases

Healthy lifestyle/ lifestyle modification: The medical officer should advise all individuals coming to their clinic about the healthy lifestyle/lifestyle modification mentioned in the MO Module under NPCDCS. Need to assess for other NCDs covered under the programme and their risk factors, e.g., Hypertension, Diabetes, CVD, Cancer (oral), etc.

Risk Reduction: all the patients reporting to the clinic with CRDs should be advised about risk reduction, focusing on exposure prevention and improving their lung capacity.

1.5.1 Smoking Cessation:

Smoking cessation is the single most cost-effective way to manage *COPD* and stop its progression. On every visit, the medical officer should practice the"5A "approach (Ask, Advise, Assess, Assist, and Arrange) for Smoking cessation for all patients suspected of COPD and Asthma. These patients may also be referred to tobacco cessation clinics associated with the National Tobacco Control Programme (NTCP).

S Kant*, B Gupta, Role of lifestyle in the development of COPD: a review. Lung India 2008,**25**: 95-101. **(18/1.014)**

These patients may also be encouraged to call the Tobacco Quitline no. 1800 112 356 and the Cessation number 011-22901701. They may also be referred to Tobacco Cessation Centers (TCC) established in the District Hospitals under the National Tobacco Control Programme (NTCP)and the TCCs established in any Dental College in the country.

1.5.2 Exposure Avoidance (Indoor/outdoor pollution/allergens):

On every visit, MO should advise.

- Using clean energy instead of solid fuels for cooking (PMUY) and ensuring adequatekitchen ventilation (E.g.,improve cross ventilation,chimney,or exhaust fan)
- Reducing exposure to secondhand smoke if not smoking himself/herself
- Adequate usage of respiratory protection in case occupational exposure is thecause.
- Avoid known allergens in case ofAsthma.
- Avoid dusty and damp settings at home or outside.
- Avoid indoor air pollutants (e.g., mosquito coils, fragrance sticks, dhoop-agarbatti, chemicals fumes used as mosquito repellents)
- Avoid going outside, exercising in heavy smoke, air pollution, etc.

1.5.3 Physical Activity:

- Considering the heterogeneity of exertional symptoms and the high prevalence of co-morbidities, it is essential that physical activity assessment and guidance be done at a higher facility level, and follow-up can be done at PHC.

Physical Activity Type	Description	Benefits for COPD Patients
Aerobic Exercise	Pursed lip breathing, Diaphragmatic breathing, Pranayama yoga breathing	• Improved physical capacity • Decreased dynamic hyperinflation and exertional dyspnoea • Enhanced exercise tolerance • Better quality of life • Fewer disease exacerbations and reported sick days, especially in COPD patients
Walking	Encourage walking for at least 30 minutes every day	• Important and neglected exercise • Numerous benefits as above for COPD patients
Stretching and Weight-Bearing Exercises	Simple stretching and weight-bearing exercises with filled water bottles	• Improves muscle mass
Resistance Training	Increases muscle mass and strength	• Augments ability to perform tasks of daily living • Improves health-related quality of life

1.6 Diagnosis and Management

A considerable proportion of individuals with Chronic Respiratory Diseases remain undiagnosed, diagnosed late or misdiagnosed, leading to inadequate/inappropriate management. Also, care coordination remains a challenge, especially for patients who are cared for at the Primary level or Secondary/Tertiary level and those who transition frequently and get admitted for exacerbation.

The algorithm for diagnosis and management of COPD and Asthma, which constitutes a major burden of morbidity and mortality in respective chapters, should be referred to by Medical Officers while dealing with patients of COPD and Asthma.

1.7 Package of Services

In line with objectives and strategies for the prevention and control of CVDs, Diabetes Mellitus (DM), Cancer and Stroke under NPCDCS, the package for preventive, promotive, curative, and supportive services for COPD and Asthma at various government health facilities are given in table 1.1.

Table 1.1: Indicative Package of services at various levels of health facilities

Health Facility	Package of services
Sub Centre/ health and wellness Centre	■ Health promotion for behavior change and counselling. ■ Awareness generation and prevention of risk factors with special focusto cessation of smoking and exposure to pollutants/ allergens. ■ Follow up of patients put on treatment and ensuring treatment compliance and lifestyle modification.
PHC	■ Health promotion for behaviour change and counselling ■ Clinical diagnosis and treatment of patients of COPD/Asthma and referral of complicated cases to CHC/DH and follow-up of patients put on treatment. Equipment: peak flow meter, Oxygen, Pulse oximeter, Nebulizer
CHC/ FRU	■ Prevention and health promotion including counselling, ■ Early confirmation of diagnosis of COPD and Asthma through clinical history and examination and investigations, ■ Management of COPD and Asthma other respiratory diseases, ■ Lab. investigations and Diagnostics: Spirometry, Blood sugar, Total Cholesterol, Lipid Profile, Blood Urea, Creatinine, X- Ray, ECG, USG, ■ Equipment's: Peak flow meter, Spirometry (to be introduced in phased manner after successful introduction and usage at DH), Oxygen cylinder, Pulse oximeter, Nebulizer, ■ Referral of complicated cases to District Hospital/higher health care facility.
District Hospital	■ Referral services for complicated cases, Diagnosis, and management of cases of COPD and Asthma other respiratory diseases, ■ Lab. investigations and Diagnostics: Pulmonary Function Test, Blood sugar, Lipid Profile, KFT, LFT, X-ray, ECG, USG ECHO, CT scan, MRI etc ■ Equipment: Peak flow meter, Oxygen cylinder, Pulse Oximeter, Nebulizer, Spirometry, Chest Xray, Arterial blood gas analyzer, Ventilator (NIV/IMV) Rehabilitation and physiotherapy services. ■ Referral of complicated cases to tertiary care hospitals. Health ■ promotion for behaviour change and counselling.
■ Medical College	■ Referral services for management of complicated cases of COPD, Asthma, and other respiratory diseases ■ Training of health personnel, Operational ■ and interventional research

Chapter 2
Diagnosis and management of COPD

Chapter 2

Diagnosis and management of COPD

- COPD Definition
- Diagnosis of COPD
- Confirmation of Diagnosis
- Assessing severity of COPD
- Management of COPD patients reporting to the health facility.
- Follow up of COPD patients.
- Algorithm
- Acute exacerbation of COPD

2.1 COPD Definition

As per the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2023: Chronic Obstructive Pulmonary Disease (COPD) is a heterogeneous lung condition characterised by chronic respiratory symptoms (dyspnea, cough, sputum production and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction.

2.2 Aetiology / Risk Factors for COPD

COPD results from **gene(G)-environment(E) interactions occurring over the lifetime(T)** of the individual (GETomics) that can damage the lungs and/or alter their normal development/ageing processes.

Factor	Description	Impact on COPD
Genetic (G)	• SERPINA1 gene mutations (α1-antitrypsin deficiency) • Other genetic variants with small individual effect size	• Rare but significant genetic risk factor for COPD • Associated with reduced lung function and increased COPD risk
Environment (E)	• Tobacco Smoking • Inhaling toxic particles and gases from household air pollution • Inhaling toxic particles and gases from outdoor air pollution	• Major environmental exposure leading to COPD
Lifetime (T)	• Gene-Environment Interactions over the Lifetime (GETomics)	• Interactions over time can damage lungs and alter normal development/aging processes
Other Factors	• Abnormal lung development • Accelerated lung aging	• Contributes to COPD risk

S Agarwal, B Kumar, SK Verma, D Bajaj, A Kumar, **S Kant**, et al., A study to compare the clinical features between post pulmonary tuberculosis associated chronic obstructive pulmonary disease (COPD) with other COPD patients. J. Evolution Med. Dent. Sci. 2017; **6(95):**7015-7019

2.3 Occupational Exposure:

Being is a chronic and slowly developing condition, and moreover, work-related respiratory conditions can have long latency periods; hence, it is difficult to clearly demarcate the role of occupational exposure and the development of COPD. Thus, a clinical diagnosis of occupational COPD, in the same way as occupational Asthma, is not feasible. Epidemiologically, the identificationof occupational COPD is based on observing the excess occurrence of COPD among workersexposed to Sulphur-dioxide, mineral dust, coal, silica, vanadium, cadmium, endotoxin, etc., in occupations such as mining, stone cutting, stone polishing, building and construction dust, gardening, fisheries, plastic molding, and farming (both crop as well as animal).

2.4 Pathophysiology of COPD:

Airflow obstruction and gas trapping

COPD results from small airway disease and emphysema, causing airflow obstruction and reduced lung elasticity. Chronic inflammation leads to structural changes, narrowing airways, and destroying lung tissue. This limits airflow during expiration, reducing lung function (FEV1) and causing gas trapping. Hyperinflation further decreases lung capacity and exercise tolerance. Bronchodilators help by opening airways, reducing gas trapping, and improving breathing and exercise abilities.

Pulmonary gas exchange abnormalities

COPD disrupts normal lung function, causing varied levels of low oxygen (hypoxemia) and sometimes high carbon dioxide (hypercapnia). Emphysema reduces lung capacity and gas transfer ability, worsening gas exchange as the disease advances. Additionally, reduced ventilation drive or medications can occasionally lead to respiratory failure.

Pulmonary hypertension

In smokers with normal breathing tests and mild COPD, there could be issues with lung blood vessels like thickening and inflammation. Severe high blood pressure in the lungs is rare in COPD but can occur late, leading to heart problems. This high pressure might stem from lung damage or narrowed arteries due to low oxygen levels. This condition can strain the heart and affect survival. Surprisingly, the size of the lung artery on CT scans might predict future flare-ups, regardless of past history.

Exacerbations

COPD exacerbations can be triggered by infections (viruses or bacteria), pollutants, or unknown reasons. These exacerbations cause more inflammation and breathing difficulty, leading to low oxygen levels and increased carbon dioxide. Sometimes, other conditions like pneumonia or heart failure can mimic or worsen COPD exacerbations, so they need to be considered during treatment.
Multimorbidity

COPD patients often have other health issues due to shared risk factors like smoking, ageing, and inactivity. Breathing problems and lung expansion impact heart function. Inflammation can lead to muscle wasting and worsen or trigger conditions like heart disease, osteoporosis, anaemia, diabetes, and metabolic syndrome.

2.5 Diagnosis of COPD based on Clinical History:

Symptoms: Revised as per the recent symptom list of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2023 guidelines. Consider the diagnosis of COPD and perform Spirometry if any of these clinical indicators are present;

Symptoms suggestive of COPD	
Dyspnea:	Persistent, progressive, characteristically worse on exertion
Chronic cough (> 8 weeks):	may be intermittent and may be unproductive, associatedwith recurrent wheeze , more commonly noticed in the winter months and on getting up early in the morning
Chronic sputum production:	Any pattern
Recurrent lower respiratory tract infections	
History of risk factors	Tobacco smoke Smoke from home cooking and heating fuels Occupational dust, vapours, fumes, gases and other chemicals Host factors(e.g., genetic factors, developmental abnormalities, low birth weight, prematurity, childhood respiratory infections etc.)

Apart from respiratory symptoms, it is important to look for risk factors. These can be genetic (COPD can run in families) or environmental (tobacco smoke, biomass fuel smoke, chronic exposure to other indoor air pollutants and occupational exposures to dust, fumes, and gases. Recurrent respiratory tract infections during childhood, previous history of pulmonary TB, poorly treated chronic persistent Asthma and poor socio-economic class are other important risk factors for COPD. In tobacco smoking, bidi smoking causes more harm than cigarette smoke because it contains more tar. Chillum and hookah smoking are also associated with COPD.

**One session of hookah smoking for 45 minutes causes smoke equivalent to 100 cigarettes to enter the lung. The belief that when smoke passes through water, it absorbsand cleans the smoke is a myth. Even flavoured hookahs are equally harmful.

For COPD diagnosis, we need respiratory symptoms, exposure to risk factors and poorly reversible airflow obstruction.

2.6 Physical Examination

Physical examination is rarely diagnostic in COPD. Physical signs of airflow limitation are usually not present until significant impairment of lung function has occurred.

Inspection	Features of hyperinflation– a barrel shaped chest
Inspection	Barrel shaped chest (antero-posterior diameter is same or greater thanlateral diameter), use of accessory muscles of respiration (sternocleidomastoid, scalene, trapezius), reduced chest wall movements(may also be checked through palpation), reduced crico- sternal distance.
Percussion	Hyper-resonant chest along with obliterated cardiac dullness and downward displacement of the liver dullness usually seen in theemphysematous phenotype of COPD
Auscultation	Breath sounds have a prolonged expiratory phase, are uniformly diminished in intensity, and may be accompanied with rhonchi.
Additional signs that support COPD	Cyanosis or red skin due to polycythemia, raised jugular venous pressure indicated right heart failure. Loud P2 on heart auscultation.

Note: Absence of above-mentioned sign does not exclude the COPD diagnosis.

2.7 Differential Diagnosis of COPD

Diagnosis	Suggestive features
Asthma	Onset early in life (often childhood). Symptoms vary widely from day to day and worse at night/early morning Allergic rhinitis, allergic rhino conjunctivitis and/or eczema mayalso be present. Family history of Asthma or other atopic diseases is usually present.
Pulmonary Tuberculosis	Onset at any age, often presents with low-grade fever, anorexia, weightloss and persistent cough. Sputum smear positive for Acid Fast Bacilli (AFB), hemoptysis may be present Chest X-ray shows abnormalities.
Bronchiectasis	Large volumes of purulent sputum with/without Hemoptysis areCommonly associated with bacterial infection. Chest X-ray/CT shows bronchial dilation, bronchial wall thickening.
Heart failure	Orthopnea, Paroxysmal nocturnal dyspnea, nocturnal cough, pedaloedema. Chest X-ray showing dilated heart, pulmonary oedema.

2.8 Confirmation of Diagnosis:

According to GOLD (Global Initiative for Chronic Obstructive Lung Disease), **spirometry remains the gold standard and must be performed in all suspected COPD patients**. Spirometry measures the air volume that expired forcibly after maximal inspiration (FVC) and air exhaled during the first second (FEV1).

Airflow limitation by spirometry is defined as A post-bronchodilator forced expiratory volumein the first second (FEV1)/forced vital capacity (FVC) below < 0.7. It is the most commonly used cut-off value in COPD diagnosis. Disadvantage: frequent overdiagnosis of COPD can occur in the elderly and under-diagnosis in adults < 45 years, especially in mild cases.

2.9 Assessing the severity of COPD:

Assessing severity is important for further management and appropriate referral of COPD patients. At the primary health centre/HWC, the mMRC scale may be used to get an idea about the severity of the disease. All patients suspected of COPD must be sent to a higher centre equipped with a spirometer and other necessary equipment for diagnosis and management. However, once they are started on treatment, they may be followed up regularly at the primary health care level.

2.10 (A) Modified Medical Research Council scale (mMRC scale) Dyspnea Scale

Grade	Description of Breathlessness
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill.
2	On level ground, I walk slower than people of the same age because of breathlessness or have to stop for breath when walking at my own pace.
3	I stop for breath after walking about 100 meters or after a few minutes on level ground.
4	I am too breathless to leave the house, or I am breathless when dressing.

(Ref: Fletcher CM, BMJ 1960; 2: 1662.)

(B)Severity of airflow obstruction

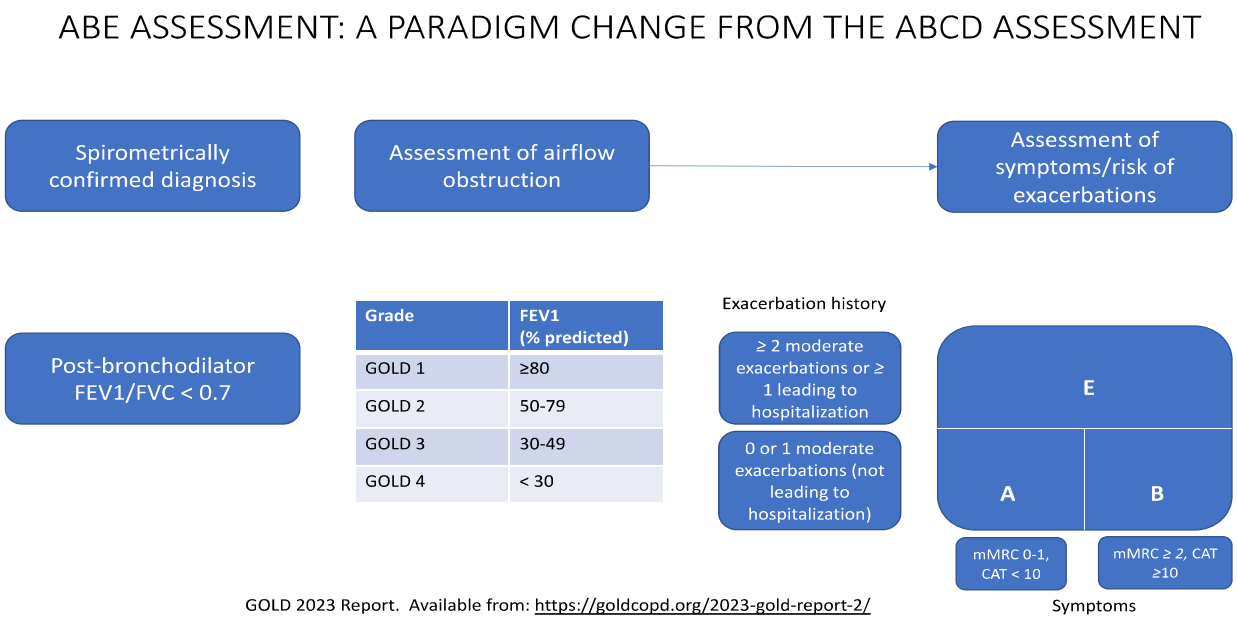
In the presence of FEV1/FVC ratio < 0.7 the assessment of **airflow limitation severity** in COPD (note that this may be different from severity of the *disease*) is based on the post-bronchodilator value of FEV1 (% reference). The specific spirometric cut points are proposed for purposes of simplicity.

In COPD patients (FEV1/FVC < 0.7):

GOLD 1:	Mild	FEV1 ≥ 80% predicted
GOLD 2:	Moderate	50% ≤ FEV1 < 80% predicted
GOLD 3:	Severe	30% ≤ FEV1 < 50% predicted
GOLD 4:	Very Severe	FEV1 < 30% predicted

Combined assessment of COPD

In 2011, GOLD introduced a combined COPD assessment based on symptoms, airflow limitation severity, and exacerbation history to guide treatment. Initially, it used airflow obstruction severity (GOLD grades) and exacerbation frequency. Later, airflow obstruction was removed due to its limited precision at the individual level. In the 2023 update, GOLD proposes a new ABCD tool merging C and D groups into a single "E" group, focusing on the clinical significance of exacerbations independently of symptom severity.



GOLD 2023 Report. Available from: https://goldcopd.org/2023-gold-report-2/

2.11 Management of COPD patients reporting to the health facility:

Health education for risk reduction, lifestyle modification, and pharmacologic intervention are important in managing COPD patients. Health education for risk reduction & lifestyle modification.

2.12 Pharmacological treatment:

Pharmacological therapy reduces the symptoms and the risk as well as the severity ofexacerbations and improves the health status and exercise tolerance of those diagnosed with COPD. Most of the drugs used for the treatment of COPD are inhaled, and hence, proper inhaler use technique is essential. It is important to provide instructions on their use, demonstrate proper inhalation technique and re-check technique and adherence to therapy every time patients visit the health facility.

2.13 Bronchodilators

It includes short-acting beta agonist (SABA), long-acting beta-agonist (LABA), short-acting muscarinic antagonist (SAMA) and long-acting muscarinic antagonist (LAMA). Oral administration of these drugs should be avoided. Theinhaled route is the preferred route of administration since it is the safest, fastest, andmost effective route of drug delivery. Inhaled medication used for treating COPD is available as pressurised metered dose inhalers (pMDI) with spacer, Dry Powder Inhalers (DPI)or as solutions to be nebulised utilising a nebulizer.

All these devices are equally effective, although each has its own advantages and disadvantages.For pMDIs, there is the need for proper technique, i.e., hand-mouth coordination.Owing to this challenge, it is always recommended to use pMDIs with Spacer. Especially for those unable to master the technique, 'spacer' is a must-have. DPIs do not need this coordination but require a minimum inspiratory flow rate for adequate drug delivery in the distal airways and thus have limited utility during acute exacerbations and in elderly patients. Ideally, they should always be used with a spacer. DPI is an equally effective and acceptable alternative to pMDIs.

Although handheld pMDIs or DPIs are effective in most patients with COPD, cognitively impaired and elderly patients may benefit more from the use of a nebuliser since these patientpopulations may have difficulty synchronizing inhalation with inhaler actuation or may be unableto generate a sufficient inspiratory flow rate against the resistance of a breath-activated DPI togenerate an effective aerosol. The choice of therapy, however, ultimately depends on a wide range of factors, including the prescribing physician, the availability of specific drug/device pairings, drug cost, and patient preferences and satisfaction. [Tashkin DP.A review of nebulized drug delivery in COPD. *Int J Chron Obstruct Pulmon Dis*2016;11:2585-2596. Published 2016 Oct 18. doi:10.2147/COPD.S114034.] (Details on Inhaler Devices at Annexure VI).

SAMA (e.g. Ipratropium) can be used as rescue medication to relieve patient symptoms but should be avoided as monotherapy for regular use. LAMA (Tiotropium or Glycopyrronium) is superior to LABA (e.g. Formoterol) as monotherapy. Still, both LAMA and LABA are useful in stable COPD to control symptoms and decrease the risk of exacerbations. Low-dose oral methyl-xanthine is not recommended as first-line therapy in patients with COPD. However,they may be used in patients noncompliant with inhalers for any reason and as add-on therapy in patients continuing to have symptoms despite optimum inhaled therapy.

NOTE: Use of oral salbutamol with or without theophylline, which is widely used, should be discouraged because of the potential side effects on heart, blood glucose and serum potassium.

2.14 Corticosteroids

Inhaled Corticosteroids (ICS) when used with long-acting bronchodilators (ICS/LABA or

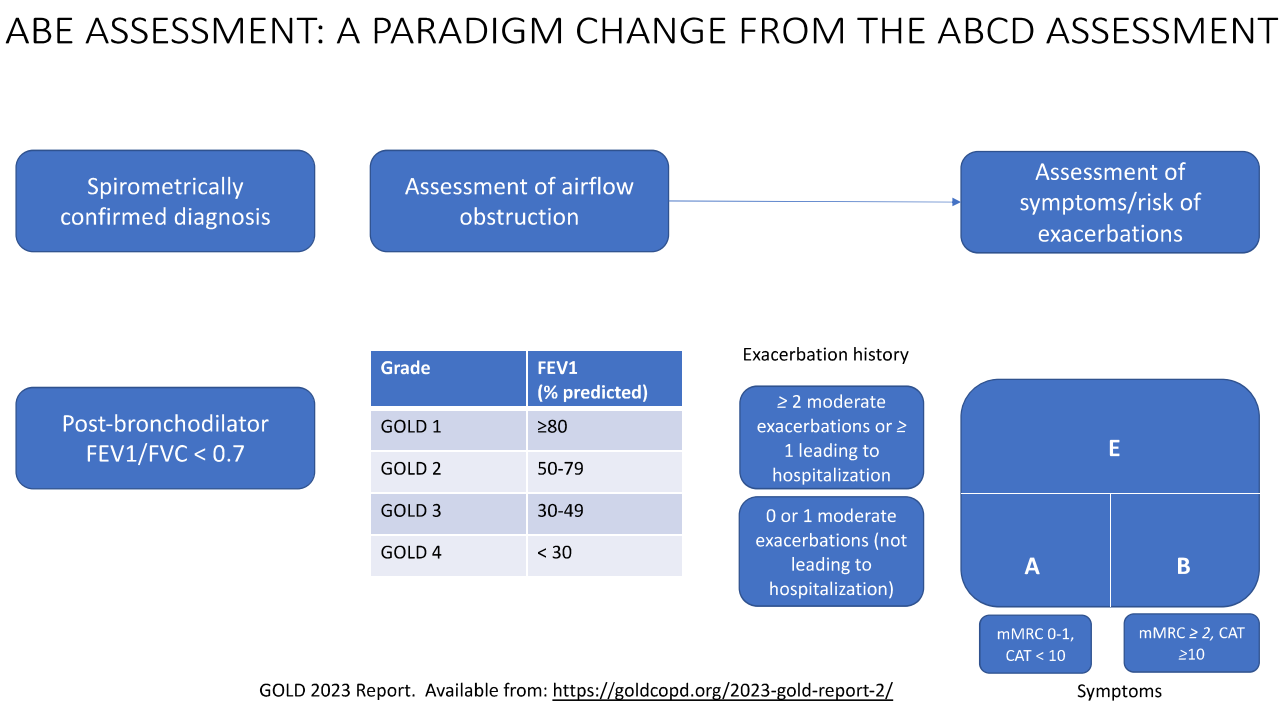
ICS/LAMA) have a beneficial effect in a subgroup of COPD patients with history of hospitalization (s) for exacerbations of COPD or patients with frequent exacerbations (≥ 2 exacerbations/ year) or patients with blood eosinophil count >300 cells/ microL or patients

Approach for initiating treatment in patients with COPD

A proposal for the **INITIATION** of pharmacological management of COPD according to the individualised assessment of symptoms and exacerbation risk following the ABE assessment scheme is shown below.

Following the implementation of therapy, patients should be reassessed to attain treatment goals and identify any barriers to successful treatment. Following a review of the patient's response to treatment initiation, adjustments in pharmacological treatment may be needed.

Table 2.2 Approach for initiating treatment in patients with COPD(GOLD 2023 Update)



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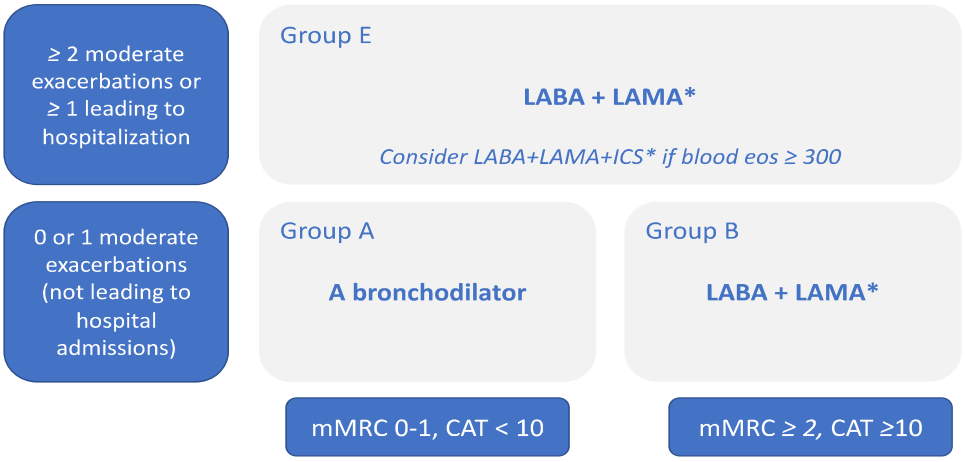
Definition of abbreviations: eos: blood eosinophil count in cells per microliter; mMRC: modified Medical Research Council dyspnea questionnaire; CATTM: COPD Assessment Test.

Initial pharmacological treatment



*single inhaler therapy may be more convenient and effective than multiple inhalers

GOLD 2023 Report. Available from: https://goldcopd.org/2023-gold-report-2/

Rescue short-acting bronchodilators should be prescribed to all patients for immediate symptom relief.

Group A

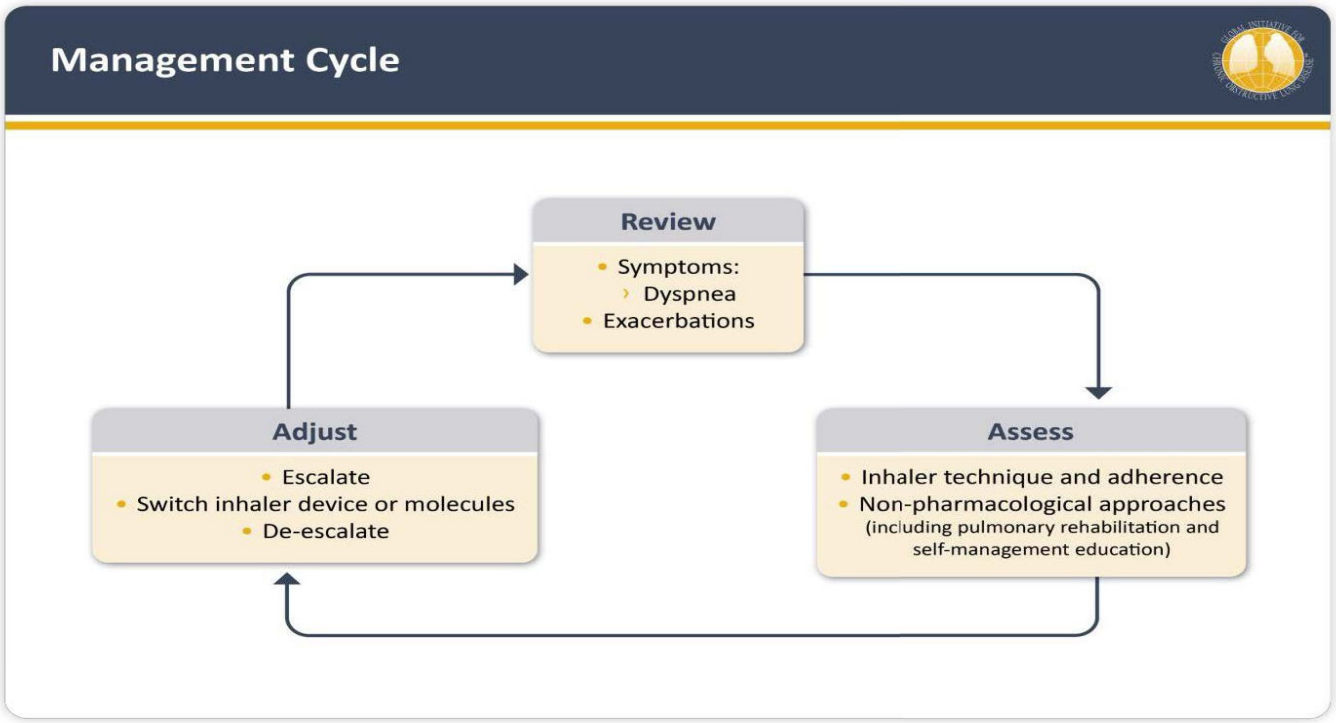
All Group A patients should receive bronchodilator treatment to help with breathlessness. This can be either a short-acting or long-acting bronchodilator. If possible and affordable, a long-acting bronchodilator is preferred, except for patients with only occasional breathlessness.

Group B

For patients with minimal exacerbations and higher breathlessness (CAT ≥ 10), starting with a LABA+LAMA combination is recommended based on evidence showing its superiority in reducing multiple endpoints. If this combination isn't suitable due to availability, cost, or side effects, there's no clear preference between LABA or LAMA alone. The choice can be based on the patient's perception of symptom relief. Patients in Group B might have additional health issues affecting symptoms and prognosis, which should be investigated and managed according to existing guidelines.

Group E

The LABA+LAMA combination is favoured for initial treatment in Group E patients, based on evidence from a comprehensive review showing its effectiveness in reducing COPD exacerbations. Using LABA+ICS is not recommended in COPD, but if ICS is needed, LABA+LAMA+ICS is preferred over LABA+ICS. In Group E, consider LABA+LAMA+ICS if blood eosinophil count is ≥ 300 cells/μL. This approach aligns with the link between ICS and exacerbation prevention tied to eosinophil levels. Treatment for COPD patients with concurrent asthma should follow asthma guidelines, mandating the use of ICS in such cases.



A separate plan is outlined for FOLLOW-UP treatment based on two key factors: ongoing breathlessness and frequency of exacerbations. This guide helps manage patients on maintenance treatment, incorporating evidence from trials and using blood eosinophil counts as a guide for ICS therapy. Any changes in treatment should be carefully reviewed, especially when considering reducing medications, which should be done under close medical supervision.

Follow-up pharmacological management

The follow-up treatment algorithm is applicable to patients already on maintenance treatment, regardless of their initial GOLD group. Assess the patient's primary concern, whether managing breathlessness or preventing exacerbations. If treatment change is needed, choose the dyspnea algorithm (Figure left column) or the exacerbations algorithm (Figure right column). If a patient needs a change in treatment for both issues, use the exacerbations algorithm. Find the box that matches the patient's current treatment and follow the recommended algorithm accordingly.
Follow-up pharmacological management should be guided by the principles of the first ***review*** and ***assess***, then ***adjust*** if needed:

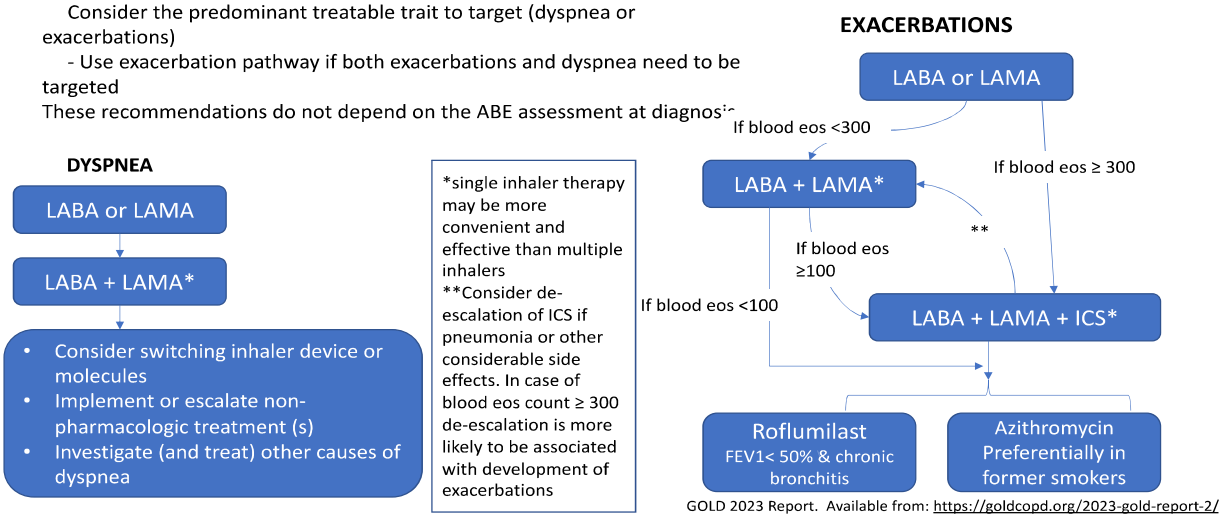
Follow up treatment

1. IF THE RESPONSE TO INITIAL TREATMENT IS APPROPRIATE, MAINTAIN IT.
2. IF NOT: **Check adherence** to **inhaler technique** and possible interfering **comorbidities**

Consider the predominant treatable trait to target (dyspnea or exacerbations)

- Use exacerbation pathway if both exacerbations and dyspnea need to be targeted

These recommendations do not depend on the ABE assessment at diagnosis



GOLD 2023 Report. Available from: https://goldcopd.org/2023-gold-report-2/

Review:

- Review symptoms (dyspnea) and exacerbation risk (history, blood eosinophils). Assess:
- Assess inhaler technique, adherence, and non-pharmacological approaches. Adjust:
- Adjust pharmacological treatment, considering escalation, de-escalation, or changing inhaler/device or medication within the same class. Monitor for side effects after any treatment change.

Dyspnea:

- For persistent breathlessness despite bronchodilator monotherapy, consider using two long-acting bronchodilators. If no improvement, consider changing inhaler/device or medication.
- Investigate and treat other causes of dyspnea, considering inhaler technique and adherence issues.

Exacerbations:

- For ongoing exacerbations on bronchodilator monotherapy, escalate to LABA+LAMA.
- Blood eosinophil counts ≥ 300 cells/µL may suggest a beneficial response to ICS. Consider LABA+LAMA+ICS for exacerbations despite mono bronchodilator treatment with high eosinophil counts.
- If exacerbations persist on LABA+LAMA+ICS or eosinophil counts < 100 cells/µL, options include adding roflumilast (for severe COPD with chronic bronchitis) or a macrolide like azithromycin (especially for non-smokers, considering the risk of resistant organisms).
- Consider withdrawing ICS if pneumonia or significant side effects occur. Reducing ICS may lead to more exacerbations if blood eosinophils are ≥ 300 cells/µL. Carefully evaluate ICS dosage to minimise potential side effects, which are more common with higher doses.

Patients under treatment with LABA+ICS

If a COPD patient without asthma features is well-controlled on LABA+ICS but experiences further exacerbations, consider escalating treatment to LABA+LAMA+ICS. If there are significant symptoms despite control, switching to LABA+LAMA might be considered.

Table 2.3: Indicative drug list for COPD

Anticholinergics	
Short acting	
Ipratropium bromide	20-40 ìg as needed
Long acting	
Tiotropium	18 ìg once daily
Beta agonists	
Short acting	
Levosalbutamol/Salbutamol	50 -100ìg as needed
LABA/LAMA combinations	
Formoterol/Glycopyrronium	12/25 mcg twice daily
LABA with Inhaled Corticosteroids combination	
Formoterol/ Budesonide	6-12/100-400 ìg twice daily
Salmeterol/ Fluticasone	25-50/ 250-500 ìg twice daily
Inhaled Corticosteroids with LABA + LAMA combination	
Formoterol / Glycopyrronium / Budesonide	12/50/400 mcg
Nebulization solution*	
Levosalbutamol respule	0.63 mg/1.25ml or 1.25 mg/2.5ml
Levosalbutamol + Ipratropium respule	1.25 mg + 500mcg or 0.63mg + 500mcg
Budesonide + Formoterol respule	0.5 mg + 20 mcg or 1mg + 20 mcg
Glycopyrronium respule	25 mcg/1 ml
Oral agents	
Antibiotics	mentioned below
Oral or IV Steroids	
Tab Prednisolone	
Inj Hydrocortisone	

procured by the state as through essential drug list under NHM/State.
**Esp. for elderly and those with cognitive impairment.*

2.15 Antibiotics:

Antibiotics (Amoxicillin (500 mg q8hr per orally for 10-14 days)/ Doxycycline (100 mg 12 hourly per orally on day 1, then 100 mg once daily for 7-14 days) / Azithromycin (500 mg once daily per orally for 3 days) should be prescribed for all exacerbations of COPD in the dose provided above. Prefer Azithromycin in former smokers.

2.16 Vaccination

Wherever available, all patients of COPD of all severities must receive the following vaccines:

Vaccine	Recommended Frequency	Target Population	Important Notes
Influenza (Flu) Vaccine	Once every year	General population, especially recommended around Sept/Oct	New strain vaccine available annually
Pneumococcal Vaccine	Once in a lifetime	Generally recommended for all adults	Includes both conjugate and other formulations
Diphtheria-Pertussis-Tetanus (DPT) Vaccine	Booster dose once in a lifetime	Generally recommended for all adults	Provides protection against diphtheria, pertussis, and tetanus
Shingles (Herpes Zoster Vaccination)	As per national guidelines	Typically a one-time vaccine	Recommended for certain age groups, may vary by country
Covid-19 Vaccine	As per national guidelines	Generally recommended for all eligible individuals	Adherence to national vaccination guidelines is crucial

Vaccinationis an essential component of COPD treatment, as it helps reduce the frequency of exacerbation by around 25%.

2.17 Follow-up of COPD patients.

Once treatment has been optimized at CHC/DH/Medical College, the patient may be asked to follow up at the primary health care level. The first follow up at one month and thereafter every 3-6months (mild to moderate disease) or every 1-3 months (severe disease):

The points to be assessed during these visits should be:

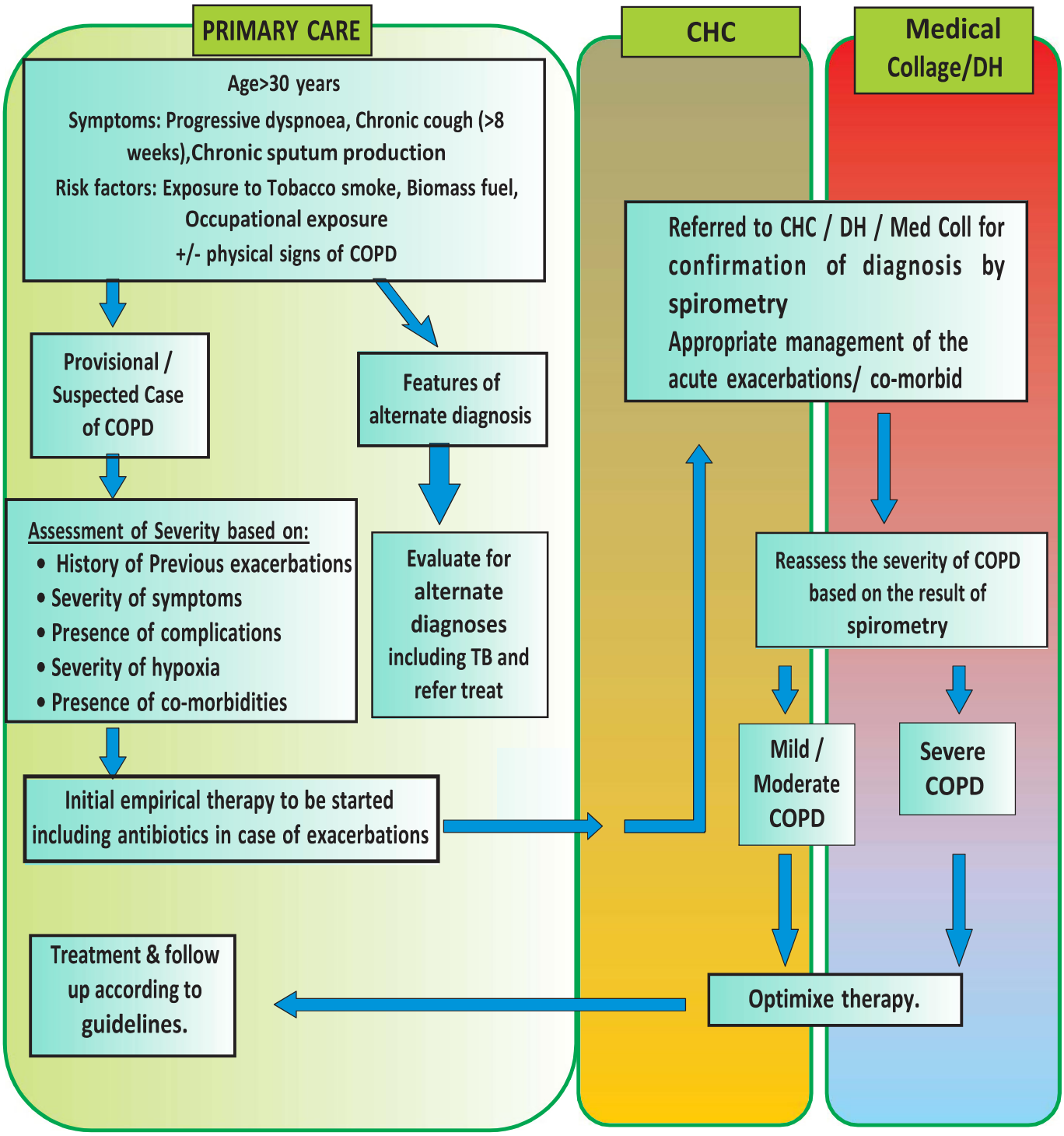
- Inhaler technique and adherence to medications
- Smoking status/efforts at cessation
- Management of symptoms and their impact on daily activities
- Dyspnea level (mMRC scale)
- Frequency of exacerbations
- Presence of co-morbidities (e.g., hypertension, ischemic heart disease, congestive heart failure, osteoporosis, weight loss, diabetes mellitus, depression) and complications (pneumonia, pneumothorax, pulmonary hypertension)
- Efficacy of medications and need for modification of the therapy.
- Assess for hypoxia using pulse oximetry.

Specialist follow-up may be advised for the following subgroup of patients:

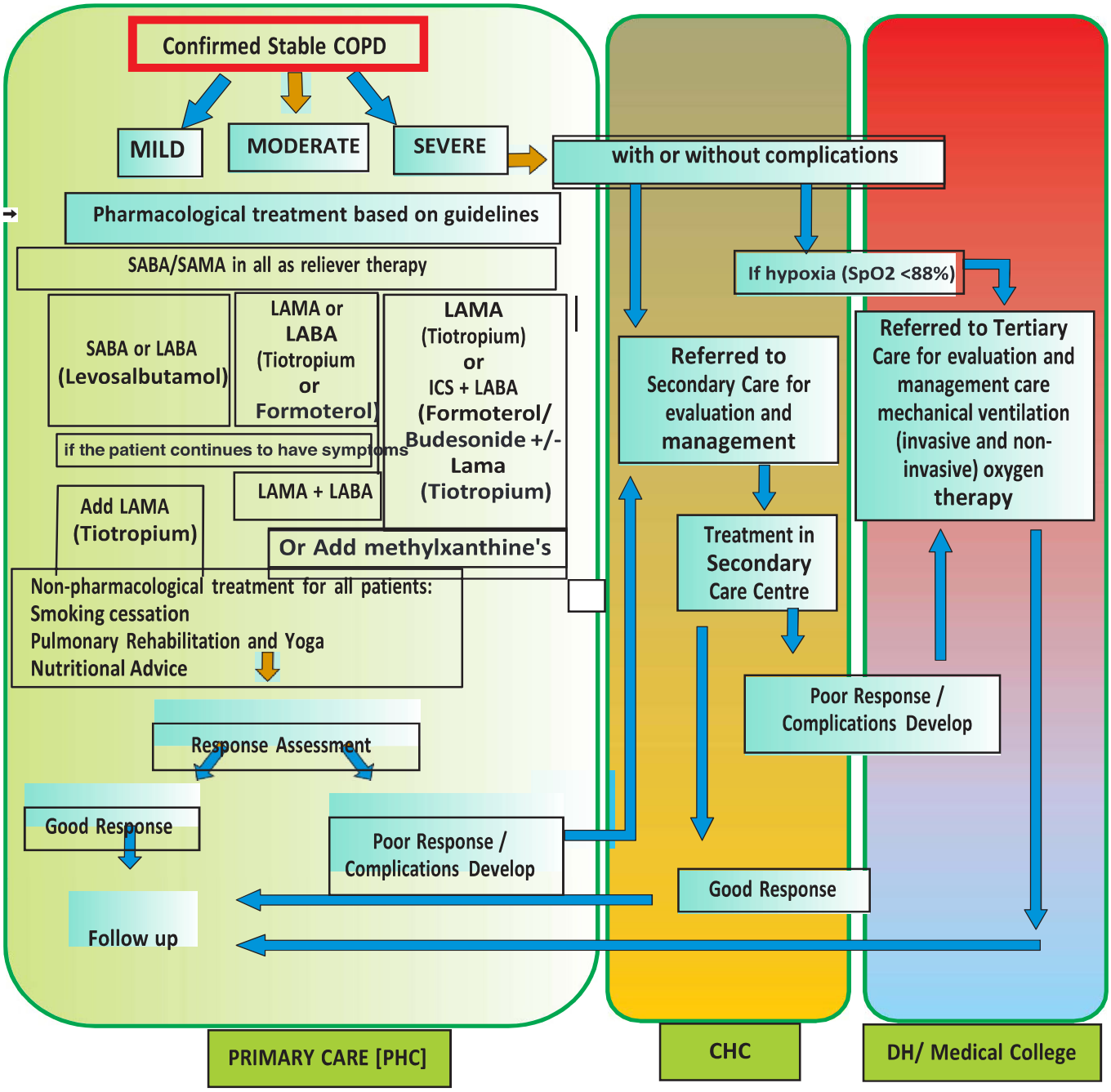
- With frequent exacerbations
- Who are candidates for long term oxygen therapy (in case of Saturation of peripheral oxygen $\leq$ 88%).

Post-tuberculosis (TB): Post-tuberculosis (TB) sequelae refers to the long-term consequences and lingering effects that individuals may experience even after successfully completing TB treatment. While effective anti-TB medications can eliminate the active infection, some individuals may still face residual challenges. Common post-TB sequelae include pulmonary issues such as fibrosis and lung damage, which can lead to chronic respiratory symptoms like coughing and shortness of breath. Additionally, individuals may suffer from nutritional deficiencies, musculoskeletal problems, and compromised immune function. The severity of post-TB sequelae varies among individuals, and factors such as the duration and extent of the initial infection, timely diagnosis, and appropriate treatment play crucial roles in determining the extent of long-term complications. Comprehensive post-TB care, including regular medical check-ups, nutritional support, and rehabilitation services, is essential to mitigate the impact of these sequelae and enhance the overall well-being of individuals who have overcome tuberculosis.

2.18 Algorithm: Management of patient reporting first time to primary Health Centre



2.19 Algorithm: Management of patients already with a confirmed diagnosis of COPD

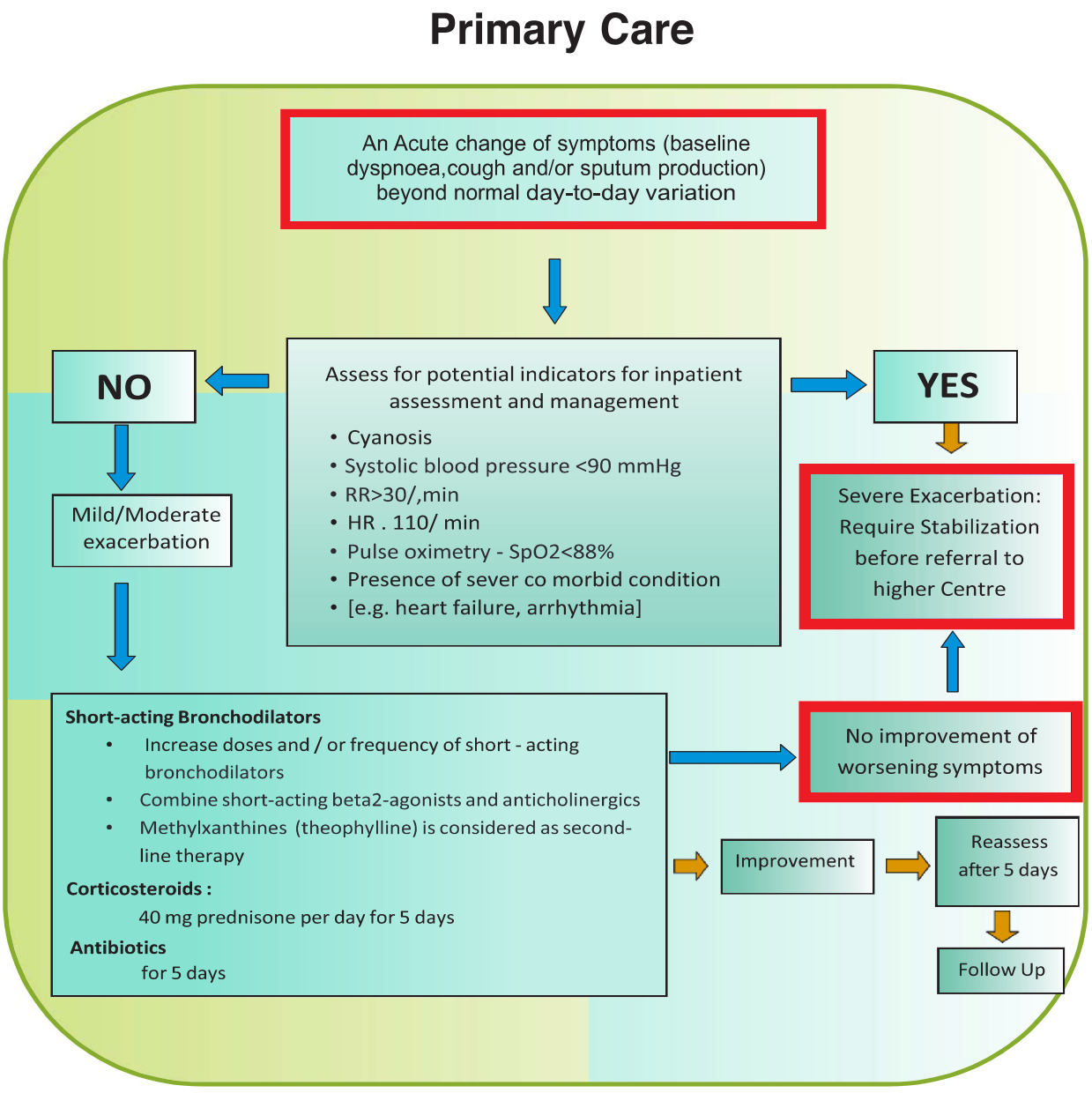


All patients of COPD must be treated with appropriate inhaled medications with only add on oral medications, whenever required. This will require patient counseling, awareness, and education. All patients of COPD must be vaccinated appropriately (if available).

2.20 Acute exacerbation of COPD

An exacerbation of COPD is an acute event characterized by worsening of the patient's respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication.

2.21 Algorithm: Management of patient with acute exacerbation of COPD



2.22 Indications for immediate referral to higher Centre(Red Flag Signs)

The following patients should be immediately referred to higher centres during acute exacerbations:

- Signs of severe exacerbation: Acute confusion, SpO2 $\leq$ 88% despite oxygen therapy, HR $\geq$ 110/minute, Systolic BP <90mmHg.
- Presence of high-risk co-morbid conditions such as cardiac arrhythmia, congestive cardiac failure, poorly controlled diabetes mellitus, renal or liver failure.

During the transfer, the patient should be continued on low-dose oxygen therapy (1-2 Lts/min) and nebulization. It should be mentioned that controlled oxygen therapy should be given to keep SpO2 between 88-92% to avoid respiratory depression. **High-flow oxygen may suppress the central respiratory drive and worsen the status and should, therefore, be avoided in patients with COPD.**

Chapter 3
Diagnosis and management of Asthma

Chapter 3

Diagnosis and management of Asthma

- Definition of Asthma
- Pathophysiology of Asthma
- Diagnosis of Asthma
  - Clinical History
  - Physical examination
- Management of Asthma patients reporting to the health facility.
- Health education for risk reduction & lifestyle modification
  - Pharmacological Management
  - Patient and family education on Asthma control

3.1 Definition of Asthma

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness and cough, that vary over time and in intensity, together with variable expiratory airflow limitation. Airflow limitation may later become persistent.

Table 3.1: Risk Factors of Asthma

Non-Modifiable Risk Factors	Modifiable Risk factors
• History of atopy: eczema, recurrent sneezing, itchy/watery eyes • Genetic - Family history of Asthma or atopy	• Indoor allergens: house dust mites, animal proteins (e.g., mouse, cat, and dog allergens), cockroaches, and fungi • Tobacco, smoke • Outdoor and indoor air pollution (mosquito coil, agarbattis, dhoop, liquid vaporizer for mosquitos) • Respiratory viral infections • Occupational dust (industrial)exposure • Formula feed and cow-milk in infancy • Obesity

3.2 Pathophysiology of Asthma:

In response to exposure to a variety of stimuli, including allergens/irritants, an IgE-dependent release of mediators from mast cells, i.e., histamine, tryptase, leukotrienes, and prostaglandins, results in the contraction of airway smooth muscle and subsequent interference with airflow. The same response through a non-Ig-E dependent mechanism occurs during exercise, cold air, and some drugs (e.g., NSAID). As the disease becomes more persistent and chronic, inflammation progresses and results in oedema, mucus secretion and the formation of inspissated mucus plugs, as well as structural changes, including hypertrophy and hyperplasia of the airway smooth muscle. These latter changes may not respond to usual treatment. Bronchial hyperresponsiveness is the hallmark feature of Asthma.

3.3 Diagnosis of Asthma

Diagnosis of asthma can usually be made based on detailed history and clinical examination. Medical officers in primary health care should be able to diagnose Asthma based on cardinal symptoms and signs and use a peak flow meter. Bronchodilator reversibility test with a peak flow meter, using an inhaled bronchodilator like salbutamol, can help to confirm Asthma diagnosis in patients, especially in resource-poor settings or unavailability of spirometer. In cases where the diagnosis is in doubt, patients may be referred to higher centers where facilities for appropriate investigations, including chest x-rays and spirometry, are available.

Clinical History:

3.3.1 Symptoms suggestive of bronchial Asthma

- Shortness of breath, which worsens on exertion.
- Wheeze
- Cough with or without phlegm. When phlegm is present, it is usually sticky and challenging to remove.
- Chest tightness
- History of recent exposure to or presence of risk factors (mentioned in Table 3.1) resulting in an increase or flare-up of symptoms.
- History of magical improvement in symptoms after using bronchodilators or corticosteroids. These symptoms can be episodic or seasonal, vary over time and intensity, and worsen during the night and early morning. The presence of variable symptoms with periods of normalcy characterizes Asthma symptoms.

3.3.2 Physical examination

- Physical examination may typically reveal bilateral wheezing and/or features of hyperinflation in severe disease. However, the patient may not have any findings if asymptomatic at the time of visiting the health provider.

3.3.3 Coexisting conditions

- Identify conditions that may coexist with or complicate Asthma, such as gastroesophageal reflux, rhinosinusitis, adenoidal hypertrophy, obesity or sleep breathing.
- Look for atopic diseases such as allergic rhinitis conjunctivitis, allergic dermatitis, and eczema.

3.4 Demonstration of variability or reversibility

Though not essential for diagnosis, effort should be made to demonstrate reversibility by spirometry. If there is the clinical demonstration of variability, spirometry is usually not required. Incases where there is an inadequate response to bronchodilators or when an alternative diagnosis is considered, further investigations, including spirometry and chest radiography, are oftenrequired. Peak expiratory flow rate measurement is associated with inconsistent findings and should not be used for the diagnosis of Asthma, however a 15% improvement in morning Expiratory Flow Rate (EFR) after 4 weeks of therapeutic trial with inhaled or oral corticosteroids often indicates presence ofAsthma.

Table 3.2: Differential diagnosis of bronchial Asthma in adults and in children

ADULTS	CHILDREN	
	5-12 years	<5 years
COPD, Heart failure, Bronchiectasis, Gastroesophageal reflux disease, Endobronchial tuberculosis, Major airway obstruction (tumour, infection, foreign body),Tropical eosinophilia	Tuberculosis, Bronchiectasis, Chronic rhinosinusitis, Adenoidal hypertrophy, Tropical eosinophilia, foreign body aspiration, Cystic fibrosis, Primary ciliary dyskinesia	Anatomic malformations e.g. tracheoesophageal fistula, tracheal compression, congenital heart diseases & tracheobronchomalacia. Infections e.g. recurrent pneumonia, tuberculosis or pertussis, Foreign body aspiration, Gastroesophageal reflux

Note: The presence of isolated cough with no other respiratory symptoms, haemoptysis, clubbing, failure to thrive, pedal oedema, and no response to an adequate trial of Asthma therapy indicates diseases other than Asthma.

3.5 Management of Asthma patients reporting to the health facility.

Although there is no permanent cure for Asthma, it can be sufficiently controlled with appropriate therapy, and most patients are able to live an everyday and symptom-free life. Inappropriate treatment, along with under-diagnosis, is still a major cause of significant morbidity and mortality. Hence, a physiciantreating Asthma should aim to achieve complete resolution of the patient's symptoms with acceptable orminimal side effects. Symptoms of Asthma can be sufficiently controlled with appropriate therapy, and most patients are able to live a normal and symptom-free life. Health education for risk reduction &lifestyle modification, and pharmacologic intervention are essential pillars in the management of Asthma patients.

3.6 Health education for risk reduction & lifestyle modification:

Exposure prevention

- Avoid Asthma triggers mentioned in Table3.1.
- Avoid drugs like NSAIDs and selective beta blockers in those sensitive
- Use damp cloths to clean furniture, sprinkling the floor with water before sweeping, cleaning blades of fans regularly.
- Use mosquito nets rather than coils and avoid the use of incense sticks.

Weight reduction (If obese or overweight)

Physical activity and regular exercises (including yoga)Avoid smoking

➢ Patient and family education

- About the reversible nature of the illness, Asthma can be controlled but mayneed continuous therapy and regular follow-up.
- Rationale for the inhaled drugs, different inhaler devices and inhalation techniques
- Inhalers are not habit-forming. Inhalers are safe and better than tablets orsyrup; other forms of therapy are not alternatives.
- Advise during therapy (To the patient or the child's family)

    - Advise the parent to carry the device at each follow-up visit.
    - Emphasise the need for adherence to the prescribed controllerdrugs.
    - Advice regarding dealing with triggers/ precipitants. Emphasise thatdiet has a minimal role in the causation of symptoms.
    - During follow- up, identify any lacunae in understanding and reinforce the above in subsequent meetings.
    - Identification of comorbidities and their treatment
    - Identify conditions that may coexist with or complicate Asthma andtreat them accordingly, such as allergic rhinitis, gastroesophageal reflux, rhinosinusitis, adenoidal hypertrophy, obesity, or sleep-disordered breathing.

3.7 Pharmacological Management of Asthma

➢ Pharmacological Management Goals for Asthma

- Achieve and maintain control of daytime as well as nocturnal symptoms
- Maintain normal activity levels, including exercise
- Minimize adverse effects from Asthma medications
- Prevent Asthma exacerbations and mortality from Asthma ➢

Inhalation therapy devices (details in Annexure VI)

- inhaled route is the preferred route of administration of drugs. Inhaled therapyallows low doses of bronchodilators or corticosteroids to be delivered rapidly and directly into airways, thereby achieving high local concentrations at the site of action while significantly reducing systemic adverse effects compared to oral or parenteral therapy.
- Inhaled medications used for the treatment of Asthma are available as pressurized metered dose inhalers (pMDI), dry powder inhalers (DPI) or nebulising solutions.

- All the devices used to deliver inhaled drugs in Asthma are equally productive.
- The major disadvantage of pMDI is proper technique ('hand-mouth' coordination). It requires a 'spacer' for those unable to master this technique, including children. It is recommended to prescribe pMDI + Spacer for best results.
- Children below 4 years of age should use a face mask for effective delivery of the drug (pMDI+ spacer+ face mask).
- DPIs do not need this coordination but require a minimum adequate inspiratory flow rate for adequate drug delivery in the distal airways. Hence, they have limited utility during acute exacerbations and in elderly patients.
- Those above 6 years may also be able to use DPIs. For a primary healthcare setting, a pMDI with a spacer is useful for all age groups and is preferable to other devices.

➢ Broadly, there are two types of medications for Asthma- Relievers and Controllers. Relievers are

- rapidly-acting bronchodilators used to reduce acute asthma symptoms (cough, wheezing, and shortness of breath) and preventfuture exacerbations. Per the GINA guidelines, the reliever medications are needed low dose ICS/Formoterol or short-acting inhaled beta-2 agonists (SABA)(e.g. Levosalbutamol). It may be noted that as per new GINA guidelines, the SABA-only treatment increases the risk of severe exacerbations and that adding any ICSsignificantly reduces the risk. Thus, for safety, GINA no longer recommends SABA-only treatment for Step 1 in adults and adolescents.

- **Controllers:** Inhaled corticosteroids (ICS) are the best available controller medications with good efficacy and acceptable safety profile. ICS should be given to all patients with Asthma, irrespective of the underlying severity. If the symptoms of Asthma are not adequately controlled by low-dose ICS alone, adding inhaled LABAto the same dose of ICS, rather than doubling the dose of ICS, is superior in terms ofAsthma control. GINA now recommends that all adults and adolescents with asthma should receive ICS-containing controller treatment to reduce the risk of serious exacerbations. The ICS can be delivered by regular daily treatment or, in mild asthma, by as-needed low-dose ICS-formoterol.

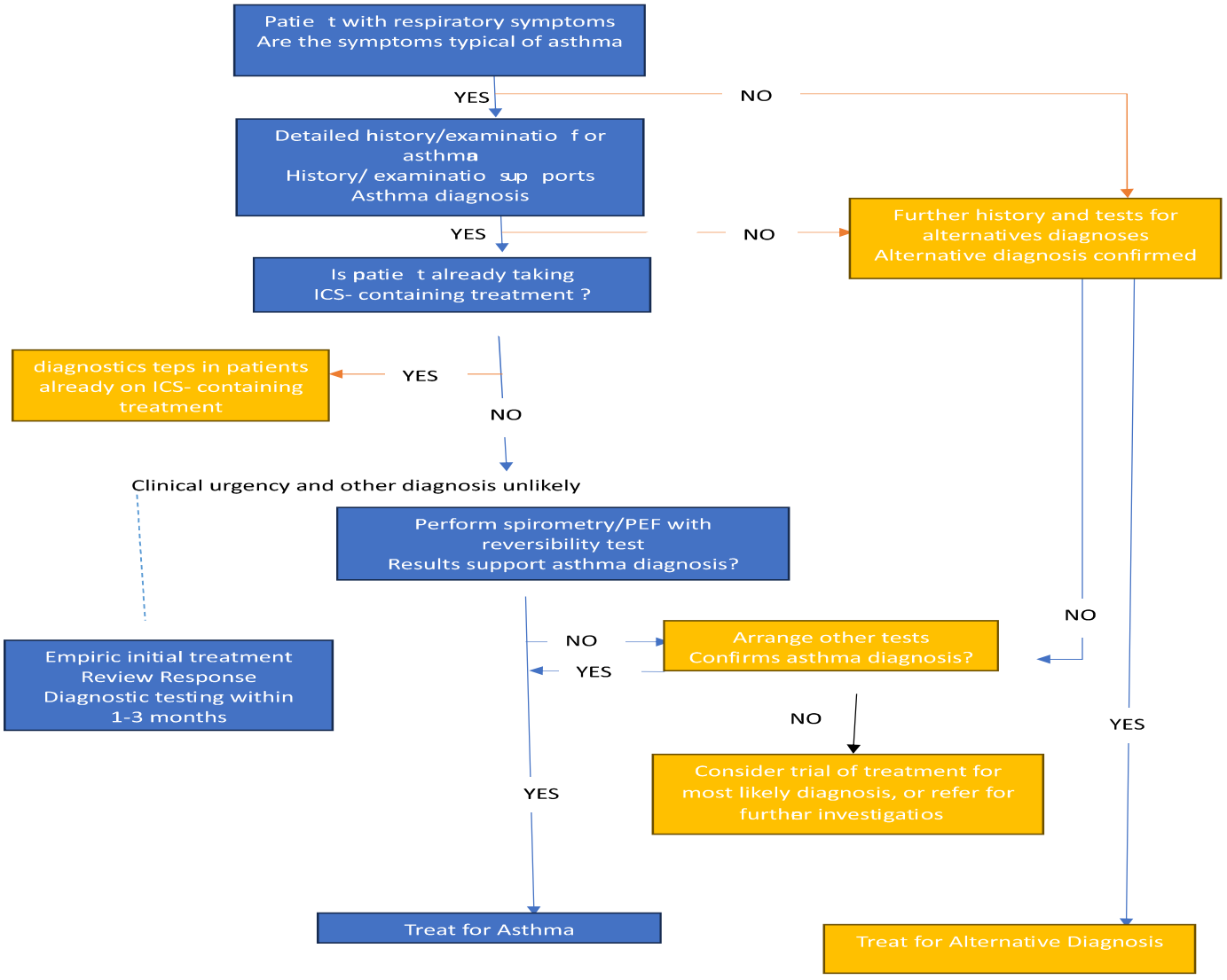
Asthma suffering and deaths can be prevented by giving all Asthma patients inhaled corticosteroids with/without LABA and, as and when required, ICS-Formoterol or SABA. SABAs on their own should be used minimally as much as possible, as overuse of SABA has been shown to increase Asthma mortality. Giving only bronchodilators to Asthma patientswithout inhaled steroids is the wrong treatment and will increase Asthma suffering and death. Using inhalers, adherence to ICS inhalers and minimal use of SABA should be reconfirmed/checked at all clinic visits.

Treatment with budesonide-formoterol simplifies escalation and de-escalation of therapyin mild to moderate persistent asthma to achieve optimal long-term control. This ispopularly known as the 'SMART' (Single Maintenance and Reliever Therapy) approach, where a single inhaler can be used both as a maintenance treatment and as a reliever. This could help patients maintain asthma control in the long run by eliminating the need to use multiple inhalers for maintenance & relief and thus promoting compliance with treatment.

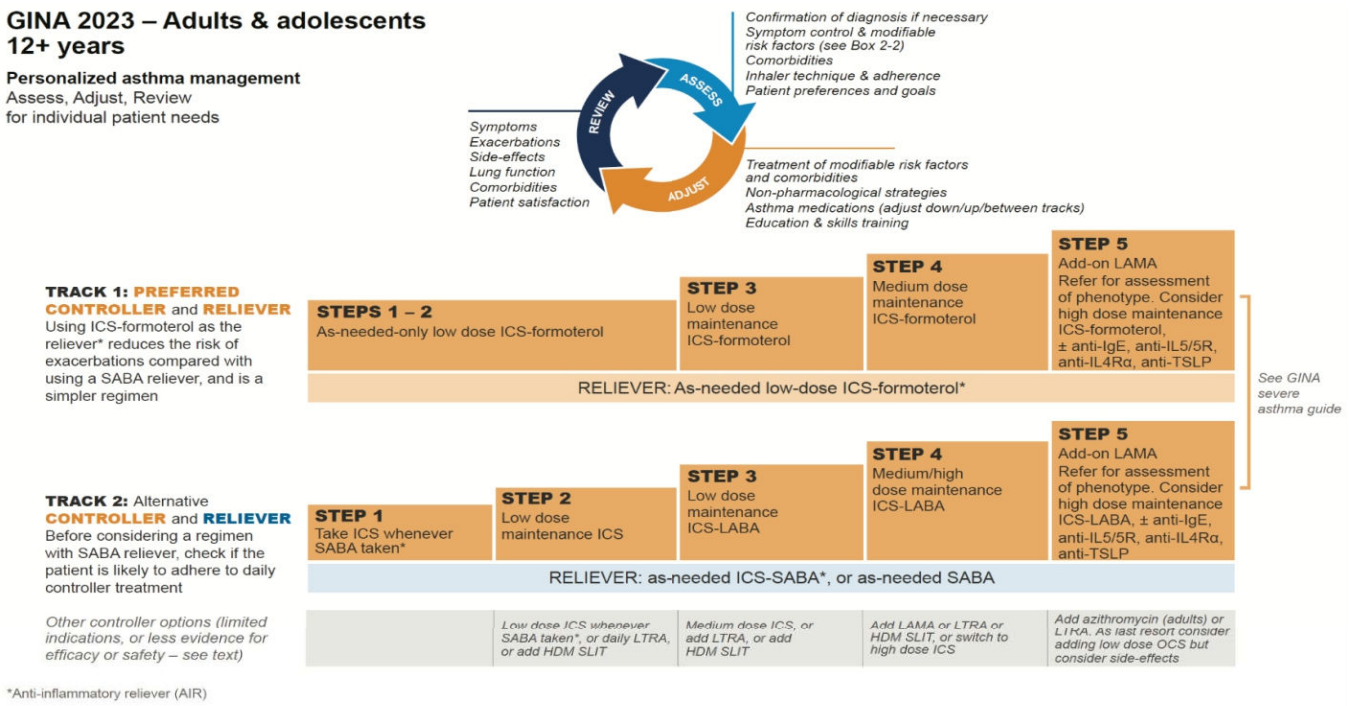
[Ref: Raja Dhar, Agam Vora: Stepping Away from the Blue Inhaler in Asthma Management- A Paradigm Shift; Journal of The Association of Physicians of India; Vol. 69; April 2021

S Kant*, Acute Severe Asthma. Current Medical Journal of India.2008; **13 (10):** 43-50]

3.8 Algorithm for Management of Asthma in Adults



Personalized management for adults and adolescents to control symptoms and minimize future risk



OCS - Oral Corticosteroids; ICS - Inhaled Corticosteroids; SOS – as and when required; SABA – Short Acting Beta2Agonists; LABA–Long Acting Beta2Agonists; LAMA–Long-Acting Muscarinic Antagonists.

*May step down if required to low dose if adequate control for > 3 months.
**May step down if required to medium dose if adequate control for > 3 months.

Adequate Control: Review after 4 weeks for adequate control. For Asthma to be adequately controlled the patient should have symptoms < 2 times per week, no night awakening, no activity limitations and FEV1 >80% or PEF >80% of personal best.

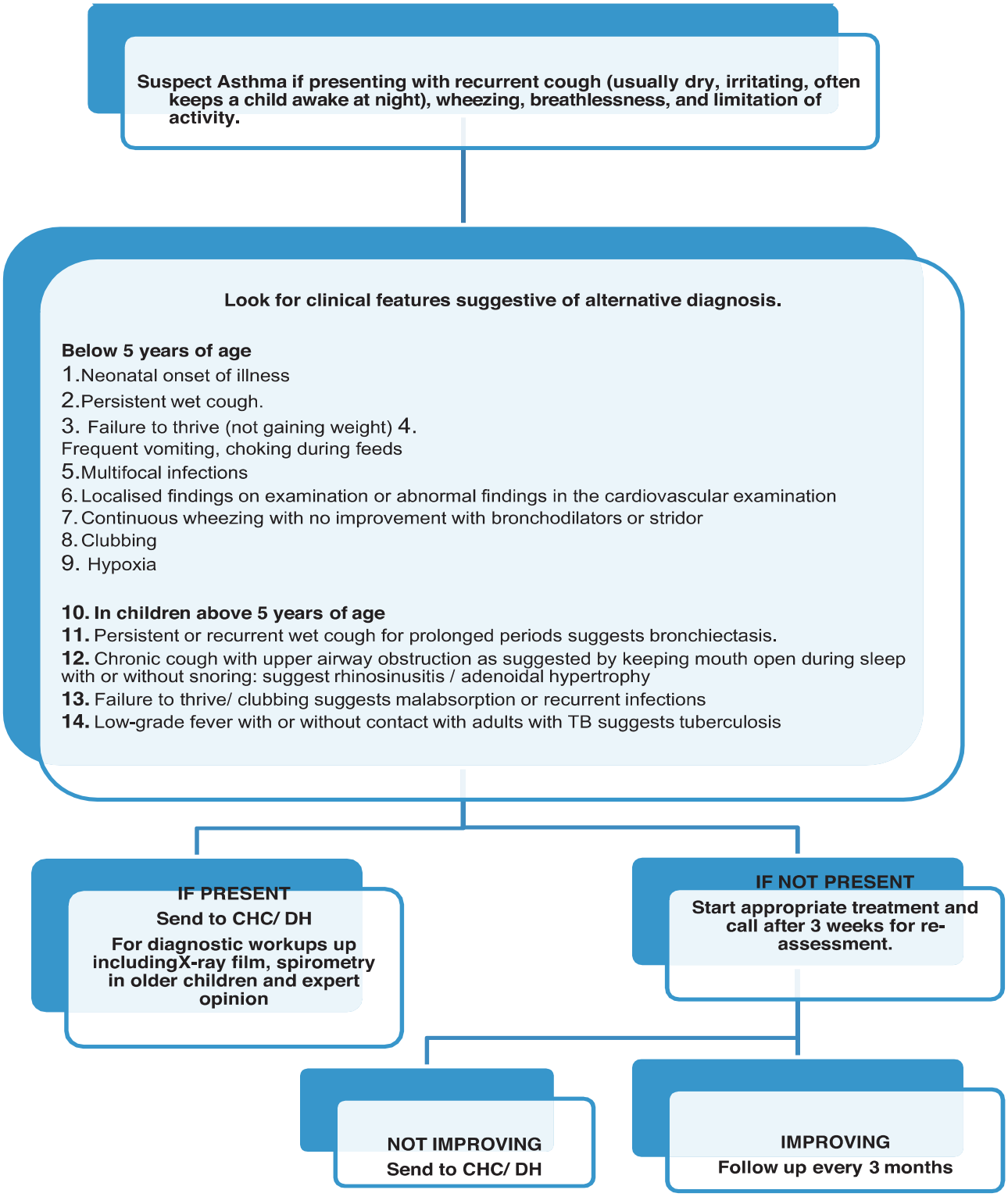
If inadequate response after 4 weeks, check & rectify:

- Faulty inhaler technique
- Non-compliance/poor adherence
- Co-morbidities (Allergic Rhinitis/ GERD)

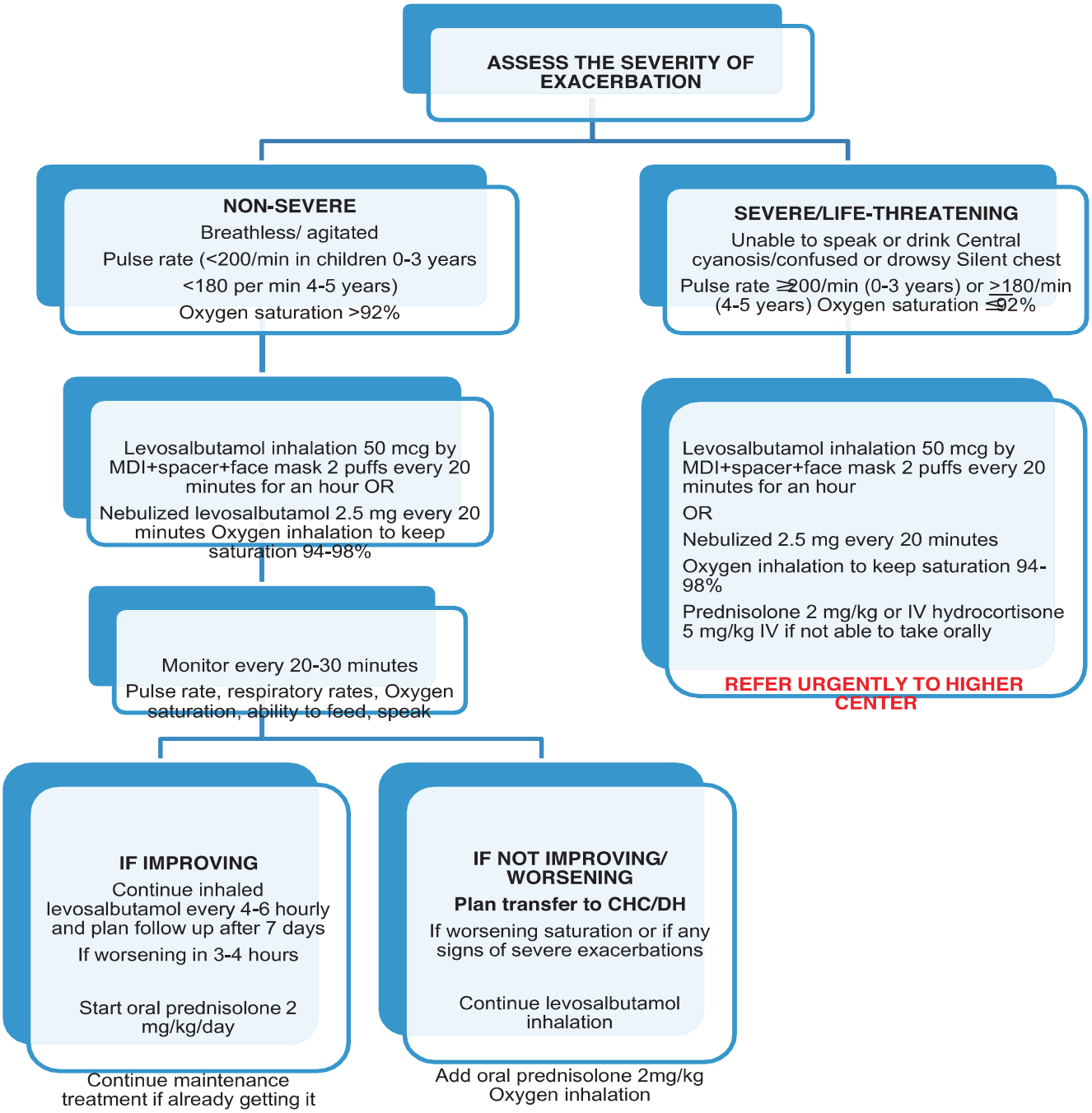
For patient with severely uncontrolled Asthma or if inadequate response 4 weeks after above corrections then consider referral to higher treatment centre.

3.9 ALGORITHM FOR MANAGEMENT OF ASTHMA EXACERBATIONS

3.10 DIAGNOSTIC ALGORITHM FOR CHILDREN WITH ASTHMA

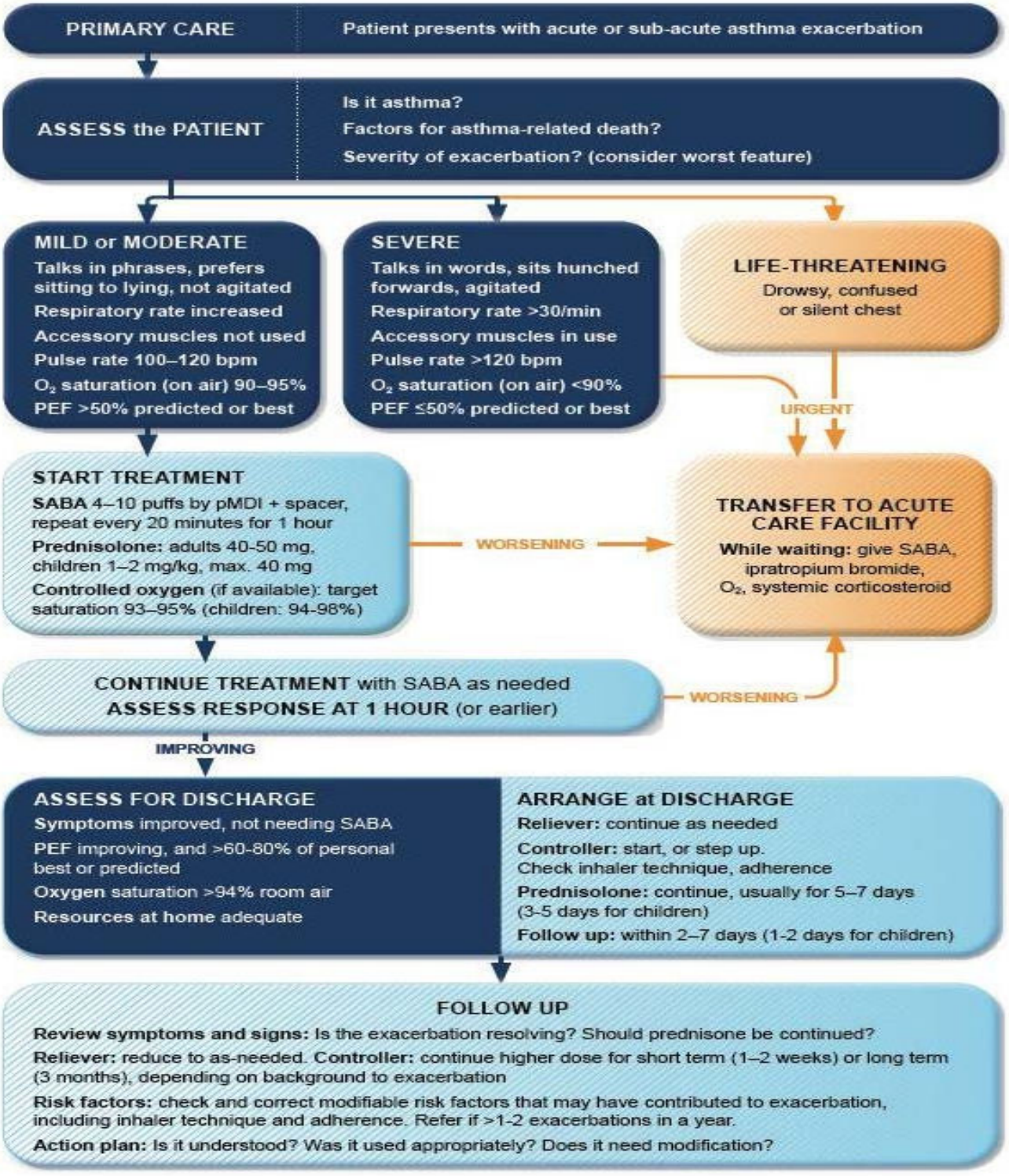


3.11 ALGORITHM FOR MANAGEMENT OF ASTHMA EXACERBATIONS FOR CHILDREN < 5 YEARS



3.12 ALGORITHM FOR MANAGEMENT OF ACUTE ASTHMA

(adults, adolescents, children 6–11 years)



***Adopted from GOLD 2023**

Discharge management after hospital or emergency department care for asthma

Medications
Inhaled corticosteroid (ICS)-containing therapy Initiate ICS prior to discharge, if not previously prescribed. Maintenance-and-reliever therapy with ICS-formoterol (MART) is preferred as it reduces the risk of future exacerbations compared with using a SABA reliever. For adults/adolescents, start at MART at Step 4 on discharge. If prescribing an ICS regimen with SABA reliever, step maintenance dose up for 2–4 weeks. Emphasize good adherence. ***Oral corticosteroids (OCS)*** To reduce the risk of relapse, prescribe at least a 5–7 day course of OCS for adults (prednisolone or equivalent 40–50 mg/day) and 3–5 days for children (1–2 mg/kg/day to a maximum of 40 mg/day) (Evidence A). Review progress before ceasing OCS. If the OCS is dexamethasone, treatment is only for total 1–2 days, but if there is failure of resolution, or relapse of symptoms, consider switching to prednisolone. ***Reliever medication – return to as-needed rather than regular use*** Transfer patients back to **as-needed rather than regular reliever medication use**, with frequency based on symptomatic and objective improvement. Regular use of SABA for even 1–2 weeks leads to beta-receptor down-regulation, increased airway hyperresponsiveness and increased eosinophilic inflammation, with reduced bronchodilator response. Ipratropium bromide, if used in the ED or hospital, may be quickly discontinued as it is unlikely to provide ongoing benefit. Patients prescribed ICS–formoterol as their reliever should return to this on discharge if SABA was substituted in ED or hospital.
Risk factors and triggers that contributed to the exacerbation
Identify factors that may have contributed to the exacerbation, and implement strategies to reduce modifiable risk factors. These may include irritant or allergen exposure, viral respiratory infections, inadequate long- term ICS treatment, problems with adherence, and/or lack of a written asthma action plan. Handwashing, masks and social/physical distancing may reduce the risk of acquiring viral respiratory infections, including influenza.
Self-management skills and written asthma action plan
• Review inhaler technique. • Provide a written asthma action plan or review the patient's existing plan, either at discharge or as soon as possible afterwards. Patients discharged from the ED with an action plan and PEF meter have better outcomes than patients discharged without these resources. For patients prescribed ICS-formoterol reliever, use an action plan template customized for this treatment. Review technique with PEF meter if used. • Evaluate the patient's response as the exacerbation develops. If it was inadequate, review the action plan and provide further written guidance to assist if asthma worsens again. • Review the patient's use of medications before and during the exacerbation. Was ICS-containing treatment increased promptly and by how much? Was the ICS-formoterol reliever (if prescribed) increased in response to symptoms? If OCS were indicated, were they taken; did the patient experience adverse effects? If the patient is provided with a prescription for OCS to be on hand for subsequent exacerbations, beware of inappropriate use, as even 4–5 lifetime courses of OCS in adults increase the risk of serious adverse effects.
Follow up communication and appointment
• Inform the patient's usual health care provider about their ED presentation/admission, instructions given on discharge, and any treatment changes. • Make a follow-up appointment within 2–7 days of discharge (1–2 days for children) to ensure that treatment is continued. The patient should be followed to ensure that asthma symptoms return to well controlled, and that their lung function returns to their personal best (if known).

Chapter 4
Pharmacological Approach for management of COPD and Asthma

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Pharmacological Approach for management of COPD and Asthma

Pharmaco-therapeutic agents in COPD and Asthma can be broadly grouped as bronchodilators, corticosteroids, and combinations drugs.

Table 4.1:Therapeutic agents for management of COPD and Asthma

Name of drug	Adult dose	Pediatric Dose	Dosing Frequency	Route	Side Effects
Bronchodilators					
Beta2 Agonists					Tachycardia hypertension, tremors, hypokalaemia hyperglycemia
Short Acting					
Salbutamol pMDI, DPI, nebulization	100-200 µg 2.5-5.0mg	100 µg 0.05mg/kg	4-6 hourly	Inhalation	
Levosal butamol pMDI, DPI, nebulization (respule)	50-100 µg 1.25mg / 2.5ml (Respule)	25-50mcg 0.31mg/2.5ml (Respule)	4-6 hourly	Inhalation	
Antimuscarinics					Dry mouth, urinary retention, tachycardia, blurred vision
Short Acting					
Ipratropium Bromide	20-40 µg (MDI)		6-8 hourly		
Long Acting					
Tiotropium	18 µg (DPI)		24 hourly		
Glycopyrronium Bromide	44 µg (DPI) 25 mcg / ml (Respule)		24 hourly		
Steroids					
Inhaled steroids					Sore throat, hoarseness, oral thrush, cough, respiratory
Beclomethasone	50-400 µg (DPI)		8-12 hourly		
Budesonide	100, 200, 400 µg (pMDI & DPI) 0.5/1 mg/ 2 ml (Respule)		12 hourly		Infection, thinning os skin, hyperglycemia, cataract
Fluticasone	50-500 µg (MDI & DPI) 0.5mg or 2mg/2ml (Respule)		12 hourly		
Ciclesonide	80-160 mcg		24 hourly		
Systemic steroids					Oral

Prednisone	0.5-1mg/kg	0.5-2mg/kg	Once daily		thrush, Hyperglycemia, Osteoporosis, Peptic ulcer, hypokalemia, anxiety
Combination drugs					
SABA/SAMA					
Respule of Levosalbutamol/ Ipratropium	0.31 mg/ 0.63 mg/ 1.25 mg + 500 µg / 2.5 ml		Every 6-8 hours		Headache, hypokalemia, pain, palpitation, a cute narrow -angle glaucoma , tachycardia, hyperglycemia
Inhaler of Levosalbutamol/ Ipratropium	50/20 mcg		4 times	Inhalation	
LABA/LAMA					
Glycopyrronium/Formoterol	50/12 mcg		12 hourly		Urinary retention, palpitation, a cute narrow-angle glaucoma, dry mouth
Indacaterol/ glycopyrronium	110/50 µg		24 hourly		Hyperglycemia, hypersensitivity, dry mouth
Tiotropium/ Formoterol	18/ 12 mcg		24 hourly		Urinary retention, palpitation, a cute narrow-angle glaucoma, dry mouth
LABA/ICS					
Formoterol/ Budesonide	6/100, 200, 400 µg 0.5/1 mg + 20 mcg / 2ml (Respule)	6/100 µg	12 hourly		Tremor,palpitations, respiratory tract infections, Sore throat, hoarseness, oral thrush, cough
Salmeterol/ Fluticasone	50/100, 250,500 µg	25/125 µg	12 hourly		
Formoterol/ Fluticasone	6/ 125, 250 mcg		12 hourly		
LABA/LAMA/ICS					
Formoterol/Glycopyrronium/Budesonide	12/50/400 mcg		12 hourly		Pneumonia, upper respiratory tract infection, Oral candidiasis, back pain, urinary tract infection
Tiotropium bromide / Formoterol fumarate/ Ciclesonide	18/12/400 mcg		24 hourly		Dry mouth, palpitation, tremors, glaucoma, urinary retention, respiratory tract infection
Miscellaneous					
Methylxanthines					Tachycardia, hypertension, tremors, syncope, nervousness, hypokalemia, coma
Theophylline R	150-300mg		Variable, up to 24 hourly		
Aminophylline	100-300mg		Variable, up to 24 hourly		
Phosphodiesterase 4 inhibitors					Headache, dizziness, diarrhea, weight loss
Roflumilast	500 µg		24 hourly		
Leukotriene modifiers					Headache, dizziness, dyspepsia, rashes
Montelukast	10mg	6m-6yrs: 4mg 6-15yrs: 5mg >15yrs: 10mg	24 hourly		
Mucolytic and Antioxidants					
N-acetylcysteine	600 mg 400mg/2ml or 1gm/5ml respules		24 hourly		Nausea, vomiting, diarrhea

The inhaled route is the preferred route of drug administration since large concentrations of the drugs can be rapidly delivered with minimal systemic side-effects.

Inhaled medications used for the treatment of COPD and Asthma are available as pressurized metered dose inhalers (pMDI), dry powder inhalers (DPI) or as solutions available for nebulizer. The major disadvantage of pMDI is the need for proper technique ('hand-mouth' coordination). It requires a spacer for those unable to master this technique especially amongst children and old age. Although DPIs do notneed this co-ordination but require minimum adequate inspiratory flow rate for adequate drug deliveryin the distal airways. Hence, they have limited utility during acute exacerbations and in elderly patients. Children below 4 years of age may use a face mask for effective delivery of drug (pMDI+ spacer+ face mask). For a primary health care setting, a pMDI with spacer is useful for all age groups. The choice of therapy, however, ultimately depends on a wide range of factors, including the prescribing physician, the availability of specific drug/device pairings, drug cost, and patient preferences and satisfaction.

Chapter 5
Protocol for Screening and Diagnosis of COPD and Asthma up to Primary Health Care Level

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Protocol for Screening and Diagnosis of COPD and Asthma up to Primary Health Care Level

5.1 Part 1: At the Community level: Assessment by ASHA while filling the CBAC form for all individuals > 30 years

1. Do you smoke tobacco in any form or consume smokeless products such as Gutkha or Khaini? Yes/No
2. Do you have cough for > 2 weeks? Yes/No, if yes, is there any?
   a. Shortness of breath. Yes/No
   b. Blood in sputum. Yes/No
   c. Fever for > 2 weeks Yes/No
   d. Loss of weight Yes/No
   e. Night Sweats Yes/No
   f. Is anyone in the family currently suffering from TB? Yes/No
   g. Are you presently taking anti-TB drugs Yes/No
   h. History of TB in family or Individual Yes/No
3. Do you use any of the following for cooking: Firewood/Crop Residue/ animal dung-cake/Coal/Kerosene?
4. Have you been exposed to any of the following in the recent past?

   Crop residue burning/burning of garbage - leaves/working in industries with smoke, gas and dust exposure, such as brick kilns and glass factories.

If yes to any question (Q1 & Q 2 or a part refer the individual to HWC

The above assessment ASHA is already doing as a part of population-level screening for NCD for all individuals > 30 years of age. All individuals with yes to any part of Questions 1 & 2 should be referred to nearby Health & Wellness Centre on priority basis for further assessment in reference to respiratory diseases along with screening for other NCDs (DM, HT, Ca Breast, Cervix and Oral). Individuals with none of the above complaints and exposure will also need to be sent to H&WC to screen other NCDs.

5.2 Part 2: Health and Wellness Centre

Community Health Officer (CHO) at the Health & Wellness Centre will ask about the cough, breathlessness and exposure by administering the following questionnaire.

5.3 Questionnaire: (Assessment of Cough and Dyspnea).

PART A

Q. 1: Do you now have a cough? Yes/No

Q. 2: For how long do you have cough: Duration in Years....., Months.....

Q. 3: Is your cough intermittent or continuous:

Q. 4: Is your cough productive? Yes/No

Q. 5: Is your cough associated with breathlessness? Yes /No; if yes, ask Q 6. Otherwise,go to Q. 9

Q. 6: Is breathlessness progressive over time? Yes/No

Q. 7: Is breathlessness persistent? Yes/no

Q. 8: Does your breathlessness get worse with exercise or on exposure to other strongstimuli: Yes/No

Q. 9: Do you have asymptomatic period between two episodes of chronic cough? Yes/No

Q. 10: Is your cough associated with wheezing? Yes /No

Q. 11: What age does chronic cough start?.....Years

Q. 12: Has anyone in your family or you yourself been diagnosed with Asthma orany allergic diseases: Yes/No

5.4 PART B mMRC Dyspnea scale: (Assessment of Dyspnea)

S. No	Severity of Dyspnea	Scoring
1	Dyspnea only with strenuous exercise	0
2	Dyspnea when hurrying or walking up a slight hill	1
3	Walks slower than people of the same age because of dyspnea or has to stop for breath when walking at own pace	2
4	Stops for breath after walking 100 meters or after a few minutes	3
5	Too dyspneic to leave house or breathless when dressing	4

Individuals with early onset of cough and dyspnea (childhood) or sometimes adult-onset, exacerbation with exercise/strong stimuli along with asymptomatic periods between episodes of cough, history of allergies and nocturnal symptoms may indicate the diagnosis of Asthma.

Individuals with adult onset of cough and or dyspnea, which is progressive & persistent, along with exposure to smoking or other noxious stimuli, may indicate a diagnosis of COPD.

All individuals with complaints of cough > 2 weeks should be assessed for TB[2]

a. Cough > 2 weeks
b. Fever > 2 Weeks
c. Significant weight loss
d. Hemoptysis (Blood in symptom)
e. Previous h/o TB in himself/herself or in the family

If suspected for TB, do sputum collection and refer to nearby PHC for further assessment.

All individuals with mMRC scale value >1 with or without cough/dyspnea need to undergo Peak Expiratory Flow measurement (PEF) using a peak flow meter at PHC/HWC (wherever it is available) for all individuals undergoing PEF assessment. It is necessary to rule out TB bytwo negative sputum sample checks.

All individuals with mMRC scale value 4 may be sent directly to a higher health facility by CHO after having a tele-consultation with MO at PHC to rule out other diseases associated with severe dyspnea and confirmation of COPD.

All individuals not at risk of TB or without cough and dyspnea should be sent back to the community after providing health education on risk reduction, such as the following:

Reference;
[2]Govt. of India. Technical and operational guidelines for TB control in India 2016. CTD. MoHFW, GoI

1. Cessation, quitting and not starting smoking/Alcohol (depending on the need ofthe Individual)
2. Weight reduction or maintaining healthy weight
3. Maintaining adequate nutrition and healthy diet
4. Adequate daily physical activity
5. Use of clean cooking fuel with adequate ventilation

Those individuals who are referred by MO to the HWC/Community with presumptive diagnosis of COPD/Asthma or other chronic respiratory diseases after initiating treatment or under follow-up should be counselled by CHO/ANM on

1. Inhaler techniques (Rotahaler / Meter Dose Inhaler with Spacer)
2. Pulmonary rehabilitation exercises at the household level
3. Tobacco cessation, quitting and not starting smoking/Alcohol (depending on theneed of the Individual)
4. Weight reduction or maintaining healthy weight
5. Maintaining adequate nutrition and healthy diet
6. Adequate daily physical activity
7. Use of clean cooking fuel with adequate ventilation

5.5 Part 3: Primary Health Care level

While undergoing the PEF assessment at PHC/HWC, (wherever it is available) the following outcomes may occur:

A. Individuals with PEF> 80 % of predicted, without cough and /or dyspnoea: They may now be sent back to the community after providing health education on risk reduction

1. Cessation, quitting and not starting smoking/Alcohol (depending on the need of the Individual)
2. Weight reduction or maintaining healthy weight
3. Maintaining adequate nutrition and healthy diet
4. Adequate daily physical activity
5. Use of clean cooking fuel with adequate ventilation

A. Individuals with PEF> 80 % of predicted, with cough and /or dyspnea: They should be assessed for other conditions particularly TB and manage accordingly, and to beeducated for

1. Cessation, quitting and not starting smoking/Alcohol (depending on the need of the Individual)
2. Weight reduction or maintaining healthy weight
3. Maintaining adequate nutrition and healthy diet
4. Adequate daily physical activity
5. Use of household clean fuel

B. Individuals with PEF< 80 % predicted + breathlessness/cough > 8 weeks OR a history compatible with Asthma): provisional diagnosis of Asthma

MO at PHC should start the empirical treatment with bronchodilator (note that Antibiotics are not recommended for Asthma management even in exacerbations unless an infection has beendocumented) for Asthma and advice about measuring and monitoring the airways conditions through PEFR using PFM. In case of any confusion in diagnosis refer to higher facility for diagnosis and management and do further follow up at PHC Health education

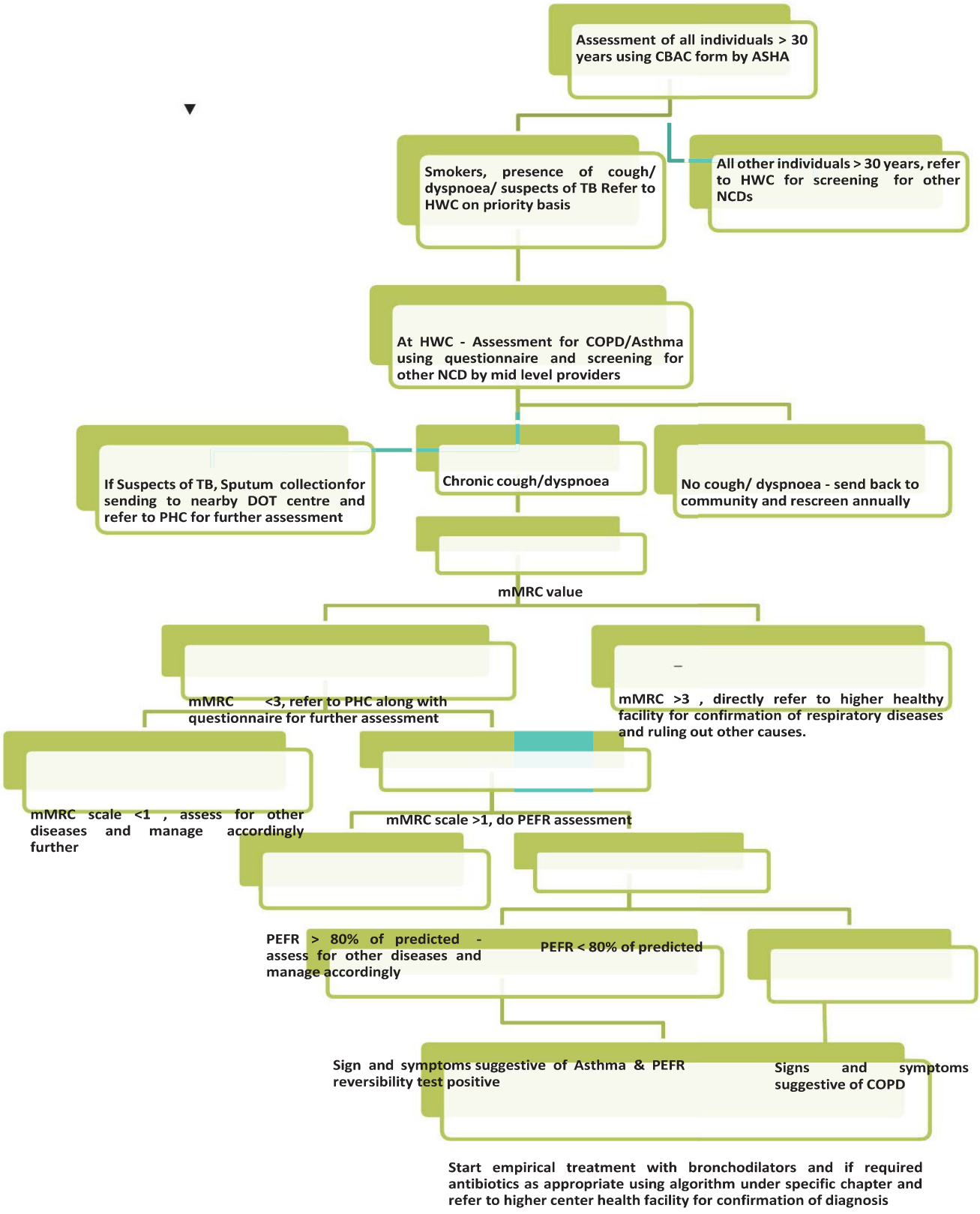
1. Inhaler techniques
2. Tobacco cessation, quitting and not starting smoking/Alcohol (depending on the need ofthe Individual)
3. Avoidance of known allergens
4. Pulmonary rehabilitation exercises at household level
5. Weight reduction or maintaining healthy weight
6. Maintaining adequate nutrition and healthy diet
7. Adequate daily physical activity
8. Use of clean cooking fuel with adequate ventilation

C. Individuals with PEF< 80 % predicted+ breathlessness/cough > 2 weeks + clinical features compatible with COPD: provisional diagnosis of COPDMO atPHC should start the empirical treatment for COPD and advice on:

1. Inhaler techniques
2. Cessation, quitting and not starting smoking/Alcohol (depending on the need of the Individual)
3. Pulmonary rehabilitation exercises at household level
4. Weight reduction or maintaining healthy weight
5. Maintaining adequate nutrition and healthy diet
6. Adequate daily physical activity
7. Use of clean cooking fuel with adequate ventilation

Refer to higher center for confirmation of diagnosis and rehabilitation once the patient isstable on current medication, follow up at DH yearly or whenever need arise.

5.6 Flow chart for screening of COPD/ASTHMA among individuals > 30years



5.7 Reporting formats and timelines for COPD

Routine monitoring mechanism through formats and with the existing apps.
The routine monitoring mechanism which is being adopted for NP-NCD will now include the indicators for COPD. Therefore, the following formats for monthly reporting from the facilities at various levels have been modified to include components of COPD.

Level	Reporting Form	Data generated from	Person responsible	Reporting to	Submission of previous month report by
Sub-centre	Form 1	ANM Screening Register	CHO of SHC-HWC	PHC	Last day of the month
PHC (including urban PHC-HWC	Form 2 & 2 A	PHC-HWC OPD Register & Compiled all Form-I	MO I/C PHCHWC	CHC NCD Clinic	5th of every month
CHC/ BPHC/ SDH	Form 3A	CHC NCD OPD Register	MO I/C CHC NCD Clinic	District NCD Cell	7th of every month
	From 3B	Compiled all forms 1 & 2	BPHC / SDH		
District Hospital	Form 4	DH-NCD OPD Register	MO I/C District NCD Clinic	District NCD Cell	7th of every month
District NCD cell	Form 5A	Form 5A Compiled all forms 3A & 4	District Nodal Officer (NCD)	State NCD Cell	10th of every month
	Form 5B	Form 5B Compiled all forms 3B			
State NCD Cell	Form 6	Form 6 Compiled all forms 5A &5B	State NodalOfficer (NCD)	National NCD cell	15th of every month

Annexure - I. Indicative list of Equipment's to be made available at different health care level

	PHC	CHC	DH/Medical college
Essential	Oxygen Pulse oximeter Peak Flow-meter with disposable mouthpiece / bacterial filter Inhaler device for DPI, pMDI Spacer device for pMDI Nebulizer	Oxygen Pulse oximeter Peak Flow-meter with disposable mouthpiece / bacterial filter Spirometry Chest x-ray Inhaler device for DPI, pMDI Spacer device for pMDI Nebulizer	Oxygen Pulse oximeter Peak Flow-meter with disposable mouthpiece / bacterial filter Spirometry Chest x-ray Arterial blood gas NIV, IMV Inhaler device for DPI, pMDI Spacer device for pMDI Nebulizer
Desirable	Arterial blood gas Non-invasive ventilation (NIV) Mechanical ventilation (IMV)		

Annexure - II. Indicative list of drugs to be made available at different centers

	PHC/CHC/DH/Medical College
Essential	**A. DPI/pMDI Inhalation Medicines:** **SABA**: levosalbutamol / Salbutamol 50-100 mcg (pMDI/DPI) **LAMA** : Tiotropium 18 mcg (DPI) **ICS:** Budesonide 100, 200, 400 mcg (pMDI/DPI) **LABA + ICS:** Formoterol/Budesonide 6 / 100,200, 400 mcg Salmeterol/Fluticasone 50 / 100, 250, 500 mcg **LABA/LAMA :** Formoterol/Glycopyrronium 12/50 mcg **LABA/LAMA/ICS:** Formoterol/Glycopyrronium/Budesonide 12/50/400 mcg **B. Nebulization solution inhalation Medicines** **SABA**: Levosalbutamol respule (0.31/0.63/1.25mg/2.5ml), **SABA/SAMA** : Levosalbutamol + Ipratropium respules (1.25mg+500mcg & 0.63mg+500mcg) **ICS+LABA: Budesonide/ Formoterol Respule (0.5 mg + 20 mcg or 1mg + 20 mcg** **LAMA**: Glycopyrronium Respule (25 mcg/1 ml) **C. Methylxanthine:** Theophylline 100 mg **D. Oral and IV steroids** Tab Prednisolone Inj. Hydrocortisone **E. Antibiotics (oral and IV)** Amoxicillin Doxycycline Azithromycin **F. Oxygen delivery devices** Nasal canulae, face masks, Venturi masks
Desirable	**Vaccination (Flu/Pneumococcal, Covid-19) for eligible COPD patients**

Annexure - III. Community Based Assessment Checklist (CBAC)

Date: DD/MM/YYYY

General Information	
Name of ASHA:	Village/Ward:
Name of MPW/ANM:	Sub Centre:
	PHC/UPHC:
Personal Details	
Name:	Any Identifier (Aadhar Card, any other UID, Voter ID e tc):
Age:	State Health Insurance Schemes: Yes/No If yes, specify:
Sex:	Telephone No. (self/family member/other - specify details):
Address:	
Does this person have any of the following: Visible defect/known disability/Bed ridden/ require support for Activities of Daily Living.	If Yes, Please specify

Part A: Risk Assessment				
Question	***Range***		***Circle Any***	***Write Score***
1.What is your age? (in complete years)	0-29 years		0	
	30-39 years		1	
	40- 49 years		2	
	50-59 years		3	
	≥ 60 years		4	
2. Do you smoke or consume smokeless products such as gutka or khaini?	Never		0	
	Used to consume in the past/ Sometimes now		1	
	Daily		2	
3.Do you consume alcohol daily	No		0	
	Yes		1	
4. Measurement of waist (in cm)	Female	Male		
	80 cm or less	90 cm or less	0	
	81-90 cm	91-100 cm	1	
	More than 90 cm	More than 100cm	2	
5. Do you undertake any physical activities for minimum of 150 minutes in a week? *(Daily minimum of 30 minutes per day-Five days a week)*	At least 150 minutes in a week		0	
	Less than 150 minutes in a week		1	
6. Do you have a family history (any one of your parents or siblings) of high blood pressure, diabetes and heart disease?	No		0	
	Yes		2	
Total Score				

Every individual needs to be screened irrespective of their scores.
A score above 4 indicates that the person may be at higher risk of NCDs and needs to be prioritized for attending theweekly screening day

Part B: Early Detection: Ask if Patient has any of these Symptoms			
B1: Women and Men	**Y/N**		**Y/N**
Shortness of breath (difficulty in breathing)		History of fits	
Coughing more than 2 weeks*		Difficulty in opening mouth	
Blood in sputum*		Any ulcers in mouth that has not healed in two weeks	
Fever for > 2 weeks*		Any growth in mouth that has not healed in two weeks	
Loss of weight*		Any white or red patch in mouth that has not healed in two weeks	
Night Sweats*		Pain while chewing	
Are you currently taking anti-TB drugs**		Any change in the tone of your voice	
Anyone in family currently suffering from TB**		Any hypopigmented patch(es) or discolored lesion(s) with loss of sensation	
History of TB *		Any thickness skin	
Recurrent ulceration on palm or sole		Any nodules on skin	
Recurrent tingling on palm(s) or sole(s)		Recurrent numbness on palm(s) or sole(s)	
Cloudy or blurred vision		Clawing of fingers in hands and/or feet	
Difficulty in reading		Tingling and numbness in hands and/or feet	
Pain in eyes lasting for more than a week		In ability to close eyelid	
Redness in eyes lasting for more than a week		Difficulty in holding objects with hands/fingers	
Difficulty in hearing		Weakness in feet that causes difficulty in walking	
B2: Women only	**Y/N**		**Y/N**
Lump in the breast		Bleeding after menopause	
Blood stained discharge from the nipple		Bleeding after intercourse	
Change in shape and size of breast		Foul smelling vaginal discharge	
Bleeding between periods			
B3: Elderly Specific (60 years and above)	**Y/N**		**Y/N**
Feeling unsteady while standing or walking		Needing help from others to perform everyday activities such as eating, getting dressed, grooming, bathing, walking or using the toilet	
Suffering from any physical disability that restricts your movement		Forgetting names of your near ones or your own home address	
In case of individual answers Yes to any one of the above-mentioned symptoms, refer the patient immediately to the nearest facility where a Medical Officer is available			
If the response is Yes- action suggested: Sputum sample collection and transport to nearest TB testing center			
*** If the answer is yes, tracing of all family members to be done by ANM/MPW*			

Part C: Risk factors for COPD
Circle all that Apply
Type of Fuel used for cooking - Firewood / Crop Residue / Cow dung cake / Coal / Kerosene / LPG
Occupational exposure - Crop residue burning/burning of garbage - leaves/working in industries with smoke, gas and dust exposure such as brick kilns and glass factories etc.

Part D: PHQ 2					
Over the last 2 weeks, how often have you been bothered by the following problems?		Not at all	Several days	More than half the days	Nearly every day
1.	Little interest or pleasure in doing things?	0	+1	+2	+3
2.	Feeling down, depressed, or hopeless?	0	+1	+2	+3
Total Score					
Anyone with total score greater than 3 should be referred to CHO/MO (PHC/UPHC)					

Annexure - IV: Peak flow meter and its use

A peak flow meter is a simple, portable, easy-to-use, cost-effective instrument that measures the Peak Expiratory Flow Rate (PEFR). PEFR is the maximum flow of air that can be generated during forceful expiration after taking a deep breath. The PEFR representsthe calibre of the large airways, i.e., it is reduced when there is obstruction in the large airways, which typically happens in Asthma and advanced chronic obstructive pulmonary disease (COPD). The PEFR can be measured by a simple instrument called the **Peak Flow Meter**. TheSpirometer can also be used to measure the PEFR. Merely relying on symptoms like cough, breathlessness, and wheezing to diagnose Asthma can be misleading at times.

In other diseases such as hypertension and diabetes, handy tools such as the sphygmomanometer and glucometer have revolutionised disease management. Similarly, a peak flow meter, which provides an objective measure of the lung function in terms of the PEFR, is an important tool in managing Asthma.

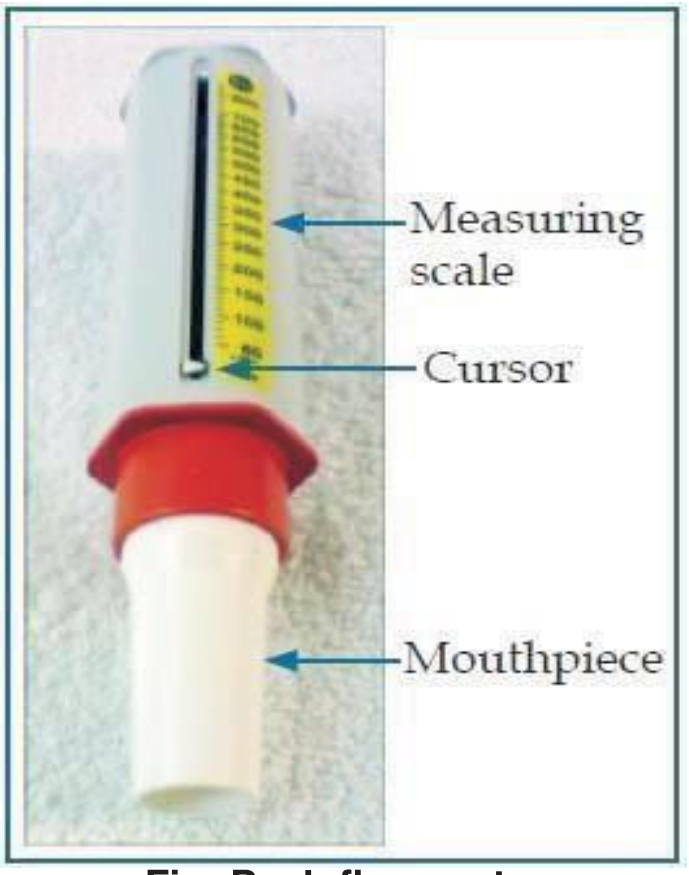


Fig. Peak flow meter

Place in Therapy:

- The situations where the application of PEFR evaluation in practice finds place are listed below:
- **In the diagnosis of Asthma**

  Excessive variability in twice daily PEF over two weeks or a good therapeutic response following two weeks of treatment with inhaled corticosteroids is an indicator for a diagnosis. sis of Asthma

  - Poor resource settings: Variable airflow meters can confirm various PEF limitations; the World Health Organization has proposed these as essential tools in the Package of Essential Non-communicable Diseases Interventions. In low-resource settings, documentation of symptoms and PEF before and after a therapeutic trial with as-needed SABA and regular ICS, often together with a 1-week course of oral corticosteroids, can help to confirm the diagnosis of Asthma before long-term treatment is commenced.
  - Special Populations: In obese patients with dyspnea on exertion, it is important to confirm the diagnosis of Asthma with objective measurement of variable airflow limitation.
  - Occupational Asthma: Frequent PEF monitoring at and away from work is often used to help confirm the diagnosis. It is important to diagnose occupational Asthma objectively as it may lead to the patient changing their occupation, which may have legal and socioeconomic implications.
  - Patients with cough variant Asthma (cough as the only presenting respiratory symptom): Patients with cough-variant Asthma have chronic cough as their principal, and lung function maybe normal. For these patients, documentation of variability in lung function is essential. These patients respond very well to inhaled corticosteroids.
  - Exercise-induced Bronchoconstriction: To document variability in airflow before and after exercise to diagnose Asthma and prevent the risk of an exacerbation following exercise.
  - Self-monitoring: Peak flow meters can help in short-term and long-term monitoring of Asthma.
  - Evaluation of a patient in primary care, whether to transfer to acute care facility depending on the severity of Asthma.
  - Self-Management of Exacerbation with a Written Asthma Action Plan:

  Personal written Asthma action plans show patients how to make short-term changes to their treatment in response to changes in their symptoms and/or PEF. They also describe how and when to access medical care.

  Thus, keeping in mind the advantages and applicability of PEF evaluation in clinical practice, especially in a country with compromised diagnostic and monitoring settings like India, the peak flow metershould be considered as an essential tool for the management of Asthma.

How to use the peak flow meter:

1. The mouthpiece should be fitted into the peak flow meter
2. Set the cursor/marker to zero. Do not touch the cursor when breathing out.
3. Stand up or sit up straight.
4. Hold the peak flow meter horizontally in front of the mouth.
5. Take a deep breath in and close the lips firmly around the mouthpiece, ensuring no air leaks around the lips.
6. Breathe out as hard and as fast as possible and note the number indicated by the cursor.
7. Again, set the cursor to zero and repeat this manoeuvre twice more.
8. The peak flow at that time is the highest or best reading of all three measurements.

Infection Control: Guidelines or information provided by the Provider Company for the PEF meter should be used to disinfect the equipment. A disposable mouthpiece, bacterial filter or properly sterilized reusable mouthpiece should be used for every patient. Cleaning the exterior surfaces of the peak flow meter and inside the red cap with an ordinary alcohol wipe (70 - 90 %) after every use, with a thorough wash and disinfection after every 50 uses or immediately if contamination is observed. Because patients only blow out into the device, it does not seem necessary to have a bacterial filter attached to the mouthpiece, unlike in Spirometry, where the patient also breathes in through the device. Biological waste generated during the procedure should be handled appropriately and disposed according BWM rule.

ANNEXURE V: Spirometry basics & place in therapy in the management of OADs

Introduction

Spirometry is a method of assessing lung functions by measuring the amount and the speed of air inhaled and exhaled by a person. The results of spirometry can aid in the diagnosis of obstructive airway diseases such as Asthma and COPD and also help in objectively evaluating response to treatment. In addition, it also aids in suspecting a diagnosis of restrictive lung diseases such as interstitial lung diseases and helps diagnose upper airway obstruction.

Spirometer

The spirometer is a device that measures the amount of air and the rate at which the air is exhaled by the subject (Figure 1). All spirometry equipment must meet the current American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines for accuracy and precision.

Spirometric Measurements

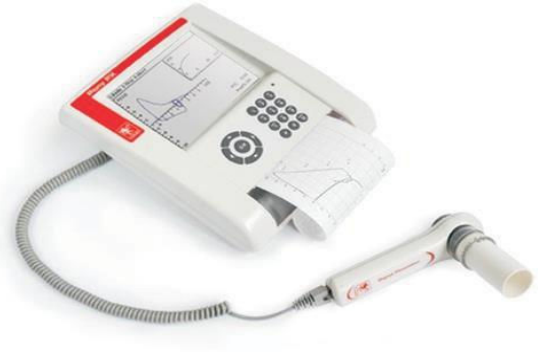


Figure 1: Spirometer device

A participant must forcefully exhale the air into the spirometer device after taking a deep breath. Such a participant's effort is called the forced expiratory maneuver. After completing the spirometry procedure, the measurements are compared with standard established values. These standards are calculated based on an individual's age, height, sex, and race/ethnicity since the diagnostic thresholds for obstructive lung disease differ by body size and by demographic subgroups.

The following are the spirometry indices:

Forced Vital Capacity (FVC): The maximum volume of air exhaled forcefully after a maximal inspiration. For adults, this forced exhalation should last for up to 12 seconds or until a plateau is reached for >1 second; however, persons with COPD may take considerably longer to exhale all their air. Children under the age of 10 years should be coached to exhale for at least 3 seconds.

Forced Expiratory Volume in One Second (FEV1): It is the volume of air exhaled during the first second of a forced expiratory maneuver. Normally, a healthy person can be expected exhale from 70 to 80 percent of the FVC in the first second of a forced expiration maneuver.

Peak Expiratory Flow (PEF): It is the highest instantaneous airflow rate measured during the FVC maneuver. PEF is measured in liters per second and will be used mainly to assess participant effort.

Forced expiratory flow at 25-75% (FEF25-75%): This is the mid-expiratory flow rate i.e. the average forced expiratory flow rate over the middle 50 percent of the FVC. It can help in the diagnosis of small airway diseases and an obstructive ventilatory pattern.

The following are the spirograms obtained by typical spirometer:

Spirometric data are viewed as graphs called spirograms. Measurements of exhaled volume (in litres), time (in seconds), and airflow rates (in litres per sec) are determined and displayed on the spirograms. There are two types of spirograms (Figure 2).

Flow-Volume: The expiratory flow vs. volume curve displays instantaneous airflow rates as a function of volume exhaled. This curve also contains points corresponding to the PEF and FVC.

Volume-Time: The basic volume vs. time curve contains points corresponding to the FEV1 and FVC.

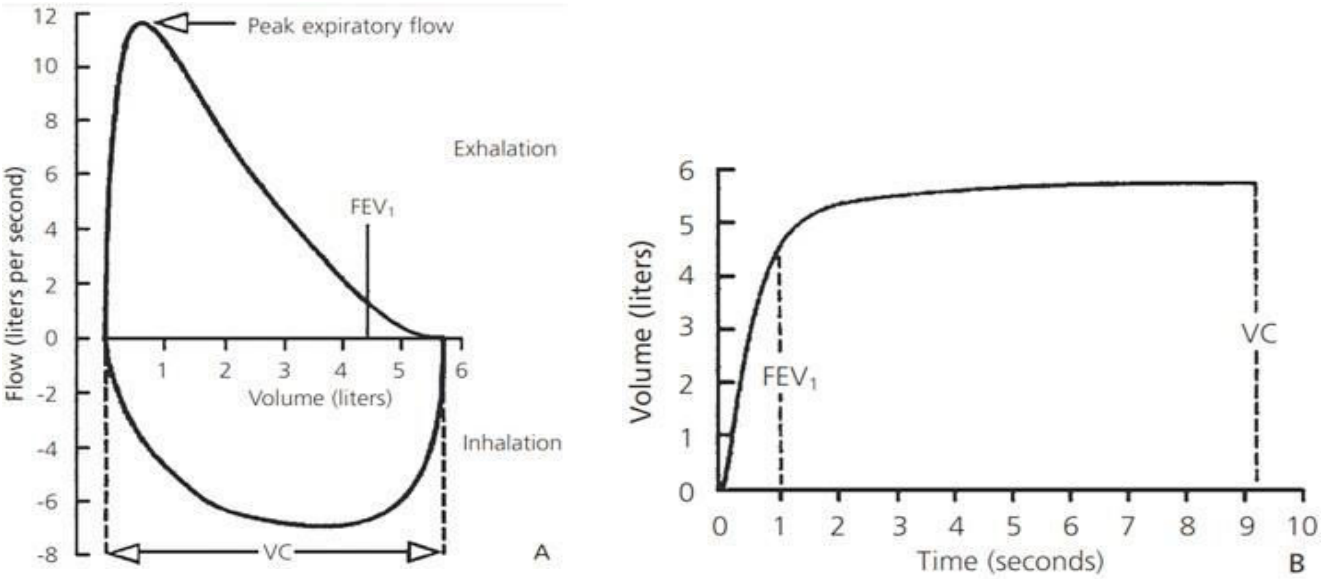


Figure : Spirograms obtained from spirometer (A) Flow Vs.Volume curve, (B)Volume Vs.Time curve

Application of spirometry in OADs

1. Diagnosis and differentiation between Asthma and COPD
2. Assessment of disease severity
3. Monitoring the response of treatment

Spirometry in Asthma

Spirometry can be used in the diagnosis of Asthma by measuring airways obstruction and its reversibility following bronchodilator administration. In patients with respiratory symptoms indicating the presence of Asthma, the reversibility testing is usually performed for confirmation.

Spirometric reversibility testing is performed after giving a bronchodilator that can either be a short-acting â2 agonist or short acting muscarinic antagonist. If the reversibility appears to be greater than 12% and 200-ml increase in FEV1 then it suggests the clinical diagnosis of Asthma. However, lack of post-bronchodilator reversibility does exclude Asthma.

Spirometry in COPD

The term chronic obstructive pulmonary disease (COPD) refers to a group of conditions characterized by progressive development of airflow limitation that is usually not fully reversible with medication treatment. Spirometry is the only diagnostic test for CODP.

After assessing clinical symptoms such as dyspnea, cough, sputum production and history of exposure to the risk factors, the confirmation of COPD relies on the spirometric measurements.

The primary measurement used to assess COPD is the post-bronchodilator ratio of forced expiratory volume in 1 second to forced vital capacity expressed (FEV1/FVC) value should be less than 0.7 (<0.7).

Further, assessment of severity of airflow obstruction in COPD can be performed and classified according to FEV1 % predicted values (Figure 3).

FEV_1% pred	Category[#]
>80	Mild
50-79	Moderate
30-49	Severe
<30	Very severe

[#]: values are post-bronchodilator and used in combination with an FEV_1FVC ration of <0.7.

Figure : Assessment of severity of airflow obstruction in COPD patients

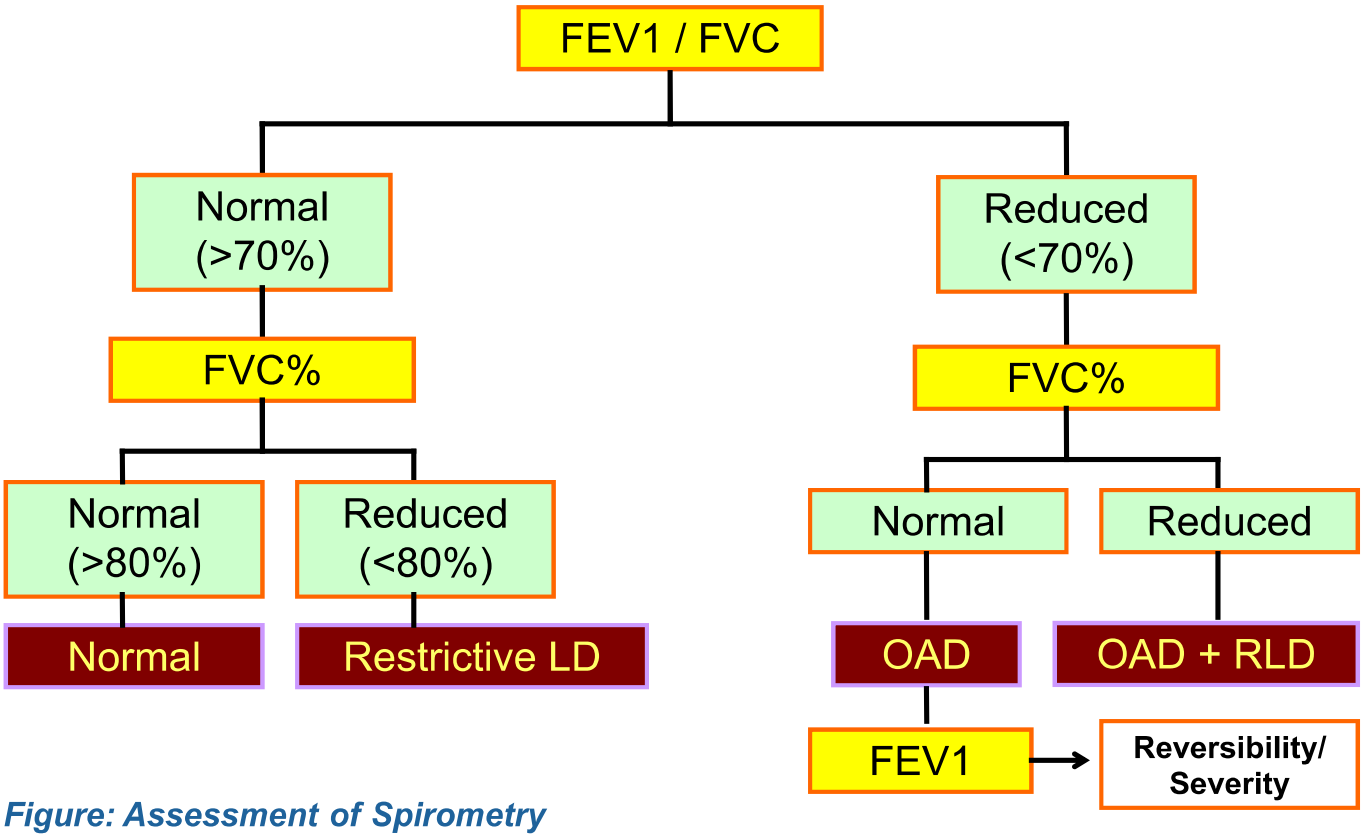


Figure: Assessment of Spirometry

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Annexure VI: Inhalation Devices

Administering drugs through the inhalation route is the most efficacious form of drug delivery in obstructive airway diseases (OADs) such as Asthma and chronic obstructive pulmonary disease (COPD). It has been recommended by various national and international guidelines, including the Global Initiative for Asthma (GINA) and Global Obstructive Lung Diseases (GOLD) guidelines, due to several advantages that this route of drug delivery offers compared to the conventional route of administration.

Advantages of Inhaled route Vs the oral (conventional) route

1) Targeted drug delivery to the lungs
2) Fast onset of action
3) Significantly less amount of drug required
4) Reduced Side effects

However, there are several myths associated with the use of inhalers, due to which many patients still do not accept inhalation therapy and prefer orals. Wrong notions, viz., inhalers are vital and should be used only as a last resort; inhalers are addictive and social stigma associated with inhalers are the common barriers to inhalation therapy. Mass awareness and patient education are the need of the hour to overcome these barriers.

Several inhaler devices are available - pressurized-metered dose inhalers (pMDIs), dry powderinhalers (DPIs) including unit-dose and multi-dose DPIs and breath-actuated inhalers (BAIs), each with its own advantages and drawbacks. A wide variety of drugs used for OAD management, including inhaled corticosteroids, short-acting and long-acting beta-agonists, anti-muscarinic agents and combinations are available in these inhalers.

A personalised approach must be followed based on each patient's needs while selecting aparticular device. Various patient, as well as device-related aspects, need to be taken into account while selecting devices, viz. severity of the disease, age of the patient, ability to understand instructions, socio-economic and educational factors, ease of use of the devices, inspiratory effort required, availability of different drugs and avoiding multiple inhalers.

Age-wise selection of device

Age (years)	Preferred device	Alternative device
< 4	MDI + spacer with face mask	Nebuliser with facemask
4-6	MDI + spacer with mouthpiece	Nebuliser with mouthpiece
>6	Dry powder inhaler, breath-actuated pressurised MDI MDI + Spacer with mouthpiece	Nebulizer with mouthpiece

Adapted from the Global Initiative for Asthma and Pedersen er aL MDI=Metered-dose inhaler

Types of Inhalation Devices

pMDIs – The pMDIs were introduced in 1956 and are still the most popular inhaler device. They contain the drug formulation along with the propellant, which helps propel the drug out of the inhaler. The propellant generally used is hydrofluoroalkane (HFA), which has helped to overcome the ozone depletion issues of the previously used chlorofluorocarbons (CFCs). The metering valve helps torelease a pre-metered quantity of the drug every time the inhaler is actuated. pMDIs do not depend onthe patient's inspiratory effort as the drug is released just by actuating the inhaler. Spacer and maskdevices are available to be used along with the pMDIs for drug delivery to infants, children, theelderly and all those patients who cannot coordinate actuation with inhalation.

However, there are some drawbacks associated with pMDI use, viz. coordination between actuation and inhalation, high velocity of the spray and cold freon effect, which may compromise optimal drug deposition. Nearly 80 -90% of the patients using the pMDIs have incorrect techniques, and several studies have demonstrated that errors in inhaler technique are associated with poor disease outcomes.

Advantages of pMDI

- Small size, lightweight
- Multiple doses (120, 200)
- Quick to use.
- Comparatively less expensive
- Consistent dosing
- Independent of inspiratory flow
- Protected from moisture.

Limitations of pMDI

- Difficulty in coordinating actuation with inhalation - It is possible to get no drug in the lungs with a verybad technique.

Spacers – These are accessory devices which can be attached to the pMDI to help overcome the technique issues of co-ordination. Spacers with valves help to hold the aerosol released from the pMDI for some time so that the patient can comfortably inhale the medication. Adding a mask to the spacer helps to provide inhaled medication to younger children and infants. Spacers help to reduce oropharyngeal deposition and, hence, the local side effects. They also help to increase lung deposition compared to a plain pMDI. However, this depends on several factors, viz., the spacer's construction material, shape and size, and type of valve. Of all these, the construction material is the most important; static material leads to the development of static charge on the walls of the spacer, so when the drug is actuated, most of it gets deposited on the walls of the spacer. Significantly less quantity is available for inhalation. Using a spacer made of ant-static material helpsto overcome this effect and enhances drug deposition in the lungs, as reported by various studies.

pMDI+spacer is also recommended for acute exacerbations and is an effective alternative tonebulisers. Several studies in adults and children have demonstrated that the pMDI+spacer is similar inefficacy compared to a nebuliser at the same time, provides a better safety profile.

Who should use spacers?

1. Patients with coordination problems
2. Children and the elderly
3. Those who are prescribed high-dose inhaled steroids
4. Patients with acute Asthma requiring high-dose bronchodilators as a substitute for nebulizers
5. Those who are prescribed anti-cholinergic drugs (to avoid the spray particles from reaching the eyes)

However, a major disadvantage of the spacer is the non-adherence by the patients due to its bulkiness and reduced portability.

DPIs – The medication in a DPI is in a powder form consisting of a micronised drug blended with larger carrier particles (mainly lactose), which enhance flow, reduce aggregation and aid in dispersion. DPIs help address the shortcomings of the pMDI - they are breath-actuated and eliminate hand-breath coordination and the need for a spacer. Since they do not require propellants, they help overcome the issue of environmental concerns and the cold freon effect associated with the pMDIs.

Advantages of DPIs

- Easy to learn, simple to teach and understand.
- Compact & Portable
- Little or no patient coordination is required.
- No propellants, hence, no cold freon effect and environment-friendly
- Multiple drugs can be administered from the same device (in the case of single-dose DPIs)
- No need for spacers
-

Disadvantages of DPIs

- Dependence on the patient's inspiratory efforts
- The inhalation process must be repeated until the capsule is empty.
- All DPIs are potentially vulnerable to humidity and moisture.

Breath Actuated Inhalers (BAIs)

These inhalers sense the patient's breath and automatically get triggered to release a metered dose of the drug, which the patient can inhale. Since these are breath-actuated, they help overcome the coordination issue seen with the pMDIs. BAIs get triggered at low inspiratory flow rates of lessthan 35 L/min; hence, they can comfortably be used by OAD patients across severities and ages. Thus, they overcome the issues of DPIs, which depend on the patient's inspiratory effort for optimal drug deposition. A dose counter helps to know the number of doses remaining in the inhaler.

Advantages of BAIs –

- Simple and easy to use
- Overcomes the drawbacks of both pMDIs and DPIs
- Multiple doses are available
- The dose counter helps to know the number of doses remaining
- Reduces errors in technique
- Doses are protected from moisture

Nebulisers –

Nebulisers help convert drug solutions and suspensions into a mist form comprising of tiny droplets. Solutions comprise drugs dissolved in a carrier liquid, whereas suspensions comprise solid drug particles suspended in the carrier liquid. An advantage of using Nebulizers includes their ability to aerosolise high doses of drugs that are not available with DPIs or pMDIs. Nebulizers come with face masks/mouthpieces that can be used by patients two years old, the elderly and those with severe respiratory distress.

Different types of nebulisers are available:

Pneumatic or jet nebulisers

Pneumatic or jet nebulisers use compressed gas flow to entrain liquid from a reservoir and break the liquid into tiny droplets by means of baffles.

Ultrasonic nebulisers

Ultrasonic nebulisers transmit sound waves generated by vibrating a piezoelectric crystal at a high frequency to the surface of the drug solution to be nebulised where the droplets are formed. Although ultrasonic Nebulizers can nebulise solutions more quickly than pneumatic jet Nebulisers, they are unsuitable for suspensions.

Vibrating mesh nebulisers

Vibrating mesh devices are either active or passive systems. In active devices, the aperture plate vibratesat a high frequency and draws the solution through the apertures in the plate. In passively vibrating mesh devices, the mesh is attached to a transducer horn, and vibrations of the piezoelectric crystal thatare transmitted via the transducer horn force the solution through the mesh to create an aerosol.

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