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# Development and Validation of patient information leaflet for HIV/AIDS patients

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ABSTRACT

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HIV/AIDS is a chronic disease and the patients are frequently prescribed with multiple long term therapy where it requires educating the patients regarding their disease and about the drugs for an effective management. Previous studies established that leaflets are a cheap and potential way to convey health information, but there is another concern is that how successfully it is ensuring quality information towards target community. This study was undertaken to develop and ensure quality information of one of the supplementary reading material, known as patient information leaflet (PIL) for educating HIV/AIDS patients. Patient information leaflet was prepared in two parts for disease and drug aspects of HIV/AIDS and tested for validity by using EQIP (ensuring quality information for patients) method. PMOSE/IKIRSCH readability scale was used for the estimation of readability and complexity of patient information leaflets. It was concluded that the leaflet for HIV/AIDS can be used as a source of patient information and can be circulated among HIV/AIDS patients to provide patient education and counseling, but it should be reviewed within one to two years.

**Keywords**: PIL, HIV/AIDS, Ensuring quality information for patients, readability

## INTRODUCTION

There are numerous studies reported that the patients will forget more than 50% of the information which is provided by the healthcare professionals and it also suggests that written information may help the patients to retain most of the information provided by healthcare professionals.[1-3]

Now-a-days printed education material is the one of the most frequently used resources for educating the patients preferably with chronic diseases.[4] In India printed education material were used most frequently to educate the patients of different kinds of diseases which may be supplied by government and non-governmental organizations including pharmaceutical companies but the evidence of validation of those education material was minimal.

Patient information leaflets play significant role in educating the patients on different aspects of drug and disease and further useful to improvise the adherence to medication by which an effective patient care can be achieved. So, education material with the vital components has to be ensured with quality information, to be clearly communicable, be evidence based and moreover it has to be validated since the prime goal is to serve the community.[5]

Quality healthcare information material comprises of three parts; proper communication, usage of evidence based information and involve patients in the development of the materials,apart from that further validation of printed education material is more important which directly affects the patient.[6]

HIV/AIDS is a chronic disease and the patients are frequently prescribed with multiple long term therapy where it requires educating the patients regarding their disease and about the drugs for an effective management of disease. Health and medicine-related education often occurs during direct patient contact, sometimes supplemented by relevant reading material. Previous studies reported that leaflets are a cheap and potential way to convey health information, but there is another concern is that how successfully it is ensuring quality information towards target community.[7] This study was undertaken to develop and ensure quality information of one of the supplementary reading material, known as patient information leaflet (PIL) for serving HIV/AIDS patients.

## AIM AND OBJECTIVE

This study aims to develop and validate the patient information leaflet regarding drug and disease aspects for HIV/AIDS patients.

## METHODOLOGY

Patient information leaflet was prepared in two parts as disease and drug aspects of HIV/AIDS according to the guidelines provided by international alliance of patients organization (IAPO) and tested for validity by using EQIP (ensuring quality information for patients) method. EQIP method is questionnaire based survey which comprises of 20 questions based on various quality criterions, questionnaire was provided with four options for an easy answering. Before administering EQIP questionnaire, printed version of

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two parts of patient information leaflet in local language was distributed to professionals and non-professionals pharmacy teachers, working pharmacists, pharmacy students, nurses, social workers, and lay persons and HIV/AIDS patients those who were residing or working in and around of Anantapur district, Andhra Pradesh, South India. They were asked to give a score for the patient information leaflet through EQIP questionnaire, and their responses were obtained.

Oral consent was obtained from all the study participants and a total of 118 completed questionnaires were collected and evaluated to ensure the quality of patient information leaflet. Interpretation of the data was done for an individual criterion and for different group of respondents PMOSE/IKIRSCH readability scale was used for estimation of readability and complexity of patient information leaflets. High response score indicates better quality and low response score indicates poor quality

## RESULTS

Initially information leaflet was prepared in English as two parts; one is for drug aspects of HIV/AIDS and another is for disease aspects of HIV/AIDS and it was translated to local language (Telugu) by experts and again it was transferred to English to validate the exact meaning of the information leaflets.

A total of 118 participants including professionals or non-professionals groups like working pharmacists (22), pharmacy students (20), nurses (23), social workers (8), pharmacy staff (10), and Lay persons (20) and HIV / AIDS patients those who are diagnosed as HIV carrier five years ago (15) were enrolles in this study, and the response for the validated EQIP (ensuring quality information for patients) questionnaire was received.

Among different study participants, clinical nurses and HIV/AIDS patients gave response with high scores of 68.23% and 68.04% respectively for the patient information leaflets through EQIP questionnaire. The scores of other participants are shown in Table 1 and it shows that the patient information leaflet has reliability for distribution to patients**.**

The readability and complexity was estimated by PMOSE/IKIRSCH formula and the readability was estimated to be proficiency level 2, considered as grade 8 and explained to be more suitable for people who have completed high school diploma or more, and the complexity level was estimated to be low.

Table 3 explains the evaluation of different criteria based on EQIP on our patient information leaflets, and the results implies that out of 20 criteria given by EQIP four got a score of more than 90%. The highest score (94.0 %) was assigned for a criteria "contains easy to understand illustrations, diagrams or photos that are relevant to the subject of the information", and the least score was given for "contain the date of information it was produced". Out of 20 criteria given by EQIP, eleven got a score range of more than 75%, 7 received a score of less than 50% and two were within the range of 50 – 75%.

**Table 1: Classification and responses to EQIP of study participants**

| S.No | Participants | Number of participants N(%) | Response (%) |
|---|---|---|---|
| 1 | Pharmacy teachers | 10(8.47) | 66.13 |
| 2 | Nurses | 23(19.49) | 68.23 |
| 3 | Pharmacy students | 20(16.94) | 62.85 |
| 4 | Working pharmacists | 22(18.64) | 60.43 |
| 5 | Social workers | 8(6.77) | 65.23 |
| 6 | Lay persons | 20(16.94) | 67.21 |
| 7 | HIV/AIDS patients | 15(12.71) | 68.04 |
| | **Total** | **118** | **65.44** |

**Table 2: Interpretation of PMOSE/IKIRSCH formula[8]**

| S.No | Proficiency | Grade level | Equivalent |
|---|---|---|---|
| 1 | Level 1 | Grade 4 | >8 years of schooling |
| 2 | Level 2 | Grade 8 | To high school diploma |
| 3 | Level 3 | Grade 12 | Some education after high school |
| 4 | Level 4 | 15 years of schooling | College degree equivalent |
| 5 | Level 5 | 16 years of schooling or more | Advanced post college degree |

The individual responses of participants were taken into consideration for testing the usability of the leaflets. 84 participants gave a response of 51to75%, 16 gave response of 76 % and above, 15 gave 26 to 50% and 3 participants gave 0 to 25% response score through EQIP questionnaire, the details are shown in Table 4.

## DISCUSSION

The provision of patient information leaflets (PILs) is an important part of health care so PILs require evaluation to ensure its quality.[9]

The quality of information provided to patients heavily contributes to the prevention and self-management of illnesses and recovery of health. The quality of such patient education material needs to be evaluated by different group of healthcare professionals prior to use by the patients.[4] In the present study, the quality of patient information leaflets was good and only few suggested to remove the patient information leaflets from circulation.

Readability is considered as a measure of the quality of

**Table 3: Scores assigned for each Quality criterions of EQIP**

| S.No | EQIP Criterions | Assigned score (%) |
|---|---|---|
| 1 | Have clearly stated aims and achieve them | 93.2 |
| 2 | Written using everyday language. Explaining unusual or medical words or abbreviations or jargon | 81.3 |
| 3 | Written using short sentences | 84.7 |
| 4 | Written so that it personally addresses the reader | 50.4 |
| 5 | Written so that the tone is respectful | 93.2 |
| 6 | Design of information satisfactory | 78.3 |
| 7 | Contains easy to understand illustrations, diagrams or photos that are relevant to the subject of the information | 94.0 |
| 8 | Presented in a logical order | 77.1 |
| 9 | Contain a space to make notes | 41.5 |
| 10 | Contain contact details for health care | 73.0 |
| 11 | Contain the date information was produced | 8.4 |
| 12 | Contain name of person or department that produced information | 89.2 |
| 13 | Indicates whether information was produced with assistance from users of service | 25.9 |
| 14 | Contains reference to quality of life issues | 41.0 |
| 15 | Uses generic names for medications or products, or identifies brand names as such | 24.7 |
| 16 | Contains details of other sources of information | 46.8 |
| 17 | Describes the purpose | 90.6 |
| 18 | Describes the benefits | 80.0 |
| 19 | Describes risks and side effects | 66.9 |
| 20 | Describes alternatives | 21.6 |

**Table 4: Feedback strategy on EQIP of patient information leaflets:**

| S.No | Specifications | Frequency (%) | Recommendations |
|---|---|---|---|
| 1 | 76 percent and above | 16 (13.55) | Continue to stock; review in two to three years |
| 2 | 51 to 75 per cent | 84 (71.18) | Continue to stock; review in one to two years |
| 3 | 26 to 50 per cent | 15 (12.71) | Begin review now and replace within six months to a year |
| 4 | 0 to 25 per cent | 3 (2.54) | Remove from circulation immediately |

written information and there are plenty of scales available to measure the same. The lower the reading level, the more likely the information can be read and understood by a large population.[10] In our study we found that the patient information leaflets is understood by people those who has completed high school/diploma, so the quality has to be improved further to reach large number of population including people who have less than 8 years of school education. Moreover, the present study results also show that our PILs have to be reviewed once in two years.

However, readability is only an aspect of reading comprehension and to evaluate the written information. There are various criteria available to evaluate the information available. In the present study, EQIP questionnaire was used to evaluate the different criteria and it was observed that majority of the criteria were fulfilled during the development of patient information leaflet. However, there are certain criteria which needs to be revised during the review, like time and date the leaflets were produced.

## CONCLUSION

It can be concluded that the leaflet developed for HIV/AIDS can be used as a source of patient information and can be circulated among the patients to provide education and counseling but it should be reviewed within one to two years.

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## STAYING HEALTHY FOR LIFE – FOR PEOPLE WITH HIV

Part - I

Having HIV does not mean you have AIDS or that you will die – it is like other illnesses – you can get medical treatment for it and stay HEALTHY

## What is HIV?

The human immunodeficiency virus (HIV) infects cells of the immune system and destroys or impairs their function. Infection with the virus results in the progressive deterioration of the immune system, leading to "immune deficiency."

## What is AIDS?

Acquired immunodeficiency syndrome (AIDS) is a surveillance term applies to the most advanced stages of HIV infection, defined by the occurrence of any of more than 20 opportunistic infections or HIV-related cancers.


## What should I do if I am diagnosed with HIV?

- Talk with someone you trust
- Tell your partner

## Work with doctor or health care provider

- Follow your doctor's instructions
- Don't make changes to your medicine on your own or because of advice from friends.



## Protect yourself and others

- Avoid reinfection
- Always prefer condom
- Avoid Sexually transmitted diseases
- Talk with your doctor if you are pregnant, nursing baby
- HIV infection is like a chain from one person to another; you can break that chain and help others by avoiding further infections

## What is the treatment for HIV or AIDS?

- Antiretroviral medicines (ART) are used for the treatment.

These powerful medicines control the virus and slow progression of HIV infection, but they do not cure it. You need to take these medicines exactly as your doctor prescribes, and it can be given as a combination for effective treatment.

- Treating other infections: If your HIV infection gets worse and your CD4 cell count falls below 200, you are more likely to get other infections, at that time physician may prescribe other medicines

## What can I do on my own to stay healthy with HIV?

*Alcohol & smoking with HIV:*

- Weaken your immune system
- Increases the risk of side effects
- Trouble sleeping

*A mix you can avoid*

- The worst effect of drinking can have is to knock you off schedule for taking medicines

*Oral health:*

- The health of your teeth, gums and mouth – affect your whole body
- Brush your teeth after every meal, or at least 2 times a day

*Oral health means more than strong teeth you know*

*Exercise:*

*Sleep*: Get enough sleep and rest.

**Take time to relax.**

**Meditation:**

Many people find that meditation or prayer, along with exercise and rest; help them cope with the stress of having HIV or AIDS

**Eating:**

- Eating well helps us stay strong have more energy and boosts our body's immune system
- Get enough calories
- Stay away from junked foods or fast food

*Some HIV medicine can make you feel sick; changing the foods you eat may help you feel better*

**Opportunistic infections:**

Take preventive measures to avoid other opportunistic infections



*Today, thousands of people are living with HIV or AIDS. Many are leading full, happy, and productive lives. You can too if you work with your doctor and other health care professionals and take the steps outlined in this leaflet to stay healthy.*

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## STAYING ON SCHEDULE

Part II

## TIPS FOR TAKING YOUR HIV MEDICATIONS

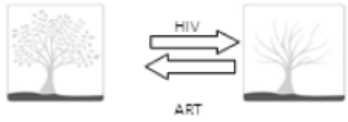
**Whatever the efficacy of drug, it cannot act unless YOU TAKE it in a proper way and on time**

**Why it is so important to take HIV Medicines on time?**


When the HIV virus infects your body the virus makes copies itself.HIV medicines can help stop HIV from making copies of it and can reduce the total amount of HIV in your body but if you do not take HIV medicines on time, they will stop working against HIV

**What is CD 4 count?**

CD 4 cells are immune cells they will be protecting our body from infections




**What is viral load?**

Once virus enters the blood stream attach with CD4 cells(immune cells) and there which will be multiplied and produces plenty of new virons, effects the other CD4 cells Thus, one infected cell turns into a factory churning out billions copies of the human immunodeficiency virus (HIV)

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**Talk with your doctor or health care provider:**

*Understand what each drug and why are you taking it*

Understand the schedule Of your drugs



**Ask the pharmacist any questions:**

⇦ Ask your pharmacist

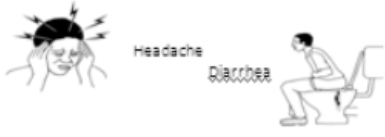
How much of the drug to take ⇨

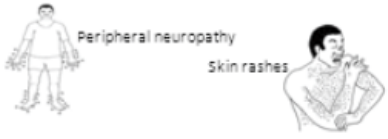
- How often you take the drug
- Whether with food or an empty stomach or how it is
- Ask about the storage of medications

**Side effects**

Don't let side effects change your schedule

Nausea, headache, and diarrhea are common when you take HIV medicines, most of the side effects go within a week


**What should I do if I miss the dose** – take it as soon as possible however if you skip the dose Do not take double dose the next to make up for it

## Instructions for taking HIV medicines

Each medicine has instructions (rules) for how to take it. Read the instructions and follow them carefully. Here are some common instructions and what they mean:

"Take three times a day" means you take the three doses 8 hours apart. If you take the first dose when you get up in the morning at 7:00 a.m., you would take the second dose 8 hours later at 3:00 p.m. You would take the third dose 8 hours later, at 11:00 p.m.

"Take twice a day" means you take the first dose early in the day and the second dose about 12 hours later. So, if you take the first dose at 8 o'clock in the morning (8:00 a.m.), take the second dose at 8 o'clock in the evening (8:00 p.m.).

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"Take with a meal" or "Take with food" means you should not take the medicine on an empty stomach. If you do not want to eat a whole meal, eat a large snack, with milk.

"Take on an empty stomach" means you should take the medicine at least 1 hour before or 2 hours after you eat a snack or meal.

*Today, thousands of people are living with HIV or AIDS. Many are leading full, happy, and productive lives only when they have good medicine taking behavior*

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