

Development and Validation of a Questionnaire to Assess Knowledge, Attitude, and Practice of Informed Consents among Dental Professionals

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Abstract

The aim of this report was to develop and validate a new questionnaire that assesses the knowledge, attitude, and practice of informed consent in dentistry. Items were developed after a comprehensive literature review of related literature. Three experts were involved in the initial review and modifications. Content validity was assessed through a panel of five experts, and a content validity index of 0.93 was achieved. Reliability was assessed through both internal consistencies using Cronbach's alpha and the test-retest method; both methods showed good reliability.

Keywords: *Informed Consent; Dental; Bioethics; Saudi; Questionnaire; Validation*

Introduction

The relationship between dentists and their patients has undergone significant changes in the recent decades. The traditional paternalistic approach to treating patients has been replaced by a model of mutual participation in which patients are more involved in their own care and decision-making [1,2]. This shift is the result of advancements in healthcare, increased patient awareness due to education and mass media, and growing emphasis on individualism [3]. Today, patient rights play a more important role in the clinical setting than ever before, as reflected by various international conventions and declarations such as the convention on human rights and medicine and the declaration on the promotion of patient rights [4].

Dental professionals are required to obtain informed consent from patients before performing therapeutic procedures. Obtaining informed consent is a crucial aspect of dental practice, as it ensures that patients are fully aware of the risks and benefits of the proposed treatment [5]. Despite the importance of informed consent, many dental professionals lack adequate knowledge about it, and it has not been shown to be used routinely [6-9].

Different researchers have attempted to assess the knowledge, attitude, and practice (KAP) of dentists in different geographic areas [6-9] but unfortunately, no validated questionnaire has been developed to date, which makes it difficult to compare findings among different populations, and the establishment of a validated questionnaire will help establish baseline data on the KAP of informed consent among dental professionals.

Aim of the Study

This study aimed to address this knowledge gap by developing and validating a new questionnaire that assesses the knowledge, attitude, and practice of informed consent in dentistry.

Materials and Methods

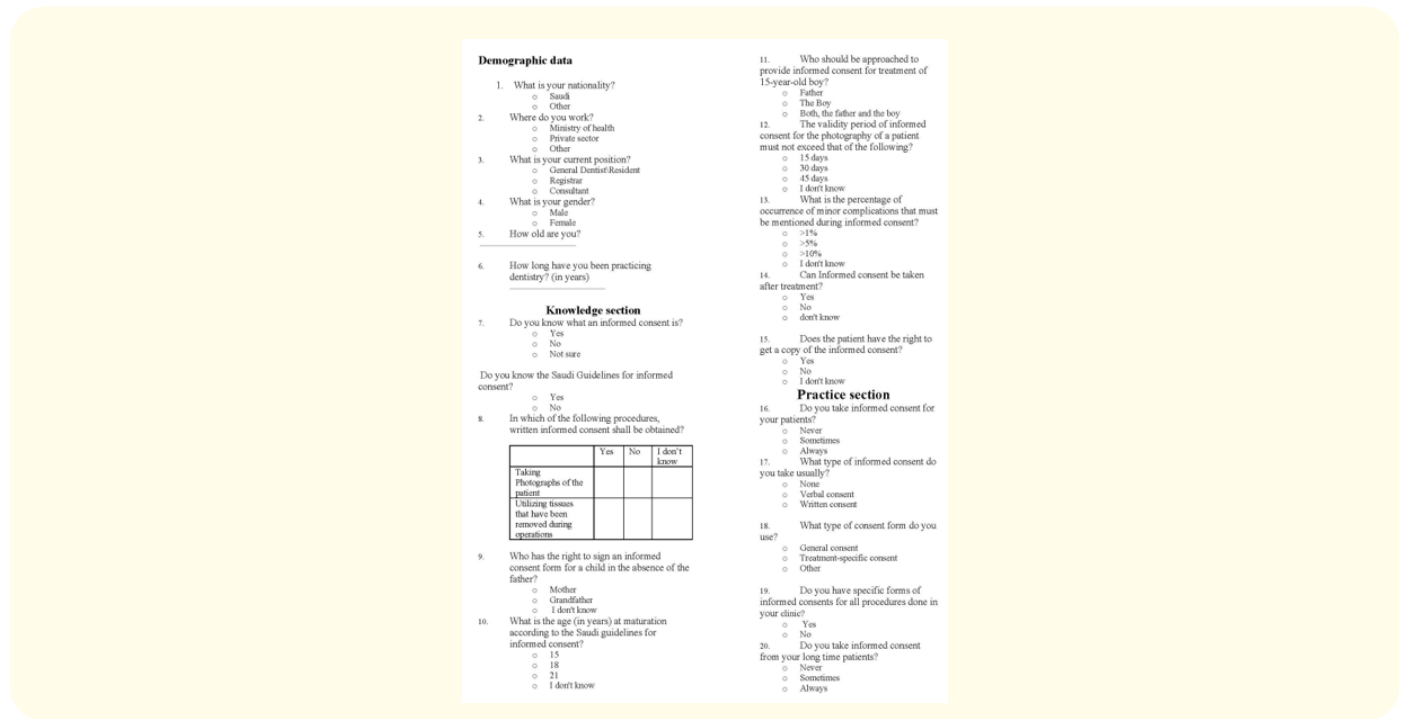
Item development

Major scientific databases including PubMed, Scopus, Google Scholar, and Elsevier were comprehensively searched for informed consent studies in dentistry. Keywords related to the topic are used for the search including “informed consent”, “dentistry”, “ethical code”. Relevant literature was retrieved and reviewed; different questionnaires concerning ethics in dentistry were found, and questionnaire items were generated from the findings of the literature.

After the initial questionnaire was developed, an expert panel of three senior dentists (orthodontists, prosthodontists, and oral surgeons) with more than 20 years of experience conducted a comprehensive review of the items. Based on the experts’ comments, some questions were removed and others were added in addition to rephrasing the questions to make them easier to understand.

The questionnaire consisted of four sections. Section I contained questions on demographic data, including nationality, gender, age, workplace, experience, and clinical rank. Section II Contained 11 questions to assess knowledge and was based mainly on Saudi guidelines for informed consent. The answers options were “Yes” and “No” and “I don’t know” or “not sure”, with one question asking about direct information related to the Saudi guidelines for informed consent. Section 3 contained six questions to assess attitude, five questions asking about the level of agreement, using five Likert scale; answers ranging from strongly agree, agree, neutral, disagree, and strongly disagree, and only one question about giving a copy informed consent with three answers “yes”, “no” and “ask for the reason before giving”.

Section 4 contained 10 questions about the practice, each question had 3 choices, answers were either:” yes”, “no” and “sometimes”; or “never”, “sometimes” and” always” (Figure 1).



21. Do you take consent from your relative patients?

- Never
- Sometimes
- Always

22. What is your main reason for taking informed consent?

- Protect myself against legal actions
- Protect the patient rights
- Other

23. Do you discuss all treatment options before starting treatment?

- Never
- Sometimes
- Always

24. Do you explain the risk or complication to the patient before starting treatment?

- Never
- Sometimes
- Always

25. Do you take consent for non-surgical procedures?

- Yes
- No
- Sometimes

Attitude section

26. What is your opinion regarding the following?

Mark only one choice per row.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Verbal consent is adequate for routine dental treatment					
Informed consent should be taken only in invasive dental procedures					
Informed consent is necessary for every patient undergoing treatment in your clinic					
Taking informed consent helps with treatment					
There is negative effects in taking informed consent					

27. Would you give a copy of the informed consent if the patient asked for?

- Yes
- No
- Ask for the reason before giving a copy

Validity is defined as the ability to measure what is intended to be measured [10], Smith [11] defined validity as “the degree to which the researcher has measured what he has set out to measure”. Kerlinger [12] defined it as a question: “Are we measuring what we think we are measuring?”.

Content validity refers to the ability of a research instrument to cover the research domain fairly and comprehensively [12]. Intuitive skills and logic were required to establish the content validity of the research instrument. The literature contains several methods for judging content validity, the most common being expert judgment.

The content validity index (CVI) was used to validate the questionnaire, and four determinants were suggested to assess the content validity index: relevance, simplicity, clarity, and ambiguity [13]. Five expert clinicians were responsible for assessing the previously mentioned points using 4 points Likert scale. The scoring system is as follows: 4 = highly relevant, 3 = quite relevant, 2 = somewhat relevant, and 1 = not relevant [14] (Table 1).

Items that have been ranked three or four by a reviewer were included, to calculate the content validity index, the total score is divided by the number of items [14]. The same score is applied to the other three determinants: clarity, simplicity, and ambiguity [13]. The item score was measured as follows: the total score obtained was divided by the number of experts to obtain the final assessment score for each item. Content validity of each item was achieved when the average item score was 0.75 [15]. The CVI for all items (relevance, clarity, simplicity, and ambiguity) was calculated by dividing the number of valid items by the total number of items.

Characteristic	1	2	3	4
Relevance	Not relevant	Item needs some revision	Relevant but needs minor revision	Very relevant
Clarity	Not clear	Item needs some revision	Clear but needs minor revision	Very clear
Simplicity	Not simple	Item needs some revision	Simple but needs minor revision	Very simple
Ambiguity	Doubtful	Item needs some revision	No doubt but needs minor revision	Meaning is clear

Table 1: Criteria for measuring content validity.

Face validation

Questionnaires were distributed to ten participants. Participants were requested to identify problems related to the questionnaire (clarity, difficulty in understanding questions, and length). Based on their responses, some questions were rephrased, and the option ‘I do not know’ was added to some other questions.

Reliability

Reliability refers to the ability to measure a variable and produce the same result when measured on different occasions. Reliability has been viewed as consistency or reproducibility, meaning that if used in a similar context, it should produce the same results [16]. Two methods can be used to assess the reliability of the questionnaires: test re-testing and internal consistency.

The test-retest technique was used by administering the same questionnaire to the same group twice with a 10-days interval. The correlation coefficients were then calculated. A correlation coefficient of 0.80 is considered adequate and can guarantee reliability [17].

Cronbach’s alpha, also called the coefficient alpha, was used to test internal consistency [18]. When the Cronbach’s alpha value is equal to one, it represents high consistency of the items; when it is equal to zero, the items lack internal consistency. There is no consensus on the value of Cronbach’s alpha that can be considered acceptable for research; however, it has been suggested that a 0.67 is acceptable [19,20].

Results and Discussion

Validity

In assessing validity of research instrument, all the questions scored more than 0.75 in content validity index, except two items which were eliminated from the questionnaire. The average of all item scores was calculated to assess the content validity of the questionnaire, twenty-six items were judged valid (for relevance, simplicity, clarity, and ambiguity) and then divided by the total number of items, yielding a CVI of 0.93, indicating good validity (Table 2).

Item	Relevance	Clarity	Simplicity	Ambiguity
1	0.80	0.80	0.80	1.00
2	1.00	1.00	1.00	0.80
3	1.00	0.80	0.80	0.80
4	0.80	1.00	0.80	1.00
5	1.00	0.80	1.00	0.80
6	1.00	0.80	0.80	0.80
7	0.80	1.00	0.80	1.00
8	1.00	0.80	0.80	0.80

9	1.00	1.00	0.80	0.80
10	1.00	0.80	1.00	1.00
11	0.80	1.00	0.80	0.80
12	1.00	1.00	1.00	1.00
13	1.00	1.00	0.80	1.00
14	1.00	1.00	1.00	1.00
15	0.80	1.00	1.00	1.00
16	1.00	1.00	1.00	1.00
17	0.80	1.00	0.80	1.00
18	1.00	1.00	1.00	1.00
19	1.00	0.80	0.80	0.80
20	1.00	1.00	0.80	1.00
21	1.00	0.80	1.00	0.80
22	1.00	1.00	1.00	1.00
23	1.00	1.00	0.80	1.00
24	1.00	0.80	0.80	0.80
25	1.00	1.00	0.80	1.00
26	1.00	0.80	0.80	0.80
27	0.60	0.40	0.40	0.40
28	0.60	0.60	0.60	0.60

Table 2: Content validity index of each item for relevance, clarity, simplicity and ambiguity.

Reliability

Two methods were used to assess reliability. In the test-retest method, 14 randomly selected dental professionals completed the questionnaire. After 10 days, the questionnaires were sent to them to answer the questionnaire again. Pearson’s correlation coefficients were calculated (Table 3).

	Pearson’s correlation coefficient	P-value
Knowledge score	0.925	< 0.001
Attitude score	0.954	< 0.001
Practice score	0.975	< 0.001

Table 3: Reliability assessment using Pearson correlation coefficient.

The Cronbach’s alpha was calculated to be 0.74.

Discussion

The development of a KAP questionnaire regarding informed consent among dental professionals will help conduct KAP assessments among dental professionals in different populations.

To the best of our knowledge, this is the first study to describe the development of a validated questionnaire examining the knowledge, attitudes, and practices of dental professionals regarding informed consent. This report describes in detail all stages of developing and validating a questionnaire.

The CVI for relevance, clarity, simplicity, and ambiguity were calculated. 93% of judged items were valid. Items scored less than 0.80 were discarded (two items). Based on the content validity index, these two items were problematic in terms of clarity, simplicity, and ambiguity. The two items were discarded. Davis [14] recommended setting a CVI score of 0.80 or more for accepting the research instrument. Yaghmaie [13] also recommended a CVI of 0.75 as an acceptable score. Accordingly, a CVI of 0.93 is considered sufficient.

Internal consistency

Reliability can be assessed using both the test-retest and Cronbach's alpha. The Pearson's correlation coefficient showed a high correlation between the two tests, indicating good reliability of the research tool (Table 3).

Internal consistency indicates how the items fit. This was performed by calculating the Cronbach's alpha, which was 0.74. Different values have been suggested for the alpha value to be considered as acceptable. Cohen., *et al.* [19,20] considered a value of 0.67 and above as adequate. Peterson 1994 indicated a range between 0.70 and 0.95 as acceptable [21].

Conclusion

A validated questionnaire to assess KAP of dental professional in regard to informed consent is developed.

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