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Development and readability assessment of patient information leaflets for chronic obstructive pulmonary disease

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ABSTRACT

Patient education is one of the major management strategies for preventing the progression of Chronic Obstructive Pulmonary Disease (COPD). Patient Information Leaflets (PILs) are major patient counseling aids. Hence the PILs were developed for imparting patient education regarding COPD. Objective of the study was to develop and assess readability of patient information leaflets for COPD. PILs were developed by referring various model leaflets which were available from the different online resources such as "Patient UK", Pubmed & MICROMEDEX Data base. Readability of the PIL was checked online by calculating Flesch Reading Ease (FRE) and Flesch Kincaid-Grade Level (FK-GL) by using the website "www.readability-score.com". Baker Able Leaflets Design (BALD) method was used to assess the layout and design characteristics of the PIL. During the preparation of leaflet, its readability was periodically assessed using FRE and FK-GL scores. After assessment, leaflets were modified and the readability scores were reassessed which showed improvement after each modification. The best Flesch Reading Ease score achieved was 68.3 and Flesch-Kincaid Grade Level score achieved was 7.4. The BALD score was 27. This study strongly suggests that patient information leaflet developed by us have standard readability score and good layout design. FRE and FK-GL scores have shown that the leaflet was fairly easy readable.

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. In individual patients, exacerbations and co-morbidities contribute to disease severity [1]. COPD is the second most common non-infectious disease in the world, causing 2.7 million deaths annually, and global mortality is predicted to be more than double by 2030 [2].

It is well known that Patient education and knowledge are directly related to improvement in treatment outcome. Patient education and patient knowledge has received suboptimal attention in India, although disease severity and psychosocial factors are well known contributors to asthma and COPD morbidity [3]. Patients' beliefs about the illness and medications will influence their decisions to follow the recommended treatment [4]. Hospital admissions and crises can be reduced by early intervention, especially from self-management plans, in some COPD patients. A positive treatment outcome can be achieved in COPD patients by health education [5].PILs are widely used by diverse health organizations and professionals as a part of patient education or health promotion efforts, in support of prevention, treatment and compliance objectives [6]. Lack of information has been identified as a major factor for the patients not taking their medicines as the prescriber intends. Patients for whom medication is prescribed must understand how to take each drug correctly. Patient counseling and the provision of educational material in the form of PILs have been shown to be effective in improving patients' knowledge, compliance and the awareness of potential side-effects of drugs [7]. Readability is "the efficiency with which a text can be comprehended by a reader, as measured by reading time, amount recalled, questions answered, or some other quantifiable measure of a reader's ability

to process a text" [8]. The Flesch/FleschKincaid readability tests were designed to show comprehension difficulty while reading a passage of academic English in contemporary style. This comprised of two tests namely, the Flesch Reading Ease and the FleschKincaid Grade Level. In the Flesch Reading Ease test, higher scores indicate that the content was easier to read whereas lower scores indicated that the content were difficult to read. The Simplified Measure of Gobbledygook (SMOG) grade is a readability measure that estimates the years of education required to fully understand a piece of writing [9]. Objective of our study was to develop a PIL for COPD and to assess the readability.

DESIGN & METHOD

PILs were prepared by referring to the primary, secondary and tertiary sources. Model leaflets were available from the different online resources such as Patient UK, Pubmed & MICROMEDEX Data base. The content of the prepared leaflet was validated by pulmonary physicians and subject experts. Changes were made as per physicians' directions and leaflet was designed after assessing the characteristics of layout and design.

Readability of the PIL was checked online by calculating FRE and FK-GL by processing on the website www.readability-score.com [10]. BALD method was used to assess its layout and design characteristics of the PIL.

RESULTS

After the preparation of PIL (Figure 1), readability was assessed using FRE and FK-GL scores. After assessment, leaflets were modified and readability scores were reassessed, which showed improvement after each modification (Table 1). The best Flesch Reading Ease score achieved was 68.3 and Flesch-Kincaid Grade Level score achieved was 7.4. The BALD score was 27.

DISCUSSION

PIL remains one of the important tools of communication because it helps to recollect the information about the disease, medications and lifestyle changes [11]. Verbal communication often fails because the information may be forgotten or misunderstood by the patient or care taker. PILs are necessary to educate the patient/users about the disease, medications and lifestyle changes. FK-GL scores translate into numerical grade. FRE measures textual difficulty which indicates how easy a text is to read. FRE Scale measures readability as follows: 100: Very easy to read, 65: Plain English, 30: A little hard to read and 0: Very hard to read. Gunning fog index calculates the years of formal education required to understand the text on a first reading. It is mainly used to verify whether the text can be read easily by the intended audience. Texts for a wider audience generally require fog index less than 12. SMOG Index readability formula measures the years of education a person needs to fully understand a piece of writing. Automated Readability Index (ARI) is a readability test used to assess the understandability of a text. Coleman Liau Index to gauge the understandability of a text. FK-GL Score of 7.4 is equivalent to 7th grade reading level in the United States. FRE Score of 68.3 indicates that the text is fairly readable. Fog index score of 10 implies that PIL is readable and understandable by the majority. SMOG index Score of 7.3 is equivalent to 7th grade reading level in the United States. Automated Reading level grade 7.6 corresponds to the typical reading level of a 14 year-old in the US. In Coleman Liau Index, the text is at a grade level of 11.2 or roughly appropriate for a first year undergraduate. A study on the readability assessment of PILs for diabetic foot ulcer revealed almost the same result [12]. In that study FRE score was 69.9 and FK-GL score was 7.1.

CONCLUSION

FRE and FK-GL scores have revealed that PIL developed by us has standard readability score and good layout design.

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Table 1 : Flesch/FleschKincaid readability tests score

Readability Formula	Grade
Flesch Kincaid Grade level	7.4
Flesch Kincaid Reading Ease	68.3
Gunning Fog Score	10
SMOG Index	7.3
Automated Readability Index	7.6
Coleman –Liau Index	11.2
Average Grade Level	**8.4**

Treatment of exacerbations

- Treatment of an exacerbation of COPD involves adding extra medicines temporarily to your usual treatment.
- This is usually steroid tablets with or without antibiotics.
- These medicines are usually taken until your symptoms settle down to what is normal for you.
- A short course of antibiotics is commonly prescribed if you have a chest infection,

End-stage chronic obstructive pulmonary disease:

- Palliative care means care or treatment to keep a person as comfortable as possible, to reduce the severity of the disease, rather than to cure it.

Home oxygen:

- This may help some people with severe symptoms or end-stage COPD. Great care has to be taken with oxygen therapy.
- Too much oxygen can actually be harmful if you have COPD

Other Treatment Options

Surgery:

This is an option in a very small number of cases. Removing a section of lung that has become useless *may* improve symptoms

Get immunized:

Two immunizations are advised.

- A yearly 'flu jab' protects against possible influenza and chest infection
- Immunization against pneumococcus.

For all inhaler users:

• Ensure the device has medication in it
• Be sure to 'empty the lungs' completely before inhaling
• Be sure to exhale away from the mouthpiece
• Ensure there is a good seal with the lips around mouthpiece
• Hold your breath for several seconds after inhaling.

Metered Dose Inhaler (MDI)

Ensure the device is shaken BEFORE EVERY dose.

Note the correct position of the inhaler and ensure there is a good seal with the lips around mouthpiece.

Metered Dose Inhaler (MDI) with Spacer

An MDI with a spacer must also have a good seal with lips around the mouthpiece

Regular follow-up

Regular review allows monitoring of the severity of your COPD, and gives an opportunity for health promotion such as help with stopping smoking or weight control.

Reviews should happen more often if you have frequent exacerbations or complications

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CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Patient Information Leaflet

Developed by

Dept. of Pharmacy Practice
Manipal College of Pharmaceutical Sciences
Manipal - 576104, Karnataka.

Dept. of Pulmonary Medicine
Kasturba Hospital, Manipal
Manipal-576 104, Karnataka

Figure 1: Patient Information Leaflets for COPD

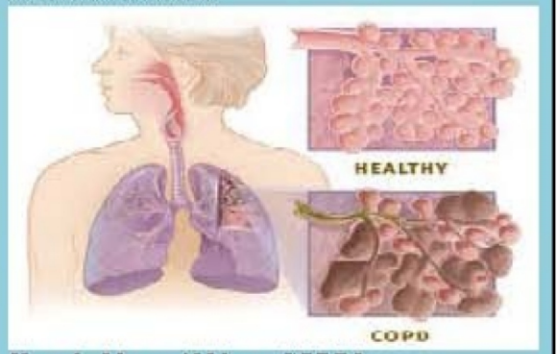
Chronic Obstructive Pulmonary Disease (COPD) is a disease of the lungs in which the airways become narrowed. This leads to a restriction to the flow of air to and from the lungs causing shortness of breath. COPD is a term that is used to include chronic bronchitis, emphysema, or a combination of both conditions. Currently the available treatment options are targeted at only symptomatic relief of COPD, which do not provide long term benefits to the patients.

What causes COPD?

COPD can be caused by many factors, although the most common cause is cigarette smoke.

Environ-mental factors and genetics may also cause COPD.

For example, heavy exposure to certain dusts at work, chemicals, and indoor or outdoor air pollution can contribute to COPD.



How do I know if I have COPD?

Shortness of breath, cough, and/or mucus production, that does not go away, are common signs and symptoms of COPD and indicate the need for a visit to your health care provider and evaluation for the need of a breathing test called spirometry.

Symptoms:

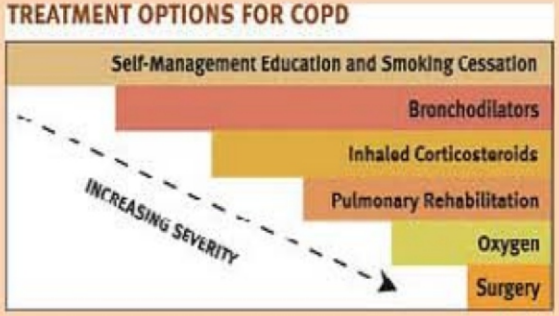
- **Cough** is usually the first symptom to develop. It is productive with sputum (phlegm). It tends to come and go at first, and then gradually becomes more persistent (chronic).
- **Breathlessness (shortness of breath) and wheeze** may occur only when you exert yourself at first.
- **Sputum** - the damaged airways make a lot more mucus than normal. This forms sputum (phlegm).
- Other symptoms of COPD are vague. Examples are weight loss, tiredness and ankle swelling.

Spirometry:

This test estimates lung volumes by measuring how much air you can blow out into a machine.

Two results are important: The amount of air you can blow out in one second (called forced expiratory volume in 1 second - **FEV_1**) and the total amount you can blow out in one breath (called forced vital capacity - **FVC**). COPD is divided into mild, moderate and severe groups, depending on the level of airflow obstruction.

- **Mild (stage 1) COPD** is an FEV_1 at least 80% of predicted value.
- **Moderate (stage 2) COPD** is an FEV_1 between 50% and 79% of predicted value.
- **Severe (stage 3) COPD** is an FEV_1 between 30% and 49% of predicted value.
- **Very severe (stage 4) COPD** is an FEV_1 less than 30% of predicted value.



Self Care

People with COPD can benefit from making some important lifestyle changes, such as:

- Stop smoking
- Improving your diet
- Exercising regularly
- Maintaining a healthy weight
- Making sure airways are clear, and
- Avoiding lung irritants.

Cessation of Smoking is the single most important and successful intervention in the treatment of COPD.

Short-acting bronchodilator inhalers

These relax the muscles in the airways (bronchi) to open them up (dilate them) as wide as possible. Typically, symptoms of wheeze and breathlessness improve within 5-15 minutes. The effect from both types typically lasts for 3-6 hours.

Eg: Levosalbutamol, Terbutaline, Ipratropium

Side-effects: tremors, headache

Long-acting bronchodilator inhalers

These work in a similar way to the short-acting inhalers, but each dose lasts at least 12 hours.

Eg: Salmetrol, Formetrol, Tiotropium

Steroid inhalers

Steroids reduce inflammation. It may help to prevent flare-ups (Exacerbations). Steroid inhalers are only used in combination with a long-acting beta-agonist inhaler.

Eg: Beclometasone, Budesonide, Ciclesonide, Fluticasone, Mometasone

Side-effects: Oral (in the mouth) thrush, sore throats and a hoarse voice. These effects can be reduced by rinsing your mouth with water after using these inhalers, and spitting out.

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