

# PRESCRIBING PATTERN OF COUGH AND COLD MEDICINES IN CENTRAL GUJARAT

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## ABSTRACT

**Background:** Cough and common cold are one of the commonest morbidities in the community. Cough and cold medicines are abundant in Indian market despite the fact that majority of them lack scientific evidence of their use in this common condition.

**Aims & Objective:** To analyze the prescribing pattern of 'cough and cold' medicines in Central Gujarat.

**Material and Methods:** An observational, cross-sectional, questionnaire-based study was carried out to assess the prescribing pattern of doctors with regard to cough and cold. A total of 100 prescribers with a graduate degree (n=50) or a post-graduate degree (n=50) from Central Gujarat were selected randomly. After interviewing all doctors, data were analyzed to find the percentage of patients prescribed 'cough & cold medicines', their types of dosage form, use of FDCs, indications, any adverse events encountered and non-pharmacological measures advocated.

**Results:** Prescribing FDCs for cough and cold was significantly higher (92% vs 72%, P<0.05) in post graduate prescribers attached to private hospitals than in graduate prescribers attached to government/teaching hospitals. Usage of solid dosage forms was significantly higher (p<0.05) in prescribers attached to government or teaching hospitals as compared to prescribers attached to private hospitals (84% vs 60%). About 18% of graduate and 25% of post graduate prescribers gave cough and cold medicines at patients' behest. Only 15% prescribers prescribed cough and cold medicines for dry cough while antihistamines were advocated by 96% of prescribers. About 50% of the physicians prescribed these medicines for conditions like upper and lower respiratory tract infections. Non pharmacological measures were recommended by 75% prescribers.

**Conclusion:** Efforts are needed to create awareness amongst prescribers about the rational use of cough & cold medicines and also pay attention to ADR caused by them. Reforms in medical education and CME are recommended.

**KEY-WORDS:** Cough and Cold Medicines; Prescribing Practice; Rational Use of Cough and Cold Medicines; Evidence Based Medicine

## Introduction

Cough is a useful physiological mechanism that serves to clear the respiratory passages of foreign material and excess secretions. When excessive or bothersome, it is also one of the most common symptoms for which patients seek medical attention.<sup>[1]</sup> A recent survey done by Nielsen India noted that 56% of Indians (the highest in the country) suffered from cold in the year 2009-10 which was fourth highest globally and the next higher percentage of ailment was cough (54%).<sup>[2]</sup>

The most common causes of cough can be categorized according to the duration of the cough. Acute cough (<3 weeks) is most often due to upper respiratory infections like common cold, acute bacterial sinusitis, and pertussis. Subacute cough (between 3 and 8 weeks) is commonly

post-infectious, resulting from persistent airway inflammation and/or postnasal drip. Chronic cough (>8 weeks) in a smoker is due to chronic obstructive lung disease or bronchogenic carcinoma. In a non-smoker the most common causes of chronic cough are postnasal drip, asthma, and gastroesophageal reflux.<sup>[1]</sup> An irritative, non-productive cough may be suppressed by an antitussive agent, which increases the threshold of the cough center.<sup>[1,3,4]</sup> A cough which produces a significant quantity of sputum should usually not be suppressed, since retention of sputum in the tracheobronchial tree may interfere with the distribution of alveolar ventilation and the ability of the lung to resist infection.<sup>[1,3-5]</sup> Treatment of productive cough depends on determining the underlying cause and then initiating specific therapy.<sup>[1,3]</sup>

Cough and cold medicines are rampantly prescribed by physicians in many countries. A study done in Hong Kong showed that 400,000 litres of cough mixtures were dispensed by 48 government outpatient clinics in 2001 and the extent of cough mixtures use in private practice is likely to be even greater.<sup>[6]</sup> However, the clinical value of many cough mixtures is debatable and their use in children and the elderly is controversial.<sup>[7]</sup> Despite the increasing concern over the effectiveness and safety of these drugs, cough and cold medicines abound in Indian market, with more than 1300 formulations, and are increasing over the years.<sup>[8]</sup> Two different studies done by Manoj KS et al and Mohanty et al showed that out of total prescribed drugs, about 10% and 39% were cough preparations respectively.<sup>[9,10]</sup>

WHO has defined “Essential drugs are those that satisfy the healthcare needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms and at a cost that individuals and the community can afford”. The Medical Council of India (MCI) dictates to its registered members that “Every physician should, as far as possible, prescribe drugs with generic names and he / she shall ensure that there is a rational prescription and use of drugs”.<sup>[11]</sup> Seventeenth model List of Essential Medicines (WHO 2011) has not included any category for cough and cold medicines.<sup>[12]</sup> Ideally prescribers should prescribe affordable and essential medicines to their patients but sometimes costly branded medicines are prescribed instead of their cheaper alternatives.<sup>[9]</sup> Irrational prescription is a common occurrence throughout the world, it is seen everywhere (in teaching and non-teaching institutions), at all levels (senior and juniors) and in all categories (family physicians, specialists, and super specialists).<sup>[13]</sup>

Though abundant literature from evidence-base is available focusing on the futility of formulations for ‘cough and cold’, more than 1300 such formulations flood the Indian market and prescribers prescribe them freely.<sup>[8]</sup> This leads not only to waste of scarce resources of our country; it may produce adverse and sometime harmful effects in the recipients. It was, therefore, thought

prudent to carry out this study to analyze and understand prescribing pattern of prescribers in central Gujarat with regard to use of medicines for ‘cough and cold’.

## Materials and Methods

This was an observational, cross-sectional, questionnaire based study carried out in the department of Pharmacology, SBKS Medical Institute & Research Centre, Sumandeep Vidyapeeth, Vadodara, Gujarat after obtaining approval of the study from the Sumandeep Vidhyapeeth Institutional Ethics Committee (SVIEC).

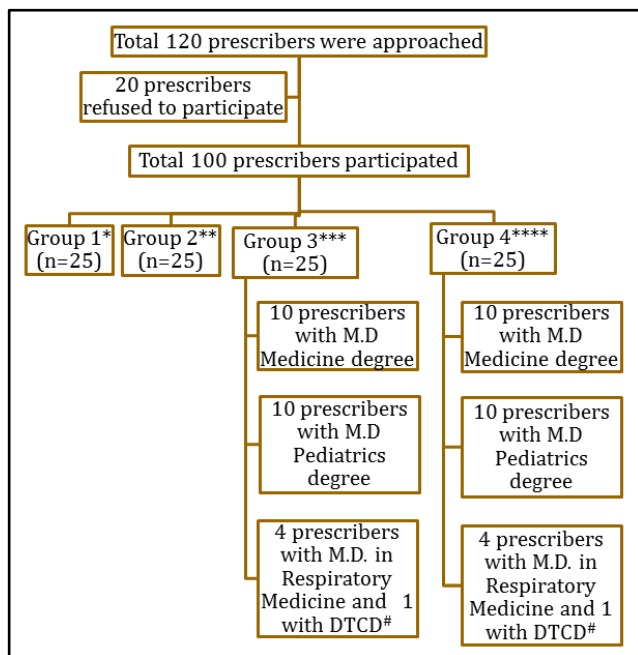
### Study Procedure

A structured questionnaire (12 questions including open - and close - ended) was prepared to assess the prescribing pattern of prescribers with regard to treatment of cough and common cold. This questionnaire was validated by two subject experts and it was pretested in 10 volunteer prescribers to check for the feasibility.

A total of 100 prescribers from different cities across Central Gujarat were selected randomly for the study. Out of these, 50 prescribers were having a graduate degree (M.B.B.S) while other 50 were having a post-graduate (M.D) degree. Only in 2 cases, the post-graduate prescribers did not have a post-graduate degree, but had post graduate Diploma in Tuberculosis and Chest Diseases (DTCD). Among post-graduate prescribers the specialities included were Medicine, Paediatrics and Respiratory Medicines. All prescribers were clearly explained about the objectives and nature of study. They were given an opportunity to ask clarification if any, and were included only after they gave written informed consent for the same. They were assured that confidentiality will be maintained at all the stages of study. They were interviewed for about 15-20 minutes after taking their prior appointments. The questionnaire was filled up on the spot in the way they were answered by respondents. At the end of the interview each respondent was given the questionnaire to read and approve the same.

Prescribers from Central Gujarat, prescribers having MBBS degree and prescribers having post-

graduate degree in Medicine, Paediatrics and Respiratory Medicines, willing to participate in the study were included. Prescribers from categories other than the above were excluded from the study. Out of the 50 graduate (M.B.B.S) doctors, 25 were engaged in private practice while the other 25 were attached to government hospitals/ tertiary care teaching hospitals as medical officers. Similarly, half of the post-graduate prescribers were doing private practice and rest half were engaged with tertiary care teaching hospitals. (Figure-1)



**Figure-1: Hierarchy Showing Prescribers with Respective Degrees Enrolled in the Study** (\* Group-1: Practitioners with MBBS degree and attached to Government/Tertiary Care Teaching Hospitals; \*\* Group-2: Practitioners with MBBS degree and engaged in private practice; \*\*\* Group-3: Practitioners with post-Graduate qualification and attached to Government/Tertiary Care Teaching Hospitals; \*\*\*\* Group-4: Practitioners with post-Graduate qualification and engaged in private practice; # Diploma in Tuberculosis and Chest Diseases)

After interviewing all doctors, data were analyzed to find the information like their professional experience, percentage of patients to whom they prescribe cough and cold medicines, whether the drug is prescribed by official (generic) or brand name, type of dosage form, prescribing of FDCs (if any), type of cough for which they prescribe these medicines, common conditions for which the drug is given, any adverse events which they encountered with use of cough and cold medicines, non-pharmacological measures advocated by them (if any) percentage of patients

for whom these medicines were prescribed at their behest (request or insistence).

### Statistical Analysis

Data were analysed using Microsoft Excel 2007 version. Chi-square test was used for statistical analysis of data. 'p' value < 0.05 were regarded as statistically significant.

### Results

All the 100 doctors, who consented to participate in the study, responded to all 12 items of questionnaire in personal interview and thus all 100 questionnaires could be completed in all regards. Out of 100 participant doctors, 60 had professional experience of 10 years or less while the other 40 had professional experience of more than 10 years.

### Prescribing Pattern

**Table-1: Prescribing Pattern of Prescribers**

	Groups				P value	
	1	2	3	4	X	Y
Patients prescribed cough and cold medicines (%)	36.95	33.87	43.88	35.93	0.55	0.56
Use of Fixed-dose Drug Combinations (%)	64.00	88.00	80.00	96.00	<b>0.0005</b>	<b>0.04</b>
Liquid dosage form used (%)	60.00	88.00	76.00	88.00	<b>0.001</b>	0.23
Solid dosage form used (%)	92.00	80.00	76.00	40.00	<b>0.0003</b>	<b>0.0001</b>
Medicines prescribed at patient's behest (%)	18.37	18.00	29.00	22.50	0.73	0.23

**Group-1:** Practitioners with MBBS degree and attached to Government/Tertiary Care Teaching Hospitals; **Group-2:** Practitioners with MBBS degree and engaged in private practice; **Group-3:** Practitioners with post-Graduate qualification and attached to Government/Tertiary Care Teaching Hospitals; **Group-4:** Practitioners with post-Graduate qualification and engaged in private practice; **X:** P value for group 1 plus 3 vs group 2 plus 4; **Y:** P value for group 1 plus 2 vs group 3 plus 4

Percentage of patients prescribed cough and cold medicines by graduate prescribers attached to government hospitals/tertiary care teaching hospitals (Group 1) and those engaged in private practice (Group 2) were 36.95% and 33.87% respectively (Table 1). Post-Graduate prescribers from government/tertiary care teaching hospital (Group 3) and those engaged in private practice (Group 4) prescribed cough and cold medicines to 43.88% and 35.93% of the patients respectively.

(Table 1) There was no significant difference between the number of patients prescribed 'cough and cold' medicines by prescribers depending either on their qualification or status of engagement ( $p > 0.05$ ) (Table 1).

Prescribing of FDCs for cough and common cold was significantly higher (92%,  $p=0.0005$ ) in prescribers engaged in private practice (group 2 and 4, Table 1) than in those attached to government/ tertiary care teaching hospitals (72%, groups 1&3, Table 1) irrespective of their qualification. Similarly prescribing FDCs of cough and cold medicines was significantly higher by postgraduate doctors (88% vs 76%, groups 3 plus 4 vs groups 1 plus 2,  $p=0.04$ ) irrespective of their engagement as private or working in government/ tertiary care teaching hospitals (Table 1).

Usage of liquid dosage form was significantly higher in prescribers engaged in private practice as compared to those working in government/tertiary care teaching hospital ( $p=0.001$ ). With relation to use of solid dosage forms we found that it was significantly higher ( $p=0.0003$ ) in prescribers attached to government hospital/ tertiary care teaching hospitals (groups 1 & 3, Table 1) as compared to prescribers engaged in private hospitals (groups 2& 4, Table 1). Similarly graduate prescribers irrespective their nature of engagement (group 1 plus 2 vs group 3 plus 4, Table 1), prescribed significantly more (86% vs 58%,  $p=0.0001$ ) solid dosage form for cough and common cold than post graduate doctors.

About 18% and 26% of patients were prescribed cough and cold medicines respectively by graduate prescribers and post graduate prescribers at patient's behest (groups 1 plus 2 and 3 plus 4, Table 1). There was no significant difference between the two ( $p > 0.05$ , Table 1).

#### ***Influence of Practising Experience on Prescribing Pattern***

Prescribers with less than 10 years of clinical experience prescribed cough and cold medicine to their 37.98 % of total patients while those who had more than 10 years of experience were prescribed to their 35.84% of patients (Table 2).

**Table 2: Years of Practice and Prescription Pattern**

Use of Cough and Cold Medicines	Years of Practice		P value*
	0-10 Years (60)	> 10 Years (40)	
Patients prescribed cough and cold medicines (%)	37.98	35.84	0.88
Use of Fixed-dose Drug Combinations, n (%)	51(85)	31(77.5)	0.27
Liquid dosage form used, n (%)	48(80)	30(75)	0.5

\* Chi square test,  $p < 0.05$  considered significant

Usage of FDCs for cough and cold did not differ significantly among prescribers with 0-10 years' experience and those with more than 10 years of experience (85% and 77.5%) (Table 2).

There was no significant difference on prescribing liquid dosage form for cough and cold with practising experience (80% and 75%).

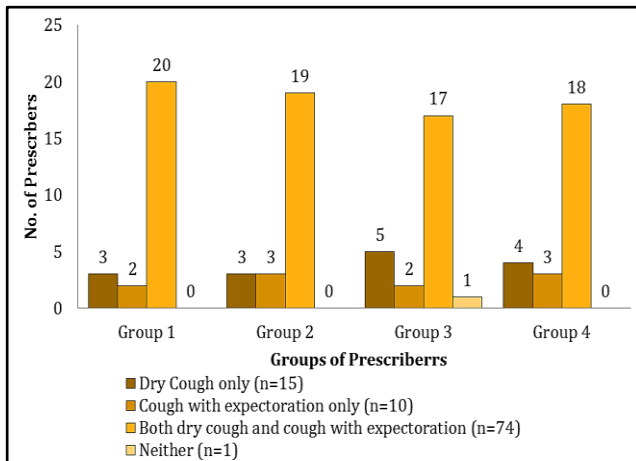
#### ***Type of Cough and Prescribing of Cough and Cold Medicines***

On inquiring about the type of cough for which the prescribers prescribed cough and cold medicines, it was noted that 74 prescribers prescribed cough and cold medicines for both dry cough as well as for cough with expectoration while only 15 prescribers prescribed these medicines just for dry cough only. Ten prescribers responded that they prescribe these medicines for cough with expectoration only while 1 prescriber said that he did not prescribe these medicines for any type of cough (Figure 2).

#### ***Common Conditions for with Cough and Cold Medicines are prescribed***

Antihistamines were advocated by 96% of prescribers for cough and cold (Table 3). Other drug groups prescribed for cough and cold were antitussives (61%), expectorants (61%), mucolytics (60%), decongestants (61%), bronchodilators (51%) and NSAIDs (49%). (Table 3) Antibiotics for treatment of cough and common cold were advocated by only 14% of prescribers (Table 3).

More than half of the prescribers prescribed cough and cold medicines for conditions like upper and lower respiratory tract infections. (Table 4)



**Figure-2: Type of Cough and Use of Cough and Cold Medicines (Group-1: Practitioners with MBBS degree and attached to Government/Tertiary Care Teaching Hospitals; Group-2: Practitioners with MBBS degree and engaged in private practice; Group-3: Practitioners with post-Graduate qualification and attached to Government/Tertiary Care Teaching Hospitals; Group-4: Practitioners with post-Graduate qualification and engaged in private practice)**

**Table-3: Prescribing Pattern of Prescribers**

Category of Cough & Cold Medicines	Groups (%)			
	1	2	3	4
Antitussive	36	88	56	64
Expectorant	48	76	52	68
Antihistaminic	100	92	92	100
Bronchodilator	16	60	60	68
Mucolytic	28	84	48	80
Decongestant	52	72	60	60
Non-steroidal anti-inflammatory drugs	40	48	64	44
Antibiotic	20	8	12	16
Non-pharmacological measure	84	56	76	80
Miscellaneous	68	28	32	44

**Group-1:** Practitioners with MBBS degree and attached to Government/Tertiary Care Teaching Hospitals; **Group-2:** Practitioners with MBBS degree and engaged in private practice; **Group-3:** Practitioners with post-Graduate qualification and attached to Government/Tertiary Care Teaching Hospitals; **Group-4:** Practitioners with post-Graduate qualification and engaged in private practice

**Table-4: Common Conditions and Use of Cough and Cold Medicines**

Common Conditions	Number of Prescribers Prescribing Cough and Cold Medicines
<b>Infectious Causes</b>	
Upper respiratory tract infection (URTI)	69
Lower respiratory tract infection (LRTI)	64
Rhinitis	43
Tuberculosis	6
<b>Non-infectious/Allergic Causes</b>	
Allergic cough	16
Asthma	21
Reactive airway disease	4
<b>Non-specific Causes</b>	
Non-specific dry cough	15
Body ache, fever, headache	7

**Table-5: Use of Cough and Cold Medicines and Adverse Effects**

Adverse Effects	Number of Prescribers (n=100)
Sedation	44
Drowsiness	21
Constipation	12
Dry mouth	8
Urticaria	6
Tremor	5
Headache	2
Diarrhoea	2
Vomiting	2
Dependence	2

**Table-6: Use of Non-Pharmacological Measures by Prescribers (n=100)**

Non-Pharmacological Measures	Number of Prescribers
Water vapour (steam) inhalation	56
Warm water saline gargle	36
Post nasal drainage	12
Sialagogues (sugar cube, ginger, clove etc.)	9
Use of eucalyptus oil	9
Consumption of hot beverages	4
Breathing exercises	2
Use of turmeric/ lemon juice	1

As shown in table 5, sedation is the most common side effect (44%) noted by doctors, followed by drowsiness (21%) and constipation (12%) with use of cough and cold medicines.

A good number of prescribers (74%) had advocated for non-pharmacological measures like water vapour inhalation, hot beverages, sialagogues etc, albeit in addition to drug therapy and not as sole remedy, expect one prescriber (Table 6). Most commonly advised non pharmacological measures included water vapour inhalation (56%) and warm saline gargles (36%). Non pharmacological measures such as water vapour inhalation and warm saline gargles for cough and common cold were recommended by 84% and 56% of graduate prescribers working with government/tertiary care teaching hospital and engaged in private practice respectively (Table 3). Seventy eight percent of post-graduate prescribers also recommended non pharmacological measures for cough and common cold (Table 3).

## Discussion

Cough and cold are one of the most common causes of morbidity.<sup>[2]</sup> Different drugs used in its

treatment have insufficient evidence base and rationale for their use in these conditions. Prescribing behaviour of physicians also varies with regard to management of cough and cold. Therefore, this study was carried out to evaluate the prescribing behaviour of different groups of practitioners for this common ailment.

Among all the Over The Counter (OTC) drugs sold in India, cough and cold preparations had almost 18% of OTC healthcare market share in the year 2010.<sup>[14,15]</sup> The cough and cold preparations category was valued at INR 16,705.6 million (\$384m) in 2009 and by the end of 2014 the cough and cold preparations category in India will be worth INR 21,524.1 million (\$494.7m).<sup>[16]</sup> These figures are alarming considering the fact that most of them are irrational and serve no good purpose in treating common cold and cough. Not only this amounts to be a wasteful expenditure, it is often associated with undesirable effects, the management of which may further escalate the cost. This is certainly a huge price to pay 'especially in developing country like India' for a self-limiting condition.

In the present study we found that physicians prescribed the cough and cold medicines routinely with more than 37% of total patients being prescribed one or the other cough or cold medicine. Despite the fact that no fixed dose combination has any rationale in treatment of cough or common cold<sup>[3, 17]</sup>, about 82% prescriber prescribed cough and cold medicine in the form of FDC. Among different categories of doctors, 96% of prescribers with post-graduate degree and engaged in private practice prescribed FDCs for cough and cold while the MBBS prescribers working in government/tertiary care teaching hospitals prescribed significantly less number (64%,  $p < 0.05$ ) FDC, multiple ingredients in a formulation increase the risk of drug interactions and adverse drug reactions and even the cost.

Liquid oral formulations are helpful for paediatric patients and elderly having dysphagia, but are generally expensive and have no more advantage over solid oral dosage forms. They also share common problems with all medicines not dispensed in tablet form, including difficulties with precise measuring of doses and the common

practice of exceeding recommended doses, which can lead to significant unintended complications. Yet 78% of prescribers in this study prescribed liquid dosage forms routinely to their patients. Among all groups of prescribers, those engaged in private practice tend to prescribe significantly more of liquid dosage formulations than doctors engaged in government/teaching hospitals.

It is generally believed that with more years of professional experience a doctor tends to be a more rational prescriber, but in this study we did not find any kind of association with percentage of patients prescribed cough and cold medicines, prescribing FDC or liquid dosage form for cough and common cold which are generally unnecessary for this condition.

It needs to be understood that cough is a useful physiological mechanism that serves to clear the respiratory passages of foreign material and excess secretions. Suppressing a productive cough can cause retention of sputum in the tracheobronchial tree and may interfere with the distribution of alveolar ventilation and the ability of the lung to resist infection.<sup>[1,3-5]</sup> Symptomatic or nonspecific therapy of cough should be considered when the cause of the cough is not known or specific treatment is not possible, and when the cough performs no useful function (dry cough) or causes marked discomfort or sleep disturbance. However, in this study we found that only 15% prescribers prescribed cough and cold medicine just for dry cough only while 10% and 74% prescribers prescribed these medicines for cough with expectoration and for both types of cough respectively. Only 1 doctor responded that he did not prescribe cough and cold medicine for any condition. This is worrisome considering the fact that suppressing cough with expectoration (productive cough) can do more harm than good. Most common conditions for which cough and cold medicines were prescribed were upper respiratory tract infections followed by lower respiratory tract infections, rhinitis, asthma, allergic cough, non-specific dry cough and others. Upper respiratory tract infections, the most common cause of cough, are mostly viral in origin, are usually self-limiting and require no drug therapy. Use of cough and cold medicines in this condition is largely ineffective.<sup>[1,17,18]</sup>

An irritative, non-productive cough may be suppressed by an antitussive agent, which increases the latency or threshold of the cough centre.<sup>[1,3,4]</sup> Sixty-one per cent prescribers responded that they prescribe antitussives for cough. Role of antihistamines for cough has not been established, except for their use in cough associated with post nasal drip and allergic rhinitis.<sup>[19-21]</sup> In spite of that 96% prescribers prescribe antihistamines for cough and common cold. Over and above this, an FDA review of records from 1969 to 2006 revealed more than 120 paediatric deaths arising from overdose of decongestants or antihistamines.<sup>[22]</sup> It is not surprising that 85% of prescribers in this study noted adverse effects like sedation, drowsiness, constipation and dry mouth which may have been caused by presence of an antihistamine and/or an antitussive in the cough and cold medicines prescribed. Our previous study analysing 1298 formulations of cough and cold medicines had shown that 71% of formulations contained an antihistamine. Use of other ingredients like expectorants, mucolytic and Non-Steroidal Anti-inflammatory Drugs (NSADs) are also of questionable value.<sup>[1,3,4,23-26]</sup> Using decongestants for symptomatic relief for cough and common cold can also lead to significant side effects in many patients.<sup>[27,28]</sup>

In patients who find it difficult to clear mucus, adequate hydration and inhalation of water vapour or hot beverages may be of some benefit.<sup>[3,17]</sup> Many patients with chest disease become dehydrated and adequate hydration along with water vapour inhalation can alone help to liquefy viscid sputum.<sup>[3]</sup> In this study 74% prescribers had advocated for some or other non-pharmacological measures notably the use of water vapour inhalation or warm saline gargle (Table 6). This is gratifying and more and more prescribers should be encouraged to use non-pharmacological measures for symptomatic relief of cough and common cold.

Though the study has given insight into prescribing behaviour of doctors with regard to use of cough and cold medicines, it suffers from a few limitations, notably inclusion of a small sample size (only 100 responders) and that to from a small geographical zone (central Gujarat)

only. Moreover, reliance has been on responses to only a questionnaire, actual prescription analysis could have served a better purpose. However, despite this limitations study has confirmed many aspects of practice already established earlier.

## Conclusion

Cough and cold are two very common complaints of many. They are largely the manifestations of respiratory tract infections, many of which are self-limiting in nature. By and large no pharmacological treatment is necessary for these symptoms except proper hydration, water vapour inhalation and throat gargles with warm saline. Use of the so called cough and cold medicines, several of which are available as OTC medicines widely, have no role to play and may become the cause of adverse effects. This knowledge is nothing new, many evidence based articles published even 30 years ago<sup>[19-21,23,24,27,28]</sup> stand testimony to this fact. Prescribers, during their training period, are expected to learn all this. Despite this, the fact is that useless, unduly expensive and at times harmful cough and cold medicines keep flooding the Indian market. Prescribers, may be due to lack of adequate training or/and lack of self-confidence, keep them prescribing. The end-result is that the gullible patient's pockets are drained of their hard-earned money and the profit margins of pharmaceutical companies become fat. It is important to address this issue by emphasizing on the need of proper training of prescribers during their formative years and re-enforcing the same through Continuous Medical Education (CME) programs.

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