(1)

Computer No.71594
No.T.21022/41/2013-NCD
Government of India
Ministry of Health and Family Welfare
(NCD Section)

Nirman Bhavan, New Delhi.
Dated the November, 2016.

To

Principal Secretary (H&FW),
All States/UTs.

Subject : Guideline for the Management of Chronic Obstructive Pulmonary Disease (COPD) and Asthma in Primary Health Care in India.

Sir,

I am directed to say that from the financial year 2016-17, Chronic Obstructive Pulmonary Disease (COPD) has been included in the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). It is also informed that all States/UTs have been requested vide this Ministry's letter No.T.20014/09/2016-NCD dated 5.10.2016 (Copy enclosed) to project the requirement of funds in their PIPs for to provide for infrastructure and training of manpower for diagnosis and treatement of COPD.

2. I am also directed to forward herewith a copy of the Guideline for the Management of Chronic Obstructive Pulmonary Disease (COPD) and Asthma in Primary Health Care in India to follow the norms as per the approved pattern of assistance.

No./SNO/NCD/20...161156
Receipt Dated 07/12/2016
Dispatch Dated / /20

Yours faithfully,

(Yogender Kumar)
Under Secretary to the Government of Inida
Tel.No.2306 1141

Encl: As above.

Copy to:-

1. Mission Director, NHM, All States / UTs.
2. State Nodal Officers (NPCDCS), All States / UTs.

DEO 2013 Reg. की मीटिंग में

SPC (NCD) Do needful

28/12/16

Inwd 13/10/2016

BY SPEED POST (2)

T.26014/09/2016 - NCD
Government of India
Ministry of Health and Family Welfare
(NCD Divison)

Nirman Bhawan, New Delhi - 110108.
Dated the, 5th October, 2016.

To

The Principal Secretary (Health & Family Welfare),
All State Governments / UT Administrations.

Subject: Inclusion of Chronic Kidney Disease (CKD) and Chronic Obstructive Pulmonary Disease (COPD) interventions and changes in existing pattern of assistance under National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke(NPCDCS) - reg.

Sir/Madam,

With reference to above noted subject, I am directed to say that the Mission Steering Group (MSG) in its meeting held on 29th March 2016, has approved the minutes of the meeting of 3rd Empowered Programme Committee (EPC) dated 19th January, 2016.

Accordingly, the following interventions / changes are included under National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke(NPCDCS):

I. **Inclusion of Chronic Kidney Disease (CKD) and Chronic Obstructive Pulmonary Disease (COPD) interventions in selected District Hospitals:**

Currently, NPCDCS does not include two important Non-Communicable Diseases viz. Chronic Kidney Disease (CKD) and Chronic Obstructive Pulmonary Disease (COPD) which are important causes of premature mortality and morbidity and being chronic in nature require long term treatment. Further, providing facilities for early diagnosis and treatment for CKD and COPD will especially help the poor people by reducing their out of pocket expenditure. Such facilities of COPD and CKD are necessary for a more complete NCD programme.

Accordingly, States can project the requirement of funds in their PIPs for (i) Setting up of Dialysis Units and (ii) To provide for infrastructure and training of manpower for diagnosis and treatement of COPD.Initially, 100 districts will be taken up in the country for these interventions.

...2/-

3

The pattern of assistance to be followed for seeking funds will be as follows:

A. CKD:

Non Recurrent Grant:	Rs. in Lakh
Equipment	110.00
Recurrent Grant:	
Drugs & Consumables	To be borne by State
Manpower	To be borne by State

The indicative list of equipments is enclosed at Annexure I.

In addition, such facility could also be provided through a PPP arrangement as well, for which instructions have been issued under the National Dialysis Programme.

B. COPD:

Non Recurrent Grant:	Rs. in Lakh
Equipments	15.00
Recurrent Grant:	
Drugs & Consumables	25.00
Manpower	To be borne by State

Indicative list of equipments and drugs is enclosed at Annexure I.

The additional financial requirement for both interventions, as above shall be met with, under "Health System Strengthening" pool of NHM within the State's resource envelope.

II. Facilites for Cardiac Care Unit (CCU) and Day Care Centres for Cancer Care in District Hospitals:

Under NPCDCS, norms exist for supporting CCUs and Day Care Cancer Centre at District Hospitals. In the existing norms, one time grant of 155.00 lakh for CCU and Day Care Cancer Centre and annual recurring grant of Rs 26.00 lakh per annum is provided for this purpose.

However, in the scheme there is a ceiling for establishing CCUs and Care Cancer Centres in only 25% of total districts covered. It has now approved that there will not be any ceiling and CCU and Cancer facilities can be established in additional districts.

The financial support for establishing CCUs and Day Care Cancer Centre shall continue to be as per existing norms under the programme.

The additional recurrent cost is proposed to be met from within the existing pattern of assistance under NPCDCS. The non-recurrent cost will be met from funding under "Health System Strengthening" head of NHM.

III. It has also been decided that following changes will be made in existing pattern of assistance under NPCDCS:

(i) Grant for Drugs and supplies provided for designated NCD Clinics:

As approved, the following changes are made in the existing pattern of assistance provided under NPCDCS:

1. Increase in the allocation under the head "Drugs and Consumables" for District NCD Clinic from existing Rs 6.00 lakh per annum to Rs 12.00 lakh per annum.

2. Additional annual recurrent grant up to Rs 18.00 lakh per annum exclusively for cancer drugs for districts where Day Care Cancer Centre is provided.

3. A recurring grant up to Rs. 25.00 lakh per annum for Drugs and Consumables for each district where COPD facilities are set up.

The funds requirement will be made out of "Free Drugs & Free Diagnostics" heads of NHM.

(ii) Contingency grant to State NCD cell:

Increase in the contingency grant from Rs.5.00 lakh per annum to Rs. 10.00 lakh per annum, for State NCD Cell for miscellaneous expenses including communication, monitoring TA/DA, POL and other contingency expenses etc.

(iii) Funds for awareness generation for NCDs:

NCDs are primarily life style diseases. Awareness generation on risk factors of NCDs is an important part of prevention strategy of the programme. Thus, allocation in funds for "Awareness Generation" activities from existing grant of Rs.10.00 lakh per annum to Rs 50.00 Lakh per annum per State NCD Cell [for 12 smaller States/UTs] and Rs 70.00 lakh per annum per State NCD Cell [for 24 bigger States] per year.

...4 -

Enhanced allocation shall help the States/UTs to carry out more effective awareness campaigns.

It is requested that this may be brought to the notice of all concerned, so that the State may prepare their proposals accordingly, for inclusion in State PIPs, in future.

This issues with the approval of competent authority.

Yours faithfully,

(Dr. D. Bachani)
DC(NCD)

Encl: Annexure as above.

Copy to:

1. Mission Director, NHM, All States/UTs
2. State Nodal Officer, NPCDCS, All States/UTs.

ANNEXURE

I) The Indicative Cost for setting up of a Hemodialysis Centre in District Hospital:

		Rs. In Lakh
1	Dialysis machines (No.4)@ Rs. 7.00 Lakh/unit (inclusive of 2 yrs. warranty & 3 yrs. CMC)	28.00
2	Cost of ancillaries (R.O system etc.) for 4 machine	12.00
3	Cost of Consumable @3.50 Lakh/machine/year for 4 machine for 5 year	70.00
	Total	110.00

II) The indicative list of Equipments and Drugs for COPD intervention:

(i) Indicative list of equipments:

1. Portable spirometer
2. Complete Pulmonary Function Test machine
3. Pulse oximeter cum capnograph
4. Finger pulse oximeter (portable)
5. Non-invasive ventilator
6. Invasive ventilator
7. Nebulizer

(ii) Indicative list of drugs:

Bronchodilators:
Inhaled : DPO, MDI, Nebulization solution, Levosalbutamol, Salbutamol, Ipratropium, Formoterol, Salmeterol

Oral: Theophylline, Salbutamol

Corticosteroids:

Parenteral: Hydrocortisone,Methyl-prednisolone,Dexamethasone

Oral: Prednisolone, Methyl prednisolone

Inhaled: MDI, DPI: Combination of LABA+ICS (Formoterol + Budesonide, Salmeterol + Fluticasone)

Nebulization solution: Budesonide, Ipravent + Levoline, Ipravent

Antibiotics: Co-amoxyclav, cephalosporin, marcolides

Oxygen: Hospital based patient, domiciliary, portable oxygen

The addenda to the Operational Guideline of NPCDCS will be released in due course.

Guidelines for the Management of Chronic Obstructive Pulmonary Disease (COPD) and Asthma in Primary Health Care in India

2016

A guide for physicians and health care workers

Introduction

Chronic respiratory diseases (CRDs) are chronic diseases of the airways and other structures of the lung. It includes many chronic respiratory ailments such as COPD, asthma, occupational lung diseases, interstitial lung disease and others. This document focuses particularly on bronchial asthma and chronic obstructive pulmonary disease (COPD), which are major public health problems accounting for a significant burden in low- and middle-income countries. According to the latest WHO estimates, as many as 334 million people may be living with asthma; more than 200 million people with chronic obstructive pulmonary disease (COPD) and more than 400 million with allergic rhinitis and other often under-diagnosed chronic respiratory diseases.(1, 2) Many people suffer from these ailments for years, and die prematurely from it or its complications. This has a major long term implications in terms of increasing burden to the patient, family, community and eventually the health care system. The prevention and control of these diseases should be addressed through key interventions at the point of care level. These interventions also need to be prioritized especially in the developing countries like India considering the limited resources available at these levels of health care. This is a guide for primary care professionals to use as an instrument to realize successful management programs based on available health care systems.

Need for the Guidelines:

- Chronic Respiratory Diseases (CRDs) are substantial causes of morbidity in India and disproportionately affect individuals with low socioeconomic status.
- Patient access to diagnostic and management facilities, disease-state education, drug therapies, and non-pharmacological interventions (e.g., pulmonary rehabilitation) needs to be improved.
- Inadequate disease-specific guidance remains a problem for health-care providers, particularly for primary care providers, who are often the first point of care.

Key challenges

- A considerable proportion of individuals with CRDs are undiagnosed, but in our setup there is no best approach for identification of these patients at the primary care level. Diagnosis in primary care is often done without the use of spirometry, which is considered the gold standard (2-3).
- Care coordination remains a substantial challenge, particularly for patients who are cared for by both primary care providers and specialists, and who transition frequently between outpatient and inpatient settings.
- Selection of COPD and asthma therapy in primary care is often not in accordance with guidelines or evidence (4), resulting in suboptimal or no treatment for many patients.
- There is a dire need to develop a surveillance strategy for the assessment of guideline implementation and adherence.
- Ensuring uninterrupted supply of currently recommended drugs at primary health care.

COPD

Definition of COPD

Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable lung disorder characterized by progressive, poorly reversible airflow limitation often with systemic manifestations, in response to tobacco smoke and/or other harmful inhalational exposures (5).

Epidemiology

GLOBAL SCENARIO

In the 12 site Burden of Obstructive Lung Disease (BOLD) study, based on questionnaires and spirometry, it was seen that the average prevalence of COPD is 10.1%, with wide regional variations (6). In USA, COPD is recognised as the fifth leading cause of deaths, fourth leading cause of years of life lost from premature deaths and second most common cause for disability adjusted life years (7).

According to WHO estimates, more than 200 million people are affected by chronic obstructive pulmonary disease (COPD). More than 3 million people died of COPD in 2005, which corresponds to 5% of all deaths globally. Chronic obstructive pulmonary disease (COPD) is now the third most common cause of death in the world and is projected as the fourth leading cause of mortality by 2030 (2) (8). Most of the information available on COPD prevalence, morbidity and mortality comes from high-income countries. Even in those countries, accurate epidemiologic data on COPD are difficult and expensive to collect. It is known that almost 90% of COPD deaths occur in low- and middle-income countries. The COPD burden is projected to increase in coming decades because of continued exposure to COPD risk factors and aging of the population (9).

INDIAN SCENARIO

Though, several epidemiological studies have addressed the prevalence of COPD in India, the limiting issue in these being the methodology adopted and the definitions employed for diagnosis. Most of the studies have been un-validated questionnaire based, supplemented on occasion by measurement of peak flows. The reported prevalence estimates have ranged from 2 to 22% in men and from 1.2 to 19% in women (10). The 'Indian Study of Asthma, Respiratory Symptoms and Chronic Bronchitis' (INSEARCH) study of 85,105 men and 84,470 women from 12 urban and 11 rural sites reported the prevalence of chronic bronchitis to be 3.49% (4.29% in males and 2.7% in females) (11). The national burden was thus estimated to be 14.84 million. However, since the

study was questionnaire based and spirometry was not utilised, it may have missed asymptomatic individuals with significant spirometric abnormalities. Spirometry based studies have shown higher prevalence of airflow obstruction ranging from 5.7 to 17.3% in males and 6.8 to 14.8% in females more than 40 years of age (12).

COPD has severe economic implications. The estimated economic loss in India due to COPD is about Rs. 350,000 millions for year 2011 and is predicted to exceed Rs. 480,000 million for year 2016. It has been calculated that proper 'program based' or 'guideline based' management of COPD can reduce these costs by approximately 70% (4).

Risk Factors

Tobacco Smoke

Smoking is by far recognized to be the most important risk factor for development of COPD (13). Smoking behaviours in India are also peculiar with a large number of people using non-conventional form of tobacco in hookah, bidi, or chillum. Bidi and other indigenous forms of tobacco smoking are at least as (or even more) harmful than cigarette smoking (14). Low tar or filtered cigarettes are not "less harmful" and there is evidence that their effect on COPD is inconsistent (15).Passive exposure to cigarette smoke (also known as environmental tobacco smoke or ETS) may also contribute to respiratory symptoms and development of COPD (16).

Solid fuel consumption

Exposure to biomass fuels like crop residues or woods or animal dung is also widely prevalent. More than one-half of the world's households uses biomass fuels and a significant proportion of this activity takes place in conditions where much of the effluent is released into the indoor living area (17). Women, who do most of the cooking for households in rural villages, are the most affected. Biomass fuels are now considered as one of the major cause of COPD (18-20).

In India, majority of the homes use biomass fuel for cooking and heating purposes in poorly ventilated kitchens, and the amount of particulate matter generated by the burning of biomass fuel is extremely high. Ninety percent of rural households and 32% of urban households cook their meals on a biomass stove with only 25% of the cooking being done with cleaner gases (21, 22).Studies have also shown that other indoor air pollutants produced during the burning of mosquito coils and incense sticks may also be associated with respiratory morbidity (23, 24).

Outdoor Air Pollution

Outdoor air pollution mainly from emission of pollutants from motor vehicles and industries is an important public health problem (25). In a community-based study, it has been observed that higher traffic density was significantly associated with lower FEV1 and FVC in women (26). In the Danish Diet, Cancer and Health cohort study involving 57,053 participants, it has been shown that COPD incidence was significantly associated with nitrogen dioxide levels (27). Particulate pollutants, ozone and nitrogen dioxide can produce bronchial hyper reactivity, airway oxidative stress, pulmonary and systemic inflammation (25).

Table 1 Etiology/risk factors for COPD

Established risk	Probable
Tobacco smoking in all forms (28)	Outdoor air pollution (25)
Environmental tobacco smoke (16, 29)	Pulmonary TB (30-31)
Exposure to biomass fuel smoke (20, 32-34)	Poorly treated asthma (35)
Occupational exposure (36-38)	Intrauterine growth retardation (39)
Alpha-1 antitrypsin deficiency (40-41)	Poor nourishment
	Repeated lower respiratory infections during childhood (39)
	Age
	Male gender
	Low socioeconomic status (42)

Pathogenesis and Pathophysiology of COPD

Chronic obstructive pulmonary disease (COPD) is characterised by poorly reversible airflow obstruction and an abnormal inflammatory response in the lungs (43). The inflammation is the result of the immune responses to long term exposure to noxious particles and gases, particularly cigarette smoke. All cigarette smokers have some inflammation in their lungs, but those who develop COPD have an enhanced or abnormal response to inhaling toxic agents (44). COPD is characterised by increased numbers of neutrophils, macrophages, and T lymphocytes (CD8 more than CD4) in the lungs. These inflammatory cells release a variety of cytokines and mediators (45). These in turn result in the pathophysiological abnormalities—mucous hypersecretion (causing a chronic productive cough) and ciliary dysfunction, airflow obstruction and hyperinflation, gas exchange abnormalities, pulmonary hypertension, and systemic effects (46).

Mucous hypersecretion and ciliary dysfunction

The hypersecretion is due to squamous metaplasia, increased numbers of goblet cells, and increased size of bronchial submucosal glands in response to chronic irritation by noxious particles and gases.

Ciliary dysfunction is due to squamous metaplasia of epithelial cells and results in an abnormal mucociliary escalator and difficulty in expectorating.

Airflow obstruction and hyperinflation or air trapping

The main site of airflow obstruction occurs in the small conducting airways that are < 2 mm in diameter. This is because of inflammation and narrowing (airway remodelling) and loss of the lung elastic recoil (due to destruction of alveolar walls) and destruction of alveolar support (from alveolar attachments)(47).These features result in breathlessness and limited exercise capacity.

Gas exchange abnormalities

In advanced disease, abnormal distribution of ventilation perfusion ratios causes abnormal gas exchange(48). The extent of impairment of diffusing capacity for carbon monoxide per litre of alveolar volume correlates well with the severity of emphysema.

Pulmonary hypertension (PAH)

Later in the disease, pulmonary arterial constriction (as a result of hypoxia), endothelial dysfunction, remodelling of the pulmonary arteries (smooth muscle hypertrophy and hyperplasia), and destruction of the pulmonary capillary bed cause the development of PAH (49). Structural changes in the pulmonary arterioles result in persistent pulmonary hypertension and right ventricular hypertrophy or enlargement and dysfunction (corpulmonale).

COPD is not only a disease of the lungs but is also a systemic inflammatory disorder. Muscular weakness, increased risk for atherosclerotic vascular disease, depression, osteoporosis, and abnormalities in fluids and electrolyte balance may all be consequences of COPD.

Diagnosis of COPD

Suspecting COPD

The initial suspicion of COPD is based on the presence of risk factors and symptomatology reported by the patent. Based on this, further investigations may be required to confirm the diagnosis of COPD and to refute other possible alternate diagnosis (eg. Pulmonary TB, bronchiectasis)

Clinical history

At first, COPD may cause no symptoms or only mild symptoms. As the disease gets worse, symptoms usually become more severe. Common signs and symptoms of COPD include

progressive breathlessness with wheezing sound (50-51), persistent cough and production of sputum often associated with generalised fatigue. The presence of one or more of these symptoms in the presence of prolonged exposure to risk factors increases the odds for the diagnosis of COPD (52-54) especially in a person more than 35 years of age. Chest pain, fever, significant weight loss, orthopnoea, paroxysmal nocturnal dyspnoea and haemoptysis are not common symptoms of COPD. Their presence should prompt the clinician to look for the presence of an alternative diagnosis.

Table 2Key Indicators for Considering a Diagnosis of COPD (especially in >35 years of age) (2)

<table>
<tr><th>Symptoms suggestive of COPD</th><th>Symptoms suggesting alternate diagnosis</th></tr>
<tr><td>Progressive dyspnoea</td><td>Chest pain</td></tr>
<tr><td>Chronic cough (> 8 weeks)</td><td>Fever</td></tr>
<tr><td>Chronic sputum production</td><td>Significant weight loss</td></tr>
<tr><td rowspan="3">Exposure to risk factors
• Tobacco smoke
• Biomass fuel
• Occupational exposure</td><td>Orthopnoea</td></tr>
<tr><td>Paroxysmal nocturnal dyspnoea</td></tr>
<tr><td>Haemoptysis</td></tr>
<tr><td colspan="2">Consider COPD, and perform spirometry, if any of these indicators are present in an individual over age 35. These indicators are not diagnostic themselves, but the presence of multiple key indicators increases the probability of a diagnosis of COPD.</td></tr>
</table>

Physical Examination

On examination, the patient may show features of hyperinflation – a barrel shaped chest and on percussion a hyper-resonant chest along with obliterated cardiac dullness and downward displacement of the liver dullness. The breath sounds have a prolonged expiratory phase, are uniformly diminished in intensity and may be accompanied with rhonchi (55). The forced expiratory time (FET) may be prolonged to more than 6 seconds and patients may have pursed lip breathing. Forced expiratory time (FET) of more than six seconds is suggestive of airflow obstruction (56).

However, the physical manifestations of airflow limitation are rarely present until significant impairment of the lung function has occurred. Hence, a diagnosis of COPD should not be excluded in the absence of physical signs.

Cor-pulmonale may manifest as signs of pulmonary artery hypertension and right ventricular enlargement and/ or failure (loud P2, parasternal heave and raised JVP and pedal oedema)

Table 3 Features suggesting alternative diagnosis

Diagnosis	Suggestive features
COPD	Onset in mid-life Symptoms slowly progressive History of tobacco smoking or exposure to other types of smoke
Asthma	Onset early in life (often childhood) Symptoms vary widely from day to day Symptoms worse at night/early morning Allergy, rhinitis, and/or eczema may also be present Family history of asthma may be present
Pulmonary Tuberculosis	Sputum smear positive for AFB Onset at any age Haemoptysis may be present Chest X-ray may show abnormalities.
Bronchiectasis	Large volumes of purulent sputum. Haemoptysis may be present Commonly associated with bacterial infection. Chest X-ray/CT shows bronchial dilation, bronchial wall thickening
Heart failure	Orthopnoea, Paroxysmal nocturnal dyspnoea, nocturnal cough, pedal oedema Chest X-ray showing dilated heart, pulmonary oedema.
Adapted from reference (2)	

Table 4 Differential diagnosis based upon symptoms

Associated Symptoms	suggesting possible alternate/co-existing diagnosis
Chest pain	Cardiac disease
Fever	Pneumonia, TB, bronchiectasis
Significant weight loss	TB, lung cancer
Orthopnoea, PND and pedal oedema	Heart Failure
Haemoptysis	TB, Lung cancer, Bronchiectasis
History of atopy or asthma	Asthma
Family history of asthma	Asthma

Investigations:

Excluding alternate diagnosis

In our country, in view of the high prevalence of TB, it is important to exclude pulmonary TB. Two sputum (not saliva) samples should be meticulously tested to rule out pulmonary TB in patients with chronic cough. Chest radiography (if available), allows us to assess for other alternate diagnosis like bronchiectasis, lung malignancy or consolidation. However, it has a limited role in diagnosing COPD. Diagnosis of COPD should not be made/ excluded on the basis of a chest radiograph.ECG may be done if cardiac disease is suspected and to look for presence of cor-pulmonale.