

Article: Research

Title: Development and Validation Training Manual on Medication Adherence for the Community Pharmacists in Southern India.

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ABSTRACT

Background: In southern India, the community pharmacists are unaware about medication adherence and counselling as they have not practiced it in their profession which is a vital part of their professional. hence there is a need for development, validated and implementing training modules to update their knowledge and encourage them to practice medication adherence techniques in their professional life which will help the patients to avoid further complications of the disease.

Objective: This study aims to develop and validate training manual on medication adherence for the community pharmacists in southern India.

Methodology: The study manual was designed based on previously published literature and suggestions on training manual of medication adherence received from registered community pharmacist. The developed manual was subjected for validation team consists of ten experts include registered community pharmacist, professors, lectures, post-graduate students, clinical pharmacist. Readability was validated using flesch readability ease. Information was validated by ensuring quality of information of study materials. layout and design were validated using BALD method.

Results: Readability was evaluated using the Flesch Reading Ease (FRE) score. The final FRE score attained was 60.1, indicating that the manual's readability is "standard" and its grade level suggests it can be easily comprehended by 15 to 16-year-old students. the EQIP score was found to be 72.66 %. A higher the EQIP score ensures high quality of the information in the manual. The BALD assessment score found to be 26 which indicates the design and layout are above standard.

Conclusion: Nowadays community pharmacists play an important role in educating patients on medication adherence which helps the patients to be adherent to their prescribed medications. The study results shows that there is a high necessity to educate community pharmacists on medication adherence. The medication adherence training manual for community pharmacists was prepared

and validated, therefore regular continuous professional development programs are necessary in updating the knowledge of community pharmacists.

INTRODUCTION:

Medication adherence, the consistent and accurate utilization of prescribed medications as directed by healthcare providers, stands as a cornerstone of effective healthcare delivery. However, the prevalent issue of medication non-adherence, with estimated rates reaching up to 50% among patients, poses significant challenges to both individual health outcomes and healthcare systems at large. The complex nature of non-adherence highlights the necessity for focused interventions aimed at tackling its underlying factors. The primary deficiency in medication non-adherence stems from deficiencies in patient understanding regarding the importance and purpose of prescribed medications. Additionally, misconceptions regarding treatment objectives and the potential consequences of non-adherence further compound this issue. Such lapses in medication adherence not only exacerbate medical conditions but also incur substantial healthcare costs, increased hospital visits, prolong the hospitalization, and heighten the risk of drug resistance. Community pharmacists, as accessible and trusted healthcare professionals, play a pivotal role in mitigating medication non-adherence. In contemporary practice, pharmacists offer a spectrum of advanced services, including medication therapy management, medication synchronization programs, patient education initiatives, immunization services, drug information dissemination, and health promotion and screening services. Harnessing these services, pharmacists are uniquely positioned to engage patients, optimize medication adherence, and improve overall health outcomes. In light of these considerations, the development and validation of a scientifically accurate medication adherence training manual tailored for registered community pharmacists in India emerge as an imperative. Such a manual serves as a comprehensive resource, equipping pharmacists with evidence-based strategies to effectively address medication non-adherence. By providing standardized guidelines and protocols, the manual ensures consistency and quality in patient education efforts, thereby enhancing the pharmacist's ability to enact meaningful interventions. Furthermore, the implementation of a medication adherence training manual represents a strategic investment in advancing healthcare quality and reducing the societal burden of non-adherence-related complications. By enhancing pharmacists' proficiency in medication

adherence strategies, the manual not only optimizes patient outcomes but also reinforces the pivotal role of pharmacists within the healthcare

METHODOLOGY:

This research was conducted as part of a larger investigation into the implementation of training modules aimed at enhancing medication adherence among registered community pharmacists. Prior to commencing the study, approval was obtained from the institutional ethics committee (JSSMC/IEC/260822/30 NCT/2022-23 Date: 01.09.2022). full time registered community pharmacists employed at selected pharmacies in southern India were invited to participate. Those who declined to participate were excluded.

Development and validation of training manual.

The study manual was designed based on previously published literature and suggestions on training manual of medication adherence received from registered community pharmacist. The prepared training manual contains. The information on definition of medication adherence with its two different methods direct and indirect method, advantages & disadvantages of medication adherence programs, incidence of non-adherence, technologies of medication adherence, barriers for medication non-adherence in patients, community pharmacist benefits on medication adherence, strategies to improve medication and role of community pharmacist. The developed manual was subjected for validation team consists of ten experts include registered community pharmacist, professors, lectures, post-graduate students, clinical pharmacist. The two-checklist given to the validation team experts & necessary changes was made based on suggestions from validation team experts and final draft of prepared training manual was validated. Readability was validated using flesch readability ease. Information was validated by ensuring quality of information of study materials, layout and design was validated by BALD method

Assessment of readability:

1) Flesch readability score:

Readability of prepared manual was assessed using Flesch Readability Ease (FRE) formula which was developed by Rudolf Flesch and J. Peter Kincaid. The analysis is based on the average sentence length (in words) of selected samples and the average

word length measured by syllables per 100 words of the samples. A higher score indicated easier reading.

$$RE = 206.835 - 1.015 SL - 0.846 WL,$$

Where RE is the reading ease scores, SL is the average sentences length in words and WL is the average word length measured as syllables per 100 words.

Were,

RE = Readability Ease

ASL = Average Sentence Length (i.e., the number of words divided by the number of sentences)

ASW = Average number of syllables per word (i.e., the number of syllables divided by the number of words).

2) Flesch-Kincaid readability test:

The Flesch-Kincaid readability test was developed to point out how difficult a passage in English is to understand. This test is based on the word length and sentence length of the educational material. The formula for Flesch- Kincaid readability test is $206.835 - 1.015(\text{total words}/\text{total sentences}) - 84(\text{total syllabus}/\text{total words})$

SCORE	SCHOOL LEVEL	NOTES
70.0-60.0	7 th , 8 th , 9 th grade	Plain English , easily understood by 13 to 15 year old students
60.0-50.0	10 th to 12 th grade	Fairly difficult to read
50.0-30.0	College	Difficult to read
30.0-0.00	College graduate	Very difficult to read, best understood by university graduate

Assessment of information:

EQIP (ensuring quality information of manual) was used to assess the quality of information added to the manual. The EQIP tools ensures the quality, validity and readability of the contents included in the manual. Once the score has been calculated it is then converted to action recommendation. According to the budget and staffing levels. Each user can set their own action “recommendation

SCORE	INTERPRETATION
76% and above	Continue to stock; review in two to three years
51% to 75%	Continue to stock; review in one to two years
26% to 50%	Continue to stock; begin review now and replace within 6 months to a year

0% to 25%	Remove from circulation immediately
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Assessment of layout and design:

Baker Able Leaflet Design (BALD) criteria;

The layout and design of the manual was assessed using BALD criteria. The length of the line, distance between the line, letter font size, graphics used, percent of white space, paper quality were used for scoring. manual score of 25 or more considered as “Above Standard “whereas manual score of 21 and below is considered as “poor”

Design characteristics	3 Points	2 Points	1 Points	0 Points
Lines 50-89mm long			Yes	No
Separation between lines	>2.8mm	2.2-2.8mm		<2.2mm
Lines unjustified			Yes	No
Serif typeface		Yes		No
Type size	12 Point	10-11Point	9 Point	<9Point
First line indented			Yes	No
Titles lower case			yes	no
Italics		0words	1-3 words	4 words
Positive advice		Positive		Negative
Heading's standout		Yes		No
Numbers all Arabic			Yes	no
Boxed text			0-1Box	<1Box
Pictures	Words count not replace	In between	In between	None or superfluors
Number of colours	4	3	2	1
White space	>40%	30-395	20-29%	<20%
Paper quality	>90gsm	75-90gsm		<75gs,

RESULTS:

Assessment of readability:

By calculating the FRE and FK-GL scores, the readability of the training manual was evaluated throughout its creation. Readability scores were reevaluated for improvement following each revision to the training manual. A final FRE-score of 60.1 and an FK-GL score of 5.6 were attained. The scores indicate that kids aged 15 to 16 can readily understand the prepared training manual and the

score suggests that the document's readability was "standard. The minimum FRE and FK-GL values were found to be 50.0

Flesch- kincaid readability test score interpretation (FRE score)

SCORE	SCHOOL LEVEL	NOTES
70.0-60.0	7 th , 8 th & 9 th grade	Plain English, easily understood by 13- to 15- year-old student.
60.0-50.0	10 th to 12 th grade	Fairly difficult to read
50.0-30.0	College	Difficulty to read
30.0-0.00	College graduate	Very difficult to read, best understood by university graduate

Assessment of Quality of information:

Based on the scoring assessment of quality of information was made in the beginning round. After being reevaluated the reliability of training manual for the community pharmacists was determined using EQIP which was found to be 72.66%. This indicates that the manual can be used for one or two years without any revision. Minimum score should be 50%.

Score	Interpretation
76% and above	Continue to stock; review in two to three years
51 % to 75%	Continue to stock; review in one to two years
26% to 50%	Continue to stock; begin review now and replace within six months to a year.
0% to 25%	Remove from circulation immediately

Assessment of Layout and design:

Baker Able Leaflet Design (BALD) Criteria.

According to BALD assessment of training manual showed a total of points of 26 which indicates the layout and design are 'Above standard'. The points scoring of BALD is given in table

Assessment of layout and design characteristics:

Design characteristics	Points scored
Lines 50-89mm long	1
Separation between lines	2
Lines unjustified	1
Serif typeface	2
Type size	0
First line indented	1
Tiles lower case	0
Italics	2
Positive advice	2
Heading's standout	2
Number all Arabic	1
Boxed text	0
Pictures	3
Number of colors	3
White space	3
Paper Quality	3
Total	26

DISCUSSION:

The study aimed to develop and validate a comprehensive training manual focused on medication adherence tailored specifically for community pharmacists in India. Despite an extensive body of literature addressing tools for assessing medication adherence among community pharmacists, there remains a significant gap in the creation, validation, and implementation of continuous professional development programs, particularly within the Indian context. Drawing upon an exhaustive literature review, the manual was meticulously curated to cover essential facets including the definition of medication adherence, diverse assessment methodologies, prevalence rates of non-adherence, program advantages and drawbacks, benefits for pharmacists, patient-related barriers, available technologies, strategies for enhancement, and the pivotal roles pharmacists play in promoting adherence. The manual's readability underwent assessment using

the Flesch Readability Ease (FREL) formula, initially yielding a score of 30, indicating moderate difficulty. Through subsequent revisions, a significant enhancement was achieved, with the score increasing to 60.1, indicating that the manual is easily comprehensible, akin to the literacy level of 15-16-year-olds. Additionally, the manual underwent rigorous quality evaluation utilizing the EQIP questionnaire, initially scoring at 50%. Following revisions, this score surged to 72.66%, underscoring its suitability for effective utilization over a span of one to two years. In summary, the developed and validated training manual addresses a critical need in the field of pharmacy practice in India, providing a valuable resource for community pharmacists to enhance their understanding and implementation of medication adherence practices, ultimately improving patient outcomes and healthcare delivery.

CONCLUSION:

The medication adherence training manual for community pharmacists was prepared and validated, meeting all standard criteria for readability, EQIP, layout and design and comprehension of medication adherence concepts. These validated parameters ensure that the training modules will be valuable for future research and in conducting continuous professional development programs for community pharmacists in Southern India.

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