Introduction:

This document summarizes evidence from available Indian and International guidelines/ published reviews in clinical journals and medical books. It aids physicians and other caregivers in making appropriate diagnostic and therapeutic decisions in an outpatient setting. It provides a framework for managing patients with particular symptom or condition. It covers diagnosis, clinical assessment, alarm features, clinical management, and investigations at outpatient level and referral management to inpatient facility/ hospital.

Scope and objective:

- To provide evidence backed recommendations for the identification and care of people with Cough at outpatient clinic.
- To give physicians a practical approach and guide to the care of patients with Cough
- To develop a tool that can be used with medical documentation and therefore promote compliance with best practice to standardize clinical care for patients with Cough in an outpatient setting.

Target population:

All population with new onset symptoms of Cough

Target Users:

- General Physicians
- Nurses
- Other health care professional
- Outpatient Clinics

The clinical protocol cover critical elements of patient care from patient's first visit to a physician, outpatient management, through to follow up and referral to inpatient facility/ hospital. The Clinical team can refer to these protocols and bibliography for detailed information.

Exclusions:

Person suffering from known underlying pathology have been excluded from the scope of this tool.

Disclaimer:

The clinical protocol are designed to be used by medical professionals licensed to practice in India as a guide and are not intended to substitute for informed medical decisions or judgment by a licensed medical professional.

Milliman

Cough: Outpatient Care Protocol

1. Introduction /definition *J1, J4 , J6, B1,*

Cough is a normal protective mechanism, which occurs due to irritation of the mucous membrane. When excessive then it usually is the commonest reason to seek medical attention. Cough can be either acute or chronic.

- Acute cough is defined as one lasting less than 3 weeks. Acute cough is the commonest new presentation in primary care and is most commonly associated with viral upper respiratory tract infection.
- Chronic cough is defined as one lasting more than 8 weeks *J1, B1* However, in areas where there is a high prevalence of tuberculosis (TB); chronic cough should be defined as it is in the World Health Organization Practical Approach to Lung Health (PAL) program as being 2 to 3 weeks in duration. *J10*

2. General presentation *J1,J14, J18*

A person with cough may present at the outpatient clinic with the following:

- Symptoms
  - Cough with or without mucus secretions
  - Fever associated with nasal congestion or sore throat
  - Wheezing or ronchi
  - Heart burn

In the absence of significant co-morbidity, an acute cough is normally benign and self-limiting.

3. Alarm features *J1, J6, B1*

Uncomplicated cough can be managed at outpatient clinic by providing symptomatic treatment. However, cough associated with alarm features should be immediately referred to hospital for prompt diagnosis and treatment. The alarm features are:

- Cough with dyspnea at rest or mild activity
- Cough accompanied with breathlessness and coughing up pink frothy mucus
- Intractable cough
- History of inhalation of foreign body in the lung
- Persistent cough in patients with co-existing respiratory / cardiovascular disease
- Cough with blood (hemoptysis)
- Cough with tachycardia, tachypnea, and / or high fever
- Cough with unexplained weight loss with fevers and night chills
- Cough with associated cyanosis
- Persistent cough not responsive to empirical therapy/ drug treatment
- Cough with stridor (retropharyngeal abscess)

Note: Identification of underlying pathology may warrant other potential reasons for referral.

4. Clinical diagnosis: *J1, J4 , J6, B1,*

The evaluation of cough at an outpatient clinic requires a careful review of medical history, a physical examination and occasionally diagnostic testing to determine the underlying cause of the disease which is beneficial for further management. Clinical types of Cough that guides the line of investigations and treatment may be:

- Acute (less than 3 weeks) usually due to viral / respiratory tract infection
- Persistent (cough that persists beyond 3 weeks to 8 weeks) usually due to viral or post nasal drip infection
- Chronic cough (cough lasting more than 8 weeks) may be due to one or many underlying pathology

Common risk factors:

- History of asthma or COPD
- Congestive heart failure
- Smokers / certain occupations

4.1. History *J1, J2, J4, J5, J6, J14, B1*

Physician should include history of following parameters in clinical diagnosis to determine underlying pathology and rule out other causes.
Note: Premorbid conditions should be considered in assessing the status of a person

- **Ask for:**
  - Duration (acute / sub-acute/ chronic)
  - Past medical history
  - Presence of risk factors
  - Timing and character of cough
  - Drug history, especially any recent ACE use
  - Immunization history (BCG, mumps and measles) and occupational history
  - Rash or any other signs
  - Recent flu or exposures to cold / chest infections

Questions to ask:

- *How long has the cough been present?*
  Classify acute/ subacute or chronic cough. Recent episodes of infections, sore throat or cold could indicate post nasal drip syndrome.
- *Did it start at once or developed over time?*
  Sudden onset may be associated with foreign body inhalation.
- *Is the cough worse at any particular time of day/ night or with any postural change?*
- Cough which abates overnight may be due to GERD. Wheezing at night might suggest Asthma. C*ough in left ventricular failure or post nasal drip may increase on lying down*
- *What is the pattern of cough? Is it persistent, intractable or happens in bouts, followed by intervals of freedom*
- *Is it aggravated by anything? E.g. dust/ cold air/ pollen/work/ food*
- *What other associated symptoms are present with cough?*

*B*reathlessness / wheezing may suggest Asthma High fever and heart rate >100 bpm might suggest Pneumonia. Associated myalgia may indicate influenza. Characteristic 'whoop' may suggest Pertussis. Rash and high fever associated with cough could indicate Mums or measles in a child.

- *Is sputum produced with cough?*
  Significant sputum production may indicate primary pulmonary pathology
- *What does it look like?*
  Purulent sputum may suggest acute lung infection
- *Does the cough have any blood?*
- *Is there a past history of asthma/ COPD/ GERD or Cardiac disease?*
- *Are any of the risk factors present? E.g. smoking, occupation, ACE drug use?*

4.2. Physical examination *J1, B1*

A careful physical examination should be performed by the physician and observe the person for any warning signs. It is helpful in establishing diagnosis and management thereon.

- **Check for:**

  - Vital Signs such as temperature, pulse, respiratory rate and blood pressure
  - Auscultation
  - Oropharynx examination
  - Sputum check for traces for blood or purulent
  - Check for anemia / cyanosis/ pallor/ edema/ jaundice/ clubbing / lymphadenopathy

5. Investigations *J1, J4, J6,J9, J14, B1*

Investigations are not routinely done but may be required to help determine the underlying pathology /cause of cough for appropriate treatment.

5.1. Routine investigations

- CBC
- Chest X-ray-PA view
- Spirometry
- Sinus imaging.* (recommended by Razi)

5.1.1. Indications for routine investigations

CBC and Chest X-ray is indicated if there are findings on chest auscultation and if cough noted with abnormal vital signs (suspected pneumonia)

Note: In presence of alarm features or associated conditions, additional investigations may be done. Usually no tests are required for an acute cough with negative chest findings.

5.2. Additional investigations

- Absolute eosinophil count, if CBC results show variation in DLC
- Pertussis infection nasopharyngeal culture

- Sputum culture for AFB, gram stain, eosinophil clumps
- Monteux test (TB)

Indications for additional investigations include hemoptysis, prominent systemic illness or to confirm suspicion of underlying pathology.

6. Differential Diagnosis *J1, J2, J4, J6,J9, j11, J13, J14, J17,J18, B1*

Acute cough is most frequently due to an upper respiratory infection. Chronic cough is often simultaneously due to more than one condition, but can be the sole clinical manifestation of asthma and gastro esophageal reflux disease (GERD). The most common causes of chronic cough in nonsmokers are postnasal drip syndrome (PNDS), asthma, and /or GERD. Evaluation should focus on excluding severe illnesses, particularly pneumonia.

- Suspect Pneumonia if
  - Fever >37.8 C or >100F
  - Heart rate >100bpm
  - RR > 24
- Suspect Asthma if
  - History of recurrent lower respiratory infection
  - History of recurrent wheezing and / or cough, especially at night
  - Exertional dyspnea
  - Variation in symptoms from day to day.
- Suspect Influenza if:
  - Sudden fever: > 102 F or 39C
  - Myalgia
  - Local outbreak of flu
- Suspect Pertussis if:
  - Cough > 2-3 weeks with characteristic ‘whoop’
  - coughing to the point of vomiting
  - a known community / household outbreak of pertussis
- Suspect Rhino sinusitis if:
  - Nasal purulence not improving after 7 days
  - Unilateral facial or tooth pain or tenderness
- Suspect exacerbation of chronic bronchitis if:
  - Previous diagnosis of chronic bronchitis (productive cough present 3 months / year x 2 years) or COPD
  - Increased dyspnea and cough
  - Possible increased sputum volume or purulence
- Suspect GERD if:
  - Chronic cough not exposed to environmental irritants nor a present smoker nor ACE user
  - Chest radiograph is normal and asthma symptoms have been ruled out and cough non responsive to inhaled corticosteroids.
- Suspect measles, mumps before rash as cough starts first.
- Suspect SWINE FLU- If cough presents with high fever and dyspnea
- Suspect Pneumoconiosis if chronic cough associated with
  - Prolonged exposure to dust from textile industry/ coal mining or exposure to other mineral factory work
  - Shortness of breath

- Chest X-ray may show a characteristic patchy, subpleural, bibasilar interstitial infiltrates or small cystic radiolucencies called honeycombing

- **For patients with a definite diagnosis of Tuberculosis** based on sputum smear results, knowing the category of result and medical recommendation, including the recommended phase of treatment. The patient may be categorized under one of the following categories:

Category I

- New sputum smear-positive
- Seriously ill new sputum smear-negative
- Seriously ill new extra-pulmonary

Category II

- Sputum smear-positive - Relapse
- Sputum smear-positive - Failure
- Sputum smear-positive - Treatment After default

Category III

- New Sputum smear - negative - not seriously ill
- New Extra - pulmonary - not seriously ill

7. Management of Cough *J1,J2,J3, J4,J5,J6,B1*

Acute cough, in the absence of a significant co-morbidity, is a self limiting and benign illness. Drug therapy may not be needed in a majority of cases.
Chronic cough treatment is guided by the evaluation process and identifying / ruling out underlying pathology.

7.1. Principles of management

- Symptom relief
- Eliminate exogenous agent / triggers
- Identify and treat underlying etiology
- Referral management if condition worsens or in presence of alarm features.

7.2. Drug therapy *J1,J2,J3, J4,J5,J6,B1*

Drug therapy may include antitussive agents, antipyretics, analgesics, decongestants and occasionally anti-inflammatory drugs.

- Symptomatic management: Physician may recommend symptom specific medications for precise treatment.
  - Symptomatic management of cough
    - Tried and tested home remedies – Honey, lemon, ginger, tulsi, ajwain, dhaniya
    - Antitussives
    - Expectorants
    - Expectorant mucolytics
    - Antihistamines
  - Antipyretics in case of fever
  - Analgesics based on symptom severity

- Decongestants based on symptom severity

- Avoidance of exposure
  - Smoking cessation advice should be encouraged
  - Occupational aggravants as relevant should be avoided
  - ACE inhibitors should be discontinued

- Specific drug therapy

The treatment of choice for patients with cough is based on underlying pathology. Antibiotic treatment for non specific upper respiratory tract infections or acute bronchitis or acute cough is not recommended. Antibiotics are given only in the presence of positive chest findings and in presence of signs of infection (high fever for > 3 days, yellow /greenish sputum, toxic appearance).

Table 1. Drug therapy

Indication	Therapeutic class	Drug (Generic)	Adult Dosage	Pediatric dosage	Contraindication
Symptomatic management of cough	**Antitussives (opiod)**	Codeine http://www.mims.com/Page.aspx?menuid=mng&name=codeine&brief=true&CTRY=IN&searchstring=Codeine	15mg 3 times daily x 5 days Up to maximum five days, could be one day -2 or 5. PRN	250mcg/kg 6 hourly x 5 days	Preexisting respiratory depression, asthma and high intracranial pressure. Use with caution in lactation. Has a potential risk in pregnancy.
	Antitussives (Non opiod)	Dextromethorphan http://www.mims.com/Page.aspx?menuid=mng&name=dextromethorphan&brief=true&CTRY=IN&searchstring=Dextromethorphan+	10-20 mg 3 times daily x 5 days	1-5 mg/kg/day x 5 days or PRN	Contraindicated in lactation, liver disease and respiratory depression. To avoid in 1st trimester of pregnancy
	Expectorants	Guaiphenesin http://www.mims.com/Page.aspx?menuid=mng&name=guaifenesin&brief=true&CTRY=IN&searchstring=Guaiphenesin	100 mg 3 times daily x 5 days	6 mth-2 yr: 25-50 mg. 2-6 yr: 50-100 mg. 6-12 yr: 100-200 mg. 3 times daily x 5 days	Not recommended in infants. Use with caution in lactation. Has a potential risk in pregnancy.
	Expectorant	Ambroxol Hcl	60-120	<2 yr: 7.5 mg	Lactation. To be

	mucolytics	http://www.mims.com/Page.aspx?menuid=mng&name=ambroxol&brief=true&CTRY=IN&searchstring=ambroxol+hydrochloride	mg/day in 2-3 divided doses x 5 days. Should be taken with food.	twice daily; 2-5 yr: 7.5 mg twice/thrice daily; 6-12 yr: 15 mg twice/thrice daily x 5 days Should be taken with food.	used with caution in pregnancy
Post nasal drips	**Antihistamines**	Diphenhydramine http://www.mims.com/Page.aspx?menuid=mng&name=diphenhydramine&brief=true&CTRY=IN&searchstring=Diphenhydramine	25-40 mg 3 times daily x 5 days	5mg/kg/day in divided doses x 5 days	Contraindicated in hypersensitivity. Use with caution in pregnancy and lactation
	Decongestants	Phenylephrine http://www.mims.com/Page.aspx?menuid=mng&name=phenylephrine&brief=true&CTRY=IN&searchstring=Phenylephrine	4-5 drops in each nostril 6 times daily x 3 days	2 drops in each nostril(>5 yrs) x 3 days	Use with caution in children <5 years, in lactation and pregnancy
	Nasal drops	Xylometazoline Hcl http://www.mims.com/Page.aspx?menuid=mng&name=xylometazoline+hydrochloride&brief=true&CTRY=IN&searchstring=Xylometazoline+Hydrochloride	0.1% soln Adult drops. 1-2 drops in each nostrils x 5 days	0.05% solution Pediatric drops 1-2 drops in each nostrils x 5 days	Angle closure glaucoma; dry rhinitis; post trans-sphenoidal hypophysectomy, trans-nasal, trans-oral surgery where dura mater is exposed. Use with caution in pregnancy and lactation
		Plain saline	Plain saline drops. 2 drops in each nostril PRN.	Plain saline drops. 1-2 drops in each nostril PRN	No contraindications
	Nasal spray	Beclomethasone nasal spray	(50µgm/spray) 2 spray into	Not recommended	

		http://www.mims.com/Page.aspx?menuid=mng&name=beclometasone&brief=true&CTRY=IN&searchstring=beclomethasone+nasal+spray	each nostrils 3-4 times daily		
		Budesonide nasal spray http://www.mims.com/Page.aspx?menuid=mng&name=budesonide&brief=true&CTRY=IN&searchstring=Budesonide+nasal+spray	(100 µgm / spray) 2 sprays into each nostrils once daily	Not recommended	
Rhinitis	**Antiallergic**	Pheniramine maleate http://www.mims.com/Page.aspx?menuid=mng&name=pheniramine&brief=true&CTRY=IN&searchstring=Pheniramine+maleate+	Tab up to 45 mg 3 times daily x 3 days	0.5mg/kg/day syrup 8 hourly x 3 days	Symptomatic prostatic hypertrophy; neonates and premature infants
		Cetrizine http://www.mims.com/Page.aspx?menuid=mng&name=cetirizine+hydrochloride&brief=true&CTRY=IN&searchstring=Cetrizine	10 mg once a day. Max.: 20 mg/day	5mg for<30kg and 10mg for>30kg oral once daily	Hypersensitivity. Not recommended for children below 6 years of age
		Loratadine http://www.mims.com/Page.aspx?menuid=mng&name=loratadine&b	10 mg once daily.	2-5 yr: 5 mg once daily. 6-12 yr: 10 mg once daily.	Pregnancy, lactation, children <2 yr.

		rief=true&CTRY=IN&searchstring=Loratadine			
		Fexofenadine http://www.mims.com/Page.aspx?menuid=mng&name=fexofenadine&brief=true&CTRY=IN&searchstring=Fexofenadine	120 mg once daily as single or in two divided doses.	>6 yrs: same as adults.	not recommended in <6 yrs; known hypersensitivity
Chest infection: URTI/ LRTI/ Pneumonia/Pneumocomiosis	**Macrolides**	Erythromycin http://www.mims.com/Page.aspx?menuid=mng&name=erythromycin&brief=true&CTRY=IN&searchstring=Erythromycin+	500mg 3 times daily x 5 days	5-12.5mg/kg 6 hourly in divided doses x 5 days	Contraindicated in cholestasis jaundice
		Azithromycin http://www.mims.com/Page.aspx?menuid=mng&name=azithromycin&brief=true&CTRY=IN&searchstring=Azithromycin	500mg once daily x 3 days	10mg/kg/day once daily on empty stomach for 3 days	Hypersensitivity. Special precautions in pregnancy and lactation.
	Cephalosporins	Cephalexin http://www.mims.com/Page.aspx?menuid=mng&name=cefalexin&brief=true&CTRY=IN&searchstring=Cephalexin	500mg cap 3 times daily x 5 days	7-12.5mg/kg/dose 6 hourly Max: 4 g daily. x 5 days	Hypersensitivity. Use with caution in pregnancy and lactation
		Cefixime http://www.mims.com/Page.aspx?menuid=mng&name=cefixime&brief=true&CTRY=I	200-400 mg/day as a single dose	8 mg/kg/day as a single dose or in 2 divided doses	Not recommended below 6months of age. Hypersensitivity. Use with caution in pregnancy and

		N&searchstring=Cefixime			lactation
		Cefadroxil http://www.mims.com/Page.aspx?menuid=mng&name=cefadroxil&brief=true&CTRY=IN&searchstring=Cefadroxil	2 g daily as a single or 2 divided doses	15mg/kg/dose 2 times daily;	Hypersensitivity. Use with caution in pregnancy and lactation
		Cefpodoxime http://www.mims.com/Page.aspx?menuid=mng&name=cefpodoxime&brief=true&CTRY=IN&searchstring=Cefpodoxime	100-200 mg tab every 12 hr x 5 days	Child: 8-10 mg/kg/day in 2 divided doses. Max dose: 400 mg daily	Hypersensitivity. Use with caution in pregnancy and lactation
	Quinolones	Ciprofloxacin http://www.mims.com/Page.aspx?menuid=mng&name=ciprofloxacin&brief=true&CTRY=IN&searchstring=Ciprofloxacin	250-750 mg tab 2 times daily x 5 days	5-10 mg/kg/dose 2 times daily x 5 days. *Not to be used in children <12 yr; except where benefit clearly exceeds risk*	Hypersensitivity, pregnancy and lactation. Not to be used concurrently with tizanidine. Avoid exposure to strong sunlight or sun lamps during treatment.
		Levofloxacin http://www.mims.com/Page.aspx?menuid=mng&name=levofloxacin&brief=true&CTRY=IN&searchstring=Levofloxacin	500 mg tab once daily for 7-14 days	Not recommended	Contraindicated in < 18 years of age. Use with caution in pregnancy and lactation
	Tetracyclines	Doxycycline http://www.mims.com/Page.aspx?menuid=mng&name=doxycycline&	100mg 2 times daily x 5 days	5mg/kg/day in 2 divided doses x 5 days	Contraindicated in children <12 years and in pregnancy and lactation.

		brief=true&CTRY=IN&searchstring=Doxycycline			
	Penicillin	Amoxicillin http://www.mims.com/Page.aspx?menuid=mng&name=amoxicillin+%2b+clavulanic+acid&brief=true&CTRY=IN&searchstring=amoxicillin	Mild/moderate infections: 250 mg 8 hourly or 500 mg 12 hourly Severe infections: 500 mg 8 hourly or 875 mg every 12 hrly	Mild/moderate infections: Children >3 months= 20-25 mg/kg/day in 2-3 divided doses. Severe infections: Children(>3 months)=40-45 mg/Kg/day in 2-3 divided doses Infants(<3 months): max dose 30 mg/kg/day in 2-3 divided doses.	Known hypersensitivity to β-lactam
		Ampicillin http://www.mims.com/Page.aspx?menuid=mng&name=ampicillin&brief=true&CTRY=IN&searchstring=Ampicillin	250-500 mg 6 hourly. Max. 1 g 6 hrly. Inj.: 0.5-1 g I.M. or I.V. 6 hrly.	12.5-25 mg/kg/dose oral. Neonates: 25-50 mg/Kg/dose I.V. every 12 hours	Known hypersensitivity to β-lactam
Bronchitis/ asthma/COPD /Pneumoconiosis	**Inhaled glucocorticoids**	Beclomethasone http://www.mims.com/Page.aspx?menuid=mng&name=beclometasone&brief=true&CTRY=IN&searchstring=Beclomethasone	600-800 µgm daily (1-2 puffs) in 3-4 divided doses daily	Same as adults in >12 years, 50-100 µgm (1-2 puffs) 2 times daily	Contraindicated in hypersensitivity and acute infection
	Inhaled bronchodilators	Salbutamol http://www.mims.com/Page.aspx?	100-200 µgm aerosols (1-2 puffs) 3-4	100 µgm aerosols (1-2 puffs) 3 times	Contraindicated in hypersensitivity

		menuid=mng&name=salbutamol&brief=true&CTRY=IN&searchstring=Salbutamol	times daily	daily	
	***Bronchodilators and mast cell stabilizers (for** Nebulization)*	Ipratropium Bromide http://www.mims.com/Page.aspx?menuid=mng&name=ipratropium+bromide&brief=true&CTRY=IN&searchstring=Ipratropium+Bromide	500 mcg (1 unit dose vial) 3-4 times daily.	0.4-2ml to be diluted in 2-4 ml of NS and given over 10 mints, 3-4 times daily	Use with caution in pregnancy and lactation
		Salbutamol http://www.mims.com/Page.aspx?menuid=mng&name=salbutamol&brief=true&CTRY=IN&searchstring=salbutamol	2.5-5 mg respules up to 4 times daily	2.5 ml salbutamol + 1.5 ml Normal saline (2.5-5 mg respules) up to 4 times daily	Eclampsia and severe pre-eclampsia; intra-uterine infection, intra-uterine foetal death, antepartum haemorrhage, placenta praevia and cord compression, threatened miscarriage, cardiac disease.
		Budesonide http://www.mims.com/Page.aspx?menuid=mng&name=budesonide&brief=true&CTRY=IN&searchstring=Budesonide	1-2 mg inhaled 2 times daily Maintenance dose: 0.5-1 mg 2 times daily	3 mth-12 yr: Initially, 0.5-1 mg bid. Maintenance dose: 0.25-0.5 mg 2 times daily.	Hypersensitivity. Acute infections uncontrolled by antimicrobial chemotherapy. Use with caution in pregnancy and lactation.
Tropical Eosinophilia	Anthelmintics	*Diethylcarbamazine (hetrazan)* http://www.mims.com/Page.aspx?menuid=mng&name=diethylcarbamazine&brief=true&CTRY=IN&searchstring=Diethyl	Initially, 1 mg/kg daily, increased gradually to 6 mg/kg daily over 3 days then maintained for 3 weeks	10 mg/kg/day 8 hourly for 1 month	Pregnancy, hypersensitivity; lactation; infants, elderly or debilitated patients; impaired renal function; cardiac disease.

		carbamazine+(hetrazan)+			
GERD	***PPI***	*Omeprazole* *http://www.mims.com/Page.aspx?menuid=mng&name=omeprazole&brief=true&CTRY=IN&searchstring=Omeprazole*	20 mg once daily for 4 wk	Not recommended	Exclude malignancy, prolonged use, hepatic impairment. Pregnancy, lactation, children <1 yr. Elderly and Asians (increased bioavailability).
		Lansoprazole *http://www.mims.com/Page.aspx?menuid=mng&name=lansoprazole&brief=true&CTRY=IN&searchstring=Lansoprazole*	30 mg once in the morning for 4-8 wk.	Not recommended	Special precaution in pregnancy and lactation
Tuberculosis	***AntiTB agents*** *Intensive phase (Category I)*	*http://www.mims.com/Page.aspx?menuid=pilDetail&mononame=ACTIZID%20tab&pilid=343&CTRY=IN&searchstring=Anti-TB%20Agents*	Isoniazid 600 mg thrice a week for 2 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 2 months + Pyrazinamide 1500mg thrice a week for 2 months + Ethambutol 1200mg thrice a week for 2 months For adults over the age of 50: add streptomycin 500mg thrice a week for 2 months	If symptoms of TB confirmed by Physician: Isoniazid 5-10mg/kg thrice a week for 2 months + Rifampicin 10mg/kg thrice a week for 2 months + Pyrazinamide 25mg/kg thrice a week for 2 months For asymptomatic at risk child: Isoniazid 5mg/Kg/day (maximum dose = 300mg) for three months (Review after 3 months)	Antibiotics used in the treatment should not have Anti Tuberculosis activity (e.g. co-trimoxazole. Avoid floroquinolones, rifampicin and streptomycin Contraindication: Hepatic damage

	Continuation phase (category I)	*As above*	Isoniazid 600 mg thrice a week for 4 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 4 months	Refer to section above (pediatric dosage)	
	Category II Intensive phase	*As above*	Isoniazid 600 mg thrice a week for 2 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 2 months + Pyrazinamide 1500mg thrice a week for 2 months + Ethambutol 1200mg thrice a week for 2 months + Streptomycin 500mg thrice a week for 2 months FOLLOWED BY Isoniazid 600 mg thrice a week for 1 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 1 months + Pyrazinamide 1500mg thrice a week for 1 months +	Refer to section above (pediatric dosage)	

			Ethambutol 1200mg thrice a week for 1 months		
	Category II continuation phase	*As above*	Isoniazid 600 mg thrice a week for 5 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 5 months + Pyrazinamide 1500mg thrice a week for 2 months + Ethambutol 1200mg thrice a week for 5 months	Refer to section above (pediatric dosage)	
	Category III Intensive phase	*As above*	Isoniazid 600 mg thrice a week for 2 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 2 months + Pyrazinamide 1500mg thrice a week for 2 months	Refer to section above (pediatric dosage)	
	Category III Continuation phase	*As above*	Isoniazid 600 mg thrice a week for 4 months + Rifampicin 450mg (600mg if weight>60Kg) thrice a week for 4 months	Refer to section above (pediatric dosage)	

Note: Syrups are usually given in the pediatric age group.Add treatnment for Swine Flu.

Refer to appendix for Details of treatment of Tuberculosis.

7.2.1. Drug side effects / adverse reactions

Some of these drugs may have side effects. These are listed below. While some of these side effects are brief and temporary - Alert your doctor if they become severe or refuse to go away.
Side effects of these drugs may include

- Anti-tussives (Codeine) may cause constipation,
- Anti-tussives (Dextromethorphan) may cause headache, nausea.
- Antihistamines (Diphenhydramine) may cause nausea, vomiting, dizziness, increased sleep,
- Decongestants (Phenylephrine) may cause sneezing, stinging and burning
- Nasal drops (Xylometazoline Hcl) may cause local burning, sneezing, and dryness of mouth.
- Antiallergic (Cetrizine) may cause nausea, vomiting, constipation or diarrhea, dizziness, dry mouth.
- Cephalosporins (cephalexin) may cause nausea, diarrhea, and hypersensitivity reactions like urticaria.
- Quinalones (Ciprofloxacin) may cause nausea, vomiting, diarrhea, headache and dizziness.
- Tetracyclines (Doxycycline) may cause nausea, vomiting, burning in abdomen.
- Penicillin (amoxicillin) may cause skin rashes, fever, urticaria, diarrhea, nausea.
- Inhaled glucocorticoids (Beclomethasone) may cause dryness and irritation in nose; smell and taste disturbances; hoarseness
- Inhaled bronchodilators (Salbutamol) may cause muscle cramps, trembling of hands, headache.
- Bronchodilators and mast cell stabilizers (Ipratropium Bromide) may cause Dry mouth, urinary retention, headache, nausea, constipation; hypersensitivity reactions; nasal dryness and epistaxis (nasal spray).
- Omeprazole may cause diarrhea, fatigue, constipation, flatulence, taste perversion, dry mouth, abdominal pain, skin rashes.
- Antitubercular agents can cause nausea, vomiting, loss of appetite, tiredness, headache and muscle pain.

These drugs could be taken together with food or immediately after a meal. Regular intervals and monitoring for sensitivity or reactions should be emphasized. Tetracycline, if prescribed should not be taken with milk.

8. Follow up:

- Educate the patient to immediately return to the physician if “Alarm signs” appear. (*Refer to patient advisory).*
- Inform about the next timely follow up visit.

9. Patient advice:

Patient education must be reinforced about the disease, its causes, alarm features, prevention, treatment, lifestyle changes and when to seek help.

10. Quality indicators

The quality indicators that are important in documenting the adherence to policy in the management of cough are:

- Detailed history taken
- Referral management for alarm features
- Antibiotics not prescribed for acute cough / for non specified cough
- Smoking cessation advice given if smoker
- Patient education advice given

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Annexure

Tuberculosis treatment

Treatment for tuberculosis is prescribed as per revised national tuberculosis control program

Based on sputum smear results the patient may be categorized under one of the following categories:

Category I

- New sputum smear-positive
- Seriously ill new sputum smear-negative
- Seriously ill new extra-pulmonary

Category II

- Sputum smear-positive - Relapse
- Sputum smear-positive - Failure
- Sputum smear-positive - Treatment After default

Category III

- New Sputum smear - negative - not seriously ill
- New Extra - pulmonary - not seriously ill

Dosage Strengths:

Drug

Dose (thrice a week)

Adults	Pediatric	
Isoniazid 600 mg	5-10mg/kg	referred to as **H**
Rifampicin 450mg (600 mg if wt >60 kg)	10mg/kg	referred to as **R**
Pyrazinamide 1500 mg	25mg/kg	referred to as **Z**
Ethambutol 1200 mg	-	referred to as **E**
Streptomycin 0.75 g IM (0.5 g if age>50 years)	-	referred to as **S**

Treatment composition

Treatment for category I

- Intensive phase - $2H_3R_3Z_3E_3$
- Continuation Phase - $4H_3R_3$

Treatment for category II

- Intensive phase - $2H_3R_3Z_3E_3S_3$ + 1 $H_3R_3Z_3E_3$

- Continuation phase - 5 $H_3R_3E_3$

Treatment for category III

- Intensive phase - 2 $H_3R_3Z_3$
- Continuation phase - 4 H_3R_3

Understanding drug dosages:

- The number before the letters refers to no. of months of treatment. The subscript after the letters refers to no. of doses per week.
- Patients in categories I, II who have positive sputum smear at the end of intensive phase should receive an additional month of intensive phase treatment. (This has been referred to as the continuation phase)
- For adults above 60 Kg an additional capsule of rifampicin 150 mg is recommended as addition to the treatment regimen.
- For adults over 50 years of age, streptomycin 500mg is recommended.

Drugs are supplied in patient wise boxes containing the full course of treatment and packaged in blister packs. The packs are color coded for different categories (Red for Cat I, Blue for cat II and Green for Cat III). In each box there are two pouches - one for intensive phase (A) and one for continuation phase (B). For the intensive phase, each blister pack contains medicines for one dose. For the continuation phase, each blister pack contains one week's supply of medication.

Other notes:

During pregnancy:

- All anti tuberculosis drugs used in RNTCP except streptomycin are safe during pregnancy.
- Breast feeding should be continued regardless of mother's Tuberculosis infective status.

Other drugs

- Antibiotics used in the treatment should not have Anti Tuberculosis activity (e.g. co-trimoxazole. Avoid floroquinolones, rifampicin and streptomycin).

<u>Pediatric tuberculosis</u>

Child contacts TB - < 6 years of age with sputum smear positive case:

- If the child has symptoms of tuberculosis and if it is confirmed by the treating physician – a full
- Course of ATT (CAT III) should be given.
- If the child does not have symptoms: Tuberculin test: Not available – chemotherapy for 6 months Isoniazid 5 mg/kg. If Tuberculin test: Available – child should be given INH chemotherapy for 3 months and Tuberculin test should be done, then treat as per the notes given below.
  Note:

  If induration to tuberculin test < 6mm, stop preventive chemotherapy and vaccinate with

  B.C.G (if not vaccinated previously).

If induration is >6mm, continue INH preventive chemotherapy for another 3 months.

Vaccination:

BCG vaccination does not protect an individual from developing adult type pulmonary tuberculosis. But, several studies indicate that BCG prevents serious forms of tuberculosis in children.

In case of associated conditions and complications please refer to hospital physician.

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