

Development and Validation of an Educational Module to Assess the Quality of Life Among Patients with Chronic Kidney Disease: A Randomized Interventional Study

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ABSTRACT

Chronic Kidney Disease (CKD) represents a growing public health burden in India, yet validated, culturally contextualised educational tools with rigorously assessed psychometric properties remain scarce. This study developed a structured educational module — comprising Patient Information Leaflet (PIL) and educational video — for CKD patients, and validated the questionnaires through an interdisciplinary expert panel process. Educational tools were developed through comprehensive literature review aligned with KDIGO clinical practice guidelines, incorporating simplified language, regional language adaptations, and culturally appropriate content. An eight-member expert panel — including nephrologists, general physicians, a clinical pharmacist, an intern, and a patient representative — independently rated all questionnaire items using a 5-point Likert scale. Content validity was assessed using Item-level and Scale-level Content Validity Indices (I-CVI and S-CVI) per Lynn's criteria (threshold ≥ 0.75), and internal consistency was evaluated using Cronbach's alpha (threshold ≥ 0.60). The PIL questionnaire was refined from 14 to 10 items across five domains, achieving a Cronbach's α of 0.67 (acceptable) and S-CVI of 0.78. The video questionnaire was refined from 15 to 10 items, yielding a Cronbach's α of 0.74 (good) and S-CVI of 0.82. Both instruments exceeded recommended psychometric thresholds, with four PIL items and nine video items excluded or reframed through iterative expert consensus. These validated instruments provide a robust psychometric foundation for evaluating patient education programmes targeting quality of life in CKD populations, and offer a reproducible methodology for instrument development in other chronic disease contexts.

Keywords: Chronic kidney disease, Content validity index, Cronbach's alpha, Educational module, Patient information leaflet, Questionnaire validation

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INTRODUCTION

CKD is characterised by a sustained decline in kidney function, defined by a GFR below 60 mL/min/1.73 m² or by identifiable kidney damage markers persisting for at

least three months, regardless of the underlying aetiology (Kovesdy, 2022). The condition is classified into five progressive stages based on GFR categories, with the most severe — Stage 5 — representing ESKD, which

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necessitates renal replacement therapy. Worldwide, an estimated 843.6 million individuals were affected by CKD in 2017 (Jha et al., 2013), while the Indian SEEK study documented a prevalence of approximately 17.2% (Singh et al., 2013).

CKD exerts a profound impact on patients' health-related quality of life, encompassing physical functioning, vitality, emotional well-being, and social participation (Jesus et al., 2019; Perlman et al., 2005). Patients frequently present with chronic fatigue, anaemia, dyspnoea, and psychological comorbidities including depression, which further erode quality of life (Finkelstein et al., 2009; Aggarwal et al., 2016). Evidence consistently demonstrates that structured educational interventions improve disease knowledge, medication adherence, dietary compliance, and self-management in CKD populations (Sarker et al., 2022; Ghimirey et al., 2013).

Patient Information Leaflets (PILs) and educational videos are widely used for structured patient education. Video-based tools are increasingly recognised as superior for improving comprehension and engagement in populations with variable literacy levels (Deshpande et al., 2021). The PEMAT offers a validated, uniform approach to appraising how comprehensible and actionable both printed and audiovisual educational resources are (Shoemaker et al., 2014).

The scientific credibility of any educational module rests upon the psychometric properties of instruments used to evaluate it. Content validation — assessing whether an instrument's items representatively sample the domain measured — is an essential prerequisite for educational research (Lynn, 1986; Polit & Beck, 2006). The CVI — derived at both the individual item level (I-CVI) and the overall scale level (S-CVI) — serves as a quantitative measure of expert-rated item relevance (Lynn, 1986). Cronbach's alpha, used to assess internal consistency, reflects the degree of inter-item homogeneity within a given instrument (Nunnally, 1978; George & Mallery, 2003). Despite the growing CKD burden in India, validated, culturally tailored educational tools with rigorously assessed psychometric properties remain scarce (Amin et al., 2021; Tuot et al., 2013). Clinical pharmacists are uniquely positioned to lead such development given their expertise in patient counselling and health education (Ghimirey et al., 2013).

This study was designed to: (i) develop a structured CKD educational module comprising a PIL and video, aligned with KDIGO guidelines (KDIGO CKD Work Group,

2013); (ii) validate the associated questionnaires through interdisciplinary expert panel inter-validation using I-CVI, S-CVI, and Cronbach's alpha as psychometric benchmarks; and (iii) report the complete item refinement process to provide a transparent, reproducible account of the methodology.

MATERIALS AND METHODS

Study Design and Setting

A prospective, multi-phase instrument development and validation design was implemented within the Nephrology Department at Tertiary Care Hospital and Medical Research Centre. Ethical clearance was granted by the Institutional Human Ethics Committee (Reference No.: EC/NEW/INST/2022/2571). The study was carried out in full conformity with the ethical principles of the Declaration of Helsinki. Six sequential phases were followed: (i) target group identification; (ii) development of educational tools; (iii) instrument construction; (iv) expert panel inter-validation; (v) reliability assessment; and (vi) instrument finalisation. [*Figure 1*]

Target Group and Eligibility Criteria

The target population comprised adult patients with confirmed CKD (Stages 1–5) attending the nephrology outpatient and inpatient departments. Inclusion criteria were: age ≥ 18 years; confirmed CKD diagnosis receiving pharmacological therapy or dialysis; and capacity for written informed consent. Patients were excluded if they were users of alternative medicine as primary treatment, critically ill or haemodynamically unstable, diagnosed with psychiatric disorder or cognitive impairment, pregnant or lactating, or unable to communicate due to language or sensory barriers. An enrolment target of 202 participants was calculated for the wider interventional study using the standard proportion formula (z^2pq/d^2 ; $z = 1.96$, $p = 0.06$, $q = 0.94$, $d = 0.05$), with a 10% attrition adjustment, and patients were allocated equally to PIL ($n = 101$) and video ($n = 101$) arms. The instrument validation component described here pertains to the expert panel process conducted prior to patient enrolment.

Development of Educational Tools

Educational tools were developed following a comprehensive literature review using PubMed, Cochrane Library, Google Scholar, and KDIGO guidelines, covering CKD pathophysiology, pharmacotherapy, dietary management, lifestyle

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modification, and quality of life outcomes (KDIGO CKD Work Group, 2013). The PIL was structured as a four-page bilingual document (English and regional languages: Kannada, Hindi, Marathi), incorporating simplified language, culturally appropriate illustrations, and actionable key messages. The educational video was a 12-minute animated and narrated production mirroring PIL content in audiovisual format, incorporating voice narration in Kannada and English and on-screen text overlays. Both tools were reviewed for accuracy, cultural appropriateness, and clarity before submission for expert validation.

Instrument Development and Expert Validation

Separate 5-point Likert scale questionnaires were developed for the PIL (14 initial items, six domains) and video (15 initial items, five domains). An eight-member interdisciplinary expert panel — including a nephrologist/Head of Department, nephrology and general medicine postgraduate residents (PG1–PG4), a clinical pharmacist, an MBBS intern, and a patient representative — independently evaluated all items. Each item's I-CVI was derived by determining the fraction of panel members who assigned ratings of 'relevant' or 'highly relevant' within a 4-point relevance scale. The S-CVI was subsequently obtained by averaging the I-CVI scores across all retained items. Items achieving mean Likert scores > 3.0 and I-CVI \geq 0.75 were retained; items failing thresholds were excluded or reframed by consensus, per Lynn's (1986) criteria (minimum S-CVI \geq 0.75). Reliability of each finalised questionnaire was evaluated via Cronbach's alpha coefficient, derived from the expert scoring matrices using the formula: $\alpha = (k / (k - 1)) \times (1 - \Sigma\sigma_i^2 / \sigma_x^2)$, where k = number of items, $\Sigma\sigma_i^2$ = sum of item variances, and σ_x^2 = total composite variance. The George and Mallery (2003) classification framework was applied to interpret alpha values, with a pre-set acceptability cut-off of $\alpha \geq$ 0.60 (Nunnally, 1978).

Statistical Analysis

Dataset entry and management were conducted using Microsoft Excel 2019. Descriptive statistics — mean item scores, standard deviations, and totals — were computed for both score matrices. I-CVI and S-CVI values were computed per instrument. Items below thresholds were excluded or reframed iteratively by expert consensus. Final instruments were documented with domain structure, item wording, I-CVI, S-CVI, and Cronbach's alpha. [Figure 1]

RESULTS

Development of Educational Tools

The PIL was developed as a four-page bilingual document covering: (i) What is CKD?; (ii) Dietary Management; (iii) Medication Adherence; (iv) Lifestyle Modification; and (v) When to Seek Medical Attention. It incorporated simplified language (readability target: Grade 6), culturally appropriate illustrations, and a key messages summary box. The educational video was a 12-minute animated and narrated production structured to mirror PIL content, with Kannada and English voice narration, animated kidney function diagrams, and on-screen text overlays.

Expert Panel Inter-Validation: PIL Questionnaire

Table I presents the final validated PIL questionnaire comprising 10 items across five domains. All items achieved I-CVI values \geq 0.75, meeting Lynn's (1986) threshold. The overall S-CVI reached 0.78, surpassing the minimum recommended cut-off of 0.75. [Table I]

Table II presents item-by-item Likert scores for the PIL questionnaire. All items achieved mean scores above 3.0. Mean item scores ranged from 3.88 (Q8) to 4.75 (Q3), with an overall mean total score of 42.75 across all eight reviewers (maximum: 50). [Table II] [Figure 2]

Expert Panel Inter-Validation: Video Questionnaire

Table III presents the final validated video questionnaire comprising 10 items across five domains. Each item met the required I-CVI threshold of \geq 0.75, and the instrument-level S-CVI reached 0.82. Table IV presents item-by-item expert scores. [Table III] [Table IV] [Figure 2]

Reliability Assessment: Cronbach's Alpha

Cronbach's alpha reliability outcomes for both instruments are detailed in Table V. The PIL questionnaire yielded $\alpha =$ 0.67 ($k =$ 10, $\Sigma\sigma_i^2 =$ 4.156, $\sigma_x^2 =$ 10.688), rated as Acceptable. The video questionnaire yielded $\alpha =$ 0.74 ($k =$ 10, $\Sigma\sigma_i^2 =$ 3.673, $\sigma_x^2 =$ 10.859), rated as Good. Both values exceeded the pre-specified minimum threshold of $\alpha \geq$ 0.60 (Nunnally, 1978). [Table V] [Figure 3]

Content Validity Index Summary

Table VI summarises content validity outcomes for both instruments. A total of four PIL items and nine video items were excluded or reframed, yielding streamlined, psychometrically sound final instruments of 10 items each. [Table VI] [Figure 4]

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Item Exclusion and Reframing

Table VII details all items excluded or reframed during inter-validation. Primary reasons for exclusion included: low I-CVI (< 0.75); content duplication; and conceptual merging following expert consensus. [Table VII] [Figure 5]

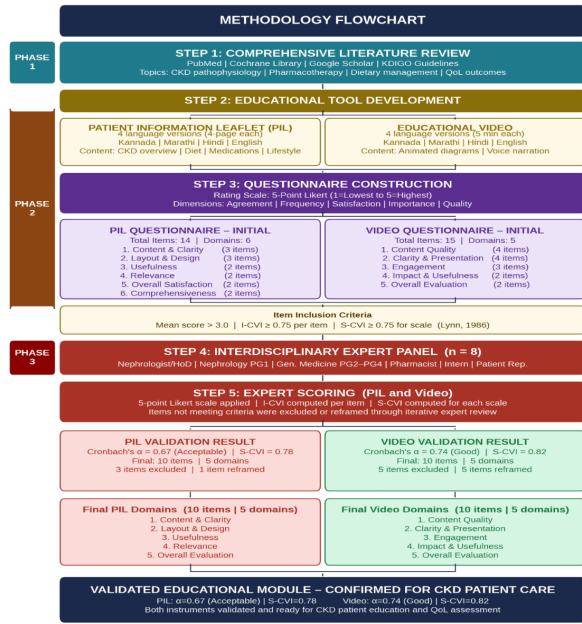


Figure 1. Methodology flowchart for the development and validation of an educational module. (Reproduced at full page width) **Abbreviations:** CKD – chronic kidney disease; PIL – Patient Information Leaflet; I-CVI – Item-level Content Validity Index; S-CVI – Scale-level Content Validity Index; KDIGO – kidney disease: Improving Global Outcomes

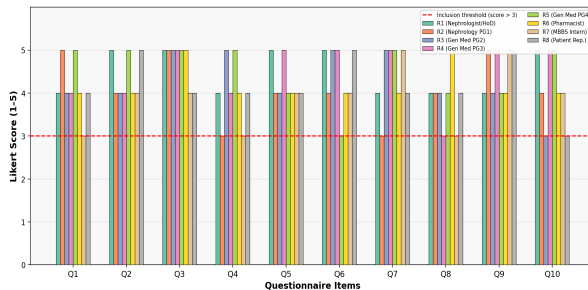


Figure 2. Expert Scores for PIL Questionnaire by Item and Reviewer (5-Point Likert Scale, $n = 8$ Experts). The red dashed line denotes the inclusion threshold (mean score > 3.0). All items exceeded threshold, confirming acceptability for inclusion. (Reproduced at full page width)

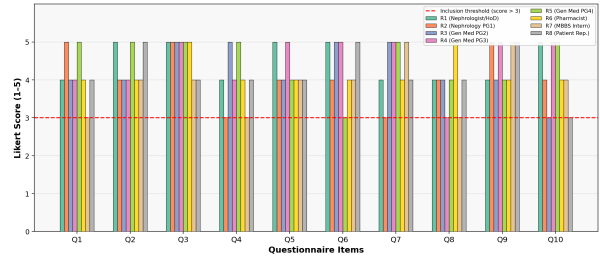


Figure 3. Expert Scores for Video Questionnaire by Item and Reviewer (5-Point Likert Scale, $n = 8$ Experts). The red dashed line denotes the inclusion threshold (mean score > 3.0). All items exceeded threshold. (Reproduced at full page width)

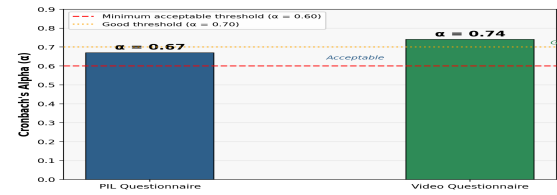


Figure 4. Bar chart depicting Cronbach's alpha values for the PIL and Video questionnaires. Reliability was quantified using Cronbach's alpha; the red dashed line marks the minimum acceptable threshold ($\alpha = 0.60$) and the gold dotted line marks the good reliability threshold ($\alpha = 0.70$), based on established psychometric criteria. Both instruments surpassed the minimum threshold, with the PIL questionnaire classified as acceptable ($\alpha = 0.67$) and the Video questionnaire classified as good ($\alpha = 0.74$). Abbreviations: PIL – Patient Information Leaflet; α – Cronbach's alpha. (Reproduced at column width)

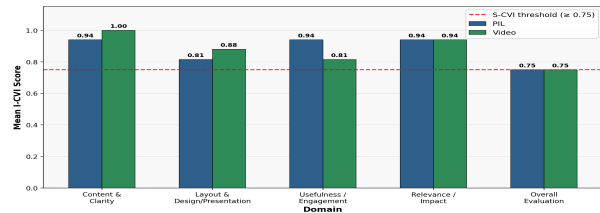


Figure 5. Mean I-CVI by Domain for PIL and Video Questionnaires. The red dashed line denotes the S-CVI threshold (≥ 0.75). All domains exceeded the recommended threshold in both instruments. (Reproduced at full page width)

Reviewer	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
R1 – Nephrologist/HoD	4	5	5	4	5	5	4	4	4	5	45
R2 – Nephrology PG1	5	4	5	3	4	4	3	4	5	4	41
R3 – Gen. Medicine PG2	4	4	5	5	4	5	5	4	4	3	43
R4 – Gen. Medicine PG3	4	4	5	4	5	5	5	3	5	5	45
R5 – Gen. Medicine PG4	5	5	5	5	4	3	5	4	4	5	45
R6 – Clinical Pharmacist	4	4	5	4	4	4	4	5	4	4	42
R7 – MBBS Intern	3	4	4	3	4	4	5	3	5	4	39
R8 – Patient Representative	4	5	4	4	4	5	4	4	5	3	42
Mean Score	4.13	4.38	4.75	4.00	4.25	4.38	4.38	3.88	4.50	4.13	–

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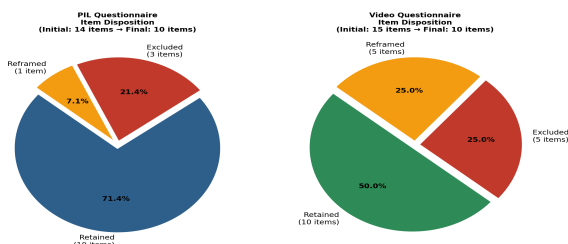


Figure 6. Item Disposition Following Expert Panel Validation – PIL (Left) and Video (Right) Questionnaires. Initial PIL comprised 14 items; initial Video comprised 15 items. Both refined to 10 final items. (Reproduced at full page width)

Table I: Final Validated PIL Questionnaire with I-CVI Values

Sr.	Domain	Question	I-CVI
Q1	Content & Clarity	The information presented in the PIL is easy to understand.	1.00
Q2	Content & Clarity	The instructions provided are clear and unambiguous.	0.88
Q3	Layout & Design	The layout and design of the PIL are visually appealing.	0.88
Q4	Layout & Design	The length of the PIL is appropriate (not too short or too long).	0.75
Q5	Usefulness	The PIL provides practical advice implementable in daily life.	1.00
Q6	Usefulness	The PIL motivates patients to adopt a healthier lifestyle.	0.88
Q7	Relevance	Topics covered are relevant to preventing disease and illness in CKD.	0.88
Q8	Relevance	The content is appropriate for the intended CKD patient population.	1.00

Sr.	Domain	Question	I-CVI
Q9	Overall Evaluation	I am satisfied with the overall quality of the PIL.	0.75
Q10	Overall Evaluation	I would recommend this PIL to others for educational purposes.	0.75

I-CVI denotes the Item-level Content Validity Index; S-CVI for the PIL instrument = 0.78; all items met the minimum I-CVI criterion of ≥ 0.75 per Lynn (1986).

Table II. Expert Scores for PIL Questionnaire by Reviewer

Reviewer ratings for each PIL questionnaire item using a 5-point Likert scale ($n = 8$ experts). Per-item mean scores were calculated across all eight reviewers. Items were required to attain a mean score above 3.0 for inclusion. R = Reviewer; Q = Questionnaire Item.

Reviewer	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
R1 – Nephrologist/HOD	4	5	5	4	5	5	4	4	4	5	45
R2 – Nephrology PG1	5	4	5	3	4	4	3	4	5	4	41
R3 – Gen. Medicine PG2	4	4	5	5	4	5	5	4	4	3	43
R4 – Gen. Medicine PG3	4	4	5	4	5	5	5	3	5	5	45
R5 – Gen. Medicine PG4	5	5	5	5	4	3	5	4	4	5	45
R6 – Clinical Pharmacist	4	4	5	4	4	4	4	5	4	4	42
R7 – MBBS Intern	3	4	4	3	4	4	5	3	5	4	39
R8 – Patient Representative	4	5	4	4	4	5	4	4	5	3	42
Mean Score	4.13	4.38	4.75	4.00	4.25	4.38	4.38	3.88	4.50	4.13	–

Table III. Final Validated Video Questionnaire (10 Items, 5 Domains) with I-CVI Values

I-CVI denotes the Item-level Content Validity Index; S-CVI for the video instrument = 0.82; all items met the minimum I-CVI criterion of ≥ 0.75 per Lynn (1986).

Sr.	Domain	Question	I-CVI
Q1	Content Quality	The video content was clear and easy to understand.	1.00
Q2	Content Quality	The video covered all relevant topics comprehensively.	1.00
Q3	Clarity & Presentation	Visuals and audio quality were appropriate for learning.	0.88
Q4	Clarity & Presentation	The pace of the video was suitable for the target audience.	0.88
Q5	Engagement	The video helped me understand the topic better.	0.88
Q6	Engagement	The video maintained my attention throughout.	0.75
Q7	Impact & Usefulness	I learned something new from the video.	1.00
Q8	Impact & Usefulness	I feel more confident about managing my condition after watching.	0.88
Q9	Overall Evaluation	I would recommend this video to others for educational/training purposes.	0.75
Q10	Overall Evaluation	I am satisfied with the overall quality of the video.	0.75

Table IV. Expert Scores for Video Questionnaire by Reviewer

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Reviewer ratings for each video questionnaire item using a 5-point Likert scale ($n = 8$ experts)

Per-item mean scores were computed across all eight reviewers. The minimum inclusion threshold was a mean score above 3.0. $R =$ Reviewer; $Q =$ Questionnaire Item.

Table V. Cronbach's Alpha Classification Scale
Cronbach's Alpha Classification Scale with Reliability

Cronbach's α Range	Internal Consistency	Applicable to
≥ 0.9	Excellent	–
0.8–0.9	Very Good	–
0.7–0.8	Good	Video Questionnaire ($\alpha = 0.74$)
0.6–0.7	Acceptable	PIL Questionnaire ($\alpha = 0.67$)
0.5–0.6	Poor	–
< 0.5	Unacceptable	–

Results for PIL and Video Questionnaires

Table VI. Summary of Content Validity and Reliability for PIL and Video Questionnaires

Questionnaire	Items (Initial)	Items Excluded	Items Reframed	Final Items	S-CVI	Cronbach's α
PIL	14	3	1	10	0.78	0.67
Video	15	5	5	10	0.82	0.74

S-CVI = Scale-level Content Validity Index; threshold ≥ 0.75 per Lynn (1986). Cronbach's α threshold ≥ 0.60 per Nunnally (1978).

Sr.	Tool	Original Item	Action	Reason
Q10	PIL	The PIL addresses the most common lifestyle-related health risks.	Excluded	Low I-CVI (< 0.75)
Q12	PIL	I recommend this PIL to others.	Reframed	Unclear intent; revised to specify educational purpose
Q13	PIL	The PIL covers all important aspects of lifestyle modification.	Excluded	Low I-CVI; redundant with Q5 and Q6
Q14	PIL	The PIL provides sufficient detail without overwhelming the reader.	Excluded	Content duplication with Q1 and Q2
Q4	Video	The information is up to date.	Excluded	Low I-CVI; difficult to assess objectively
Q5	Video	Language used in the video is clear and easy to understand.	Excluded	Merged conceptually into Q1 after reframing
Q7	Video	The audio quality was clear and free of distracting noise.	Excluded	Low I-CVI; merged into Q3
Q10	Video	The presentation style was engaging.	Excluded	Conceptually subsumed by revised Q6
Q14	Video	The video is suitable for educational/training purposes.	Excluded	Duplication of Q9 (reframed)

Table VII. Items Excluded or Reframed During Expert Panel Validation

Items Excluded or Reframed During Expert Panel Validation – PIL and Video Questionnaires.

I-CVI = Item-level Content Validity Index. 'Excluded' = removed entirely; 'Reframed' = retained with revised wording

Abbreviation	Full Form
CKD	Chronic Kidney Disease
CVI	Content Validity Index
ESKD	End-Stage Kidney Disease
GFR	Glomerular Filtration Rate
I-CVI	Item-level Content Validity Index
KDIGO	Kidney Disease: Improving Global Outcomes
PEMAT	Patient Education Materials Assessment Tool
PIL	Patient Information Leaflet
PG	Postgraduate Resident
S-CVI	Scale-level Content Validity Index
SD	Standard Deviation
WHO	World Health Organization

DISCUSSION

Both instruments demonstrated acceptable to good psychometric properties: Cronbach's $\alpha = 0.67$, S-CVI = 0.78 (PIL); and Cronbach's $\alpha = 0.74$, S-CVI = 0.82 (video), meeting thresholds recommended by Lynn (1986) and Nunnally (1978). The use of a mixed-expertise, interdisciplinary panel reflects best-practice recommendations in instrument development (Polit & Beck, 2006). Panel composition — spanning nephrology, general medicine, clinical pharmacy, and the patient perspective — ensured multidimensional content validity assessment. Inclusion of a patient representative aligns the process with patient-centred research principles and mirrors approaches employed by Aishwarya et al. (2020) in hypothyroidism KAP

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questionnaire validation (S-CVI = 80.46%), and by Sethi et al. (2018) and Ranjan et al. (2019).

The Cronbach's alpha of 0.67 for the PIL questionnaire is appropriate for a newly developed, multi-domain instrument where assessed constructs — content clarity, layout, usefulness, relevance, and overall quality — are conceptually distinct. A higher alpha could paradoxically signal item redundancy rather than superior reliability (George & Mallery, 2003). The alpha of 0.74 for the video questionnaire reflects the more homogeneous nature of multimedia evaluation criteria (Terwee et al., 2007). The iterative refinement process prioritised content representativeness over item inflation, consistent with Polit and Beck's (2006) recommendation that S-CVI, rather than alpha, should be the primary criterion for content validity. The higher exclusion rate for the video questionnaire (nine of fifteen items) reflects the difficulty of disentangling technical dimensions — pacing, audio quality — from content assessment in multimedia evaluation.

The domain structure — content quality/clarity, layout and design/presentation, usefulness/engagement, relevance/impact, and overall evaluation — is consistent with established frameworks including the PEMAT (Shoemaker et al., 2014). Study limitations include the eight-member expert panel size (a larger panel would improve I-CVI estimate stability per Lynn, 1986); absence of test-retest reliability data; limited generalizability beyond the Karnataka context; and the absence of confirmatory factor analysis for the hypothesised five-domain structure (Terwee et al., 2007). Future studies should address these gaps through larger validation panels and external replication studies.

CONCLUSION

This study successfully developed and validated two assessment questionnaires — for a PIL (Cronbach's $\alpha = 0.67$; S-CVI = 0.78) and an educational video (Cronbach's $\alpha = 0.74$; S-CVI = 0.82) — for use in a CKD patient education programme. Both instruments met established psychometric thresholds for acceptable to good internal consistency and satisfactory content validity. The iterative, expert-consensus-driven refinement process produced streamlined, content-valid instruments suitable for deployment in CKD patient education research, offering a reproducible psychometric framework applicable to instrument development in other chronic disease contexts.

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CONFLICT OF INTEREST

No Conflicts Of Interest Were Declared By Any Of The Authors.

ABBREVIATIONS

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