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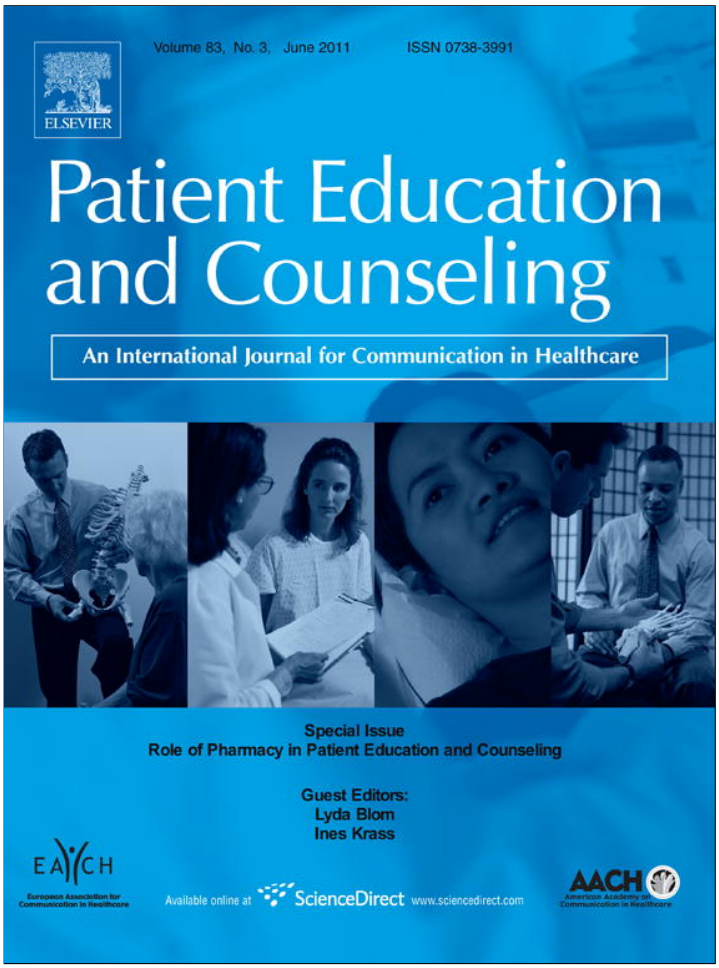

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Development and validation of the Medication-Related Consultation Framework (MRCF)

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ABSTRACT

Objectives: To develop and test a framework for evaluating the consultation skills of practitioners undertaking medication-related consultations.
Methods: Key components of medication-related consultations were identified through a literature review and compiled to form an initial consultation skills framework. This was iteratively refined through consultation with experts ($n = 21$) to form the Medication-Related Consultation Framework (MRCF). Psychometric testing was undertaken by analyzing pharmacists' ($n = 10$) assessment of fifteen pre-recorded simulated consultations.
Results: The MRCF consisted of 46 consultation behaviors, grouped into five sections. Performance was rated at individual behavior, framework section and global consultation levels. The MRCF discriminated between good, satisfactory and poor consultations at the global rating level ($p < 0.01$) with good test–retest reliability (rho = 0.59–0.95) and moderate inter-assessor reliability (Kendall's $W = 0.67$). There was also good internal consistency for the five sections (Cronbach's alphas = 0.58–0.97).
Conclusions: The MRCF demonstrated good psychometric properties at the global and section rating levels. Some inconsistencies in assessors' ratings of individual consultation behaviors were indentified, which may represent a future training need.
Practice implications: The MRCF provides healthcare professionals with a patient-centered consultation structure, serving to identify medication-related needs and potentially support adherence. It also allows the quality of a practitioner's consultation to be evaluated.
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1. Introduction

Effective consultation is central to the delivery of high quality clinical services for patients. The purpose of a medication-related consultation is to conduct a therapeutic review, with the aim of assessing a patient's pharmaceutical care needs. It is key to understanding how patients relate to their medicines, including their concerns and expectations of treatment, and to anticipate or resolve medication-related problems, in particular non-adherence.

There is evidence to suggest that current healthcare systems are failing patients by not translating the proven benefits associated with medicines into anticipated health gains [1–3]. Pharmacists, as medicines experts within the healthcare team, are ideally placed to make an important contribution to improving this situation. In recent years the clinical role of pharmacists in the United Kingdom (UK) has expanded to include medication use review [4] and non-medical prescribing [5]. Furthermore, the 'self-care' agenda highlights the pharmacist's role in enabling patients to manage their own health, through 'achieving better use of medicines' [6]. However, there is a need to ensure that pharmacists possess good consultation skills in order to deliver these services effectively. Improved undergraduate and postgraduate communication skills training has been identified as one area for development [7]. Moreover, training in consultation skills has been noted as a core

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element for the delivery of patient centered care important to commence in the early years of a pharmacist's career [8]. While pharmacists play an important role in supporting patients with their medicines both medical and nursing staff have key responsibilities in this area.

Recent adherence guidelines have highlighted the need for practitioners to take a patient-centered approach to medication-related consultations, eliciting patients' perspectives on the treatment and taking a shared approach to decision-making [9]. There is evidence to suggest that such patient-centered approaches to consultations can improve outcomes such as adherence [10]. Studies in the medical literature suggest that a patient-centered approach can be effectively taught and is preferred by patients [11–14]. However, while most medical models of consulting adopt a more patient-centered approach, they generally lack focus on medication-related issues and are therefore not ideal for teaching and evaluating medication-specific consultations [e.g., 13–18].

The pioneering work of James et al. [19] described the design and evaluation of a simulated-patient training programme to develop the consultation skills of undergraduate pharmacy students. The approach drew on the principles of patient-centered pharmaceutical consultation, to incorporate the principles of pharmaceutical care [20] and the "perceptions and practicalities" adherence model [21]. The authors postulated that this allowed the practitioner to work with the patient, reviewing their medication-taking behavior, identifying actual and potential medication related problems and developing, with the patient, a plan for their resolution. The perceptions and practicalities approach recognizes that patients may not take their medication as prescribed due to both unintentional factors (e.g. forgetting, misunderstanding, physical barriers) and intentional factors (e.g. actively deciding not to take the medication as prescribed). Intentional non-adherence is likely to occur when adherence does not 'make sense' in the context of the patient's personal illness or medication beliefs [22]. In order to support self-management, it is important that the practitioner elicits the patient's views about their proposed treatment and addresses any misconceptions patients may hold, either about the necessity of prescribed medication or concerns about possible adverse effects, to enable the patient to make an informed choice about their treatment. This underpins the concept of concordance, where a clear partnership is formed between the patient and the practitioner to support medicines use [23].

These theories provide a strong foundation for teaching patient-centered medication-related consultation skills but there is a need to delineate the activities and processes involved in a medication-related consultation, and provide a validated means of measuring the quality of the practitioner's consultation skills. Medication-related consultation guidelines exist [24–27] yet do not appear to be grounded in theory or appropriately validated. For example the Medication Counseling Behavior Guidelines, developed in the US, outline a clear consultation process, listing 35 relevant items, each with a 10-point rating scale [26]. While this approach has obvious merit, there is no empirical evidence to support the guidelines' development and research suggests that awareness and use of these guidelines, in clinical practice, is limited [28–30].

The availability of a validated, theory-based medication-related consultation framework would facilitate the teaching and evaluation of consultation skills and provide a structured format for feedback. Furthermore, it would help to identify practitioners' learning needs in order to target areas for improvement. The aims of this work were to (1) develop a framework specifically to evaluate medication-related consultations and (2) to test the validity of the framework.

2. Method

2.1. Stage 1: development and content validation of the Medication Related Consultation Framework (MRCF)

A comprehensive literature review of the healthcare consultation literature was conducted in order to identify key components of medication-related consultations [31]. This included a search of online databases (Medline, Web of Science, Pharmline, and PsycINFO) including search terms to reflect models of medical, pharmaceutical or healthcare professional consultations (e.g. "consultation*" or "communication*" or "medication counseling" or "interaction"), in combination with "model" or "framework" or "theory". A manual search of relevant journals and a reference list search were also conducted to identify any additional relevant papers or books. The search was limited to English language material. Papers and books were selected for review when they described health-care related consultation models, supported by theoretical and/or empirical evidence. Consultation activities and behaviors were extracted from the models and grouped in a logical way to reflect the intuitive order of a consultation (i.e. from consultation initiation to closure).

Three members of the research team reviewed a number of rating scales to evaluate the observable consultation behaviors, using published criteria for the development of effective evaluation tools [32–34]. Different framework versions were assembled by combining the list of activities and behaviors generated through the literature review with the various rating systems. These pilot frameworks were tested by members of the research group who used the frameworks to rate videotaped simulated consultations. Consensus was reached on the most appropriate and practical rating system.

The draft framework was evaluated for content validity using individuals with a range of expertise who satisfied at least two of the following criteria; involvement in the teaching of consultation skills in healthcare; extensive experience of consulting with patients about their medicines; conversant with practitioner-patient consultation theories. The framework was presented to two discussion panels; the first consisting of five senior academic pharmacists from the local School of Pharmacy with a background in teaching consultation skills and the second consisting of five senior clinical pharmacists routinely conducting medication-related consultation in the local hospitals. Eleven face to face semi-structured interviews were conducted with experts in the field of consultation, identified principally from the published literature, representing a variety of disciplines including medicine, nursing and psychology. These experts systematically reviewed the framework for structure, content and clarity and, in addition, were asked to feedback on the rating system employed. All interviews and discussions were recorded and transcribed in full. Two researchers reviewed the transcripts and identified issues of clarity and any suggestions made by the experts for improving the framework. These were taken to a Framework Development Panel, consisting of four members of the research team, all with expertise in consultation skills training, to further refine the framework. Over the consultation period, the panel met regularly to revise the framework in response to the feedback from the experts.

2.2. Stage 2: validation of the MRCF

2.2.1. Ethical approval

This study was reviewed and approved by the 'Brighton Local Research Ethics Committee (LREC)' [Ref: (B) 03/16].

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2.2.2. Participants and procedure

A purposive sample of Pharmacy experts, including senior pharmacists, pharmacy academics and pharmacists holding a joint position between academia and practice ($n = 10$), participated in this study which involved using the MRCF to assess recorded simulated consultations. Each participant (also referred to as 'assessor') received a structured one-to-one tutorial explaining (1) the design and content of the framework; (2) how to use the rating system; and (3) the study procedure. Each participant assessed three recorded consultations using the MRCF as part of the training programme. The participants then independently assessed fifteen video-taped simulated consultations and re-assessed a sub-sample ($n = 6$) six to eight weeks later.

2.2.3. Consultation videos

The consultation videos were selected from an existing pool of recorded medication-related consultations between community pharmacists and simulated patients, conducted in a film studio specifically designed for this purpose. The research team selected 15 videos classified into three distinct groups based on their quality: those that failed to meet (poor, $n = 5$), only partially met (satisfactory, $n = 5$) or fully met (good, $n = 5$) the pharmaceutical needs of the patient. These 15 recordings were used for the MRCF validation study. Participants were blind to the consultation quality ratings.

2.2.4. Analysis

Assessors' MRCF ratings for each recorded consultation were entered on a Statistical Package for Social Sciences (SPSS) version 11.00 database. Ten percent of the cases were randomly selected and checked for typing and coding errors. Since the data produced were ordinal, non-parametric statistics were employed.

2.2.4.1. Discriminant validity. This study explored the extent to which the framework could discriminate between consultations of different quality, i.e. between poor, satisfactory and good consultations. Assessors' median global rating was calculated for each consultation. *Kruskal–Wallis* test, with *Mann–Whitney post hoc* analysis, was used to compare assessors' ratings of consultations that had *a priori* been selected as good, satisfactory and poor.

2.2.4.2. Inter-assessor reliability. The degree to which assessors awarded similar ratings when observing the same consultations was investigated. Each assessor's ratings at the individual item, section rating and global rating level were ranked across the 15 simulated consultations. Kendall's coefficient of concordance was calculated to assess the degree of agreement between assessors' ranked ratings at each level.

2.2.4.3. Intra-assessor (test–retest) reliability. The extent to which assessors produced consistent ratings when applying the MRCF to the same consultation at two time points was assessed. Spearman's correlation coefficients were calculated for each assessor between the ratings at Time 1 and Time 2 (six to eight weeks later).

2.2.4.4. Internal-consistency. Internal consistency measures the extent to which each item in a scale is related to other aspects of the scale. Cronbach's alpha coefficients were calculated to determine whether individual activities/behaviors within each section demonstrated internal consistency.

3. Results

3.1. Stage 1

Development of the Medication Related Consultation Framework (MRCF)

Table 1
Consultation skills models identified in the literature review.

Calgary Cambridge Observation Guide	[13,14]
DREAM consultation	[35]
E4 model for physician–patient communication	[36]
Frederikson information exchange model	[37]
Inner consultation	[15]
Patient-centered clinical model	[38,39]
Pendleton and colleagues consultation model	[18]
SEGUE framework	[17]
Three function model of the medical interview	[16]

3.1.1. Initial framework

Nine consultation skills models were identified through the literature review (see Table 1), which represented key models used for consultation skills teaching in undergraduate and postgraduate medical programmes.

Forty-seven specific activities and behaviors relevant to medicine-related consultations were identified from these models. These were grouped to form the initial framework consisting of six sections reflecting *what* should be covered in a consultation and *how* it should be delivered. These were: scene setting; data collection; solutions; closing the consultation; structuring the consultation; and building relationships.

A number of different methods of evaluating observable behaviors were identified in the education literature. These included various Likert scales (e.g. five point scale from unacceptable to excellent) and dichotomous ratings (e.g. was the activity undertaken – yes or no) [34,40]. Following the piloting exercise a four option rating system was adopted where each activity and behavior to be undertaken was assessed as 'not at all', 'touched upon', 'adequate' and 'very good'. Assessors could also select 'not applicable' if the activity was not relevant to the specific consultation. Space was provided for qualitative feedback. In addition, assessors were asked to provide information on the overall quality of the practitioner's consultation performance using a three option global rating system: 'unable to meet the patient's needs', 'partially able to meet patient's needs' and 'fully able to meet the patient's needs'.

3.1.2. Content validation

The framework was further developed iteratively through a process of expert consultation and modification by the Framework Development Panel. Modifications were made at many levels, from the overall structure, to inclusion of individual items, the wording of the items and the format of the rating system.

The final version of the Medication-Related Consultation Framework (MRCF) consisted of forty-six activities and behaviors, grouped into five sections (see Table 2). Four sections (A to D) focused on the specific activities which form the content of the consultation (i.e. *what* should be covered). Section (E) focused on the consultation behaviors which underpin the process (i.e. *how* the practitioner delivers the consultation).

3.2. Outline of the five MRCF sections

(A) *Scene setting*, where the practitioner engages with the patient; (B) *data collection and problem identification*, where relevant information is obtained from the patient and the pharmaceutical care needs identified and prioritized. This is an important section that requires the practitioner to identify what medicines a patient takes, how they use them, in particular addressing concerns and questions a patient may have about their medicines; (C) *actions and solutions*, which involves a discussion on how the problems identified might be resolved or prevented and to negotiate shared management strategies; (D) *closing;* where the

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Table 2
Mediction-related consultation framework (MRCF) sections, corresponding aims and examples of activities.

Sections	Aims	Number of activities/ behaviors	Examples of activities/behaviors
(A) Scene setting	To build a therapeutic relationship with the patient	6	Invites patient to discuss medication and/or health-related issues
			Negotiates shared agenda
(B) Data collection and Problem Identification	To identify the pharmaceutical needs of the patient	15	Assess patient's understanding of prescribed treatment
			Elicits concerns about treatment
			Asks how often patient misses dose(s) of treatment
			Identifies reasons for missed doses
(C) Actions and solutions	To establish an acceptable management plan with the patient	8	Relates information to illness and treatment beliefs (addresses information gaps, communicating anticipated benefits and addressing concerns/risks of treatment
			Gives advice on how and when to take treatment, negotiates follow-up
(D) Closing	To negotiate safety netting strategies with the patient	3	Discusses what to do if patient has difficulties with plan
			Offers opportunity to ask further questions with regard to the issues discussed during the consultation
(E) Consultation behaviors	To demonstrate specific consultation behaviors throughout the consultation	14	Listens actively and allows patient to complete statements
			Shares thinking with the patient to encourage patient involvement
			Adopts a structured and logical approach to the consultation
			Manages time effectively

practitioner discusses contingency plans with the patient, in case something goes wrong, and negotiates and agrees a follow-up plan; and the final section (E) lists consultation behaviors to be demonstrated throughout the consultation.

During the expert-consultation process, it was argued that in addition to the ratings of individual activities and behaviors, a rating for each section would enable more useful feedback to be provided to the practitioner. A section rating scale was therefore added to sections A to D (consultation activities). Assessors were asked to rate whether the aim of each section was achieved on a 5 point scale from '0 = not able' to '4 = fully able'. There was no section rating for section E, because this represented general consultation behaviors that should be applied by the practitioner throughout the entire consultation as opposed to a particular section. An example of the rating system for a section of the MRCF is shown in Fig. 1. In addition, the global rating was modified so that a judgment on the practitioner's overall competence could be made using a 5 point scale ('Not competent – poor', 'Not competent – borderline', 'Competent – satisfactory', 'Competent – good' and 'Competent – very good').

3.3. Stage 2: validation of the MRCF

3.3.1. Discriminant validity

The global ratings made by assessors were found to discriminate between good, satisfactory and poor consultations (*Kruskal–Wallis Chi-square* = 12.5; $df = 2$; $p < 0.01$) (see Fig. 2). *Post-hoc Mann–Whitney* analyses revealed that there were significant differences between each quality category ($z = 2.61$, $p < 0.01$ for all three comparisons).

Did the practitioner undertake the following activities? 1 = not at all, 2 = touched upon; 3 = adequate; 4 = very good; N/a = not applicable

D. CLOSING THE CONSULTATION		1	2	3	4	N/a
D1.	Explains what to do if patient has difficulties to follow plan and whom to contact	☐	☐	☐	☐	☐
D2.	Provides further appointment or contact point	☐	☐	☐	☐	☐
D3.	Offers opportunity to ask further questions with regard to issues discussed in the consultation	☐	☐	☐	☐	☐

Section rating of *Closing* section

The practitioner was **not** able to negotiate 'safety netting' strategies with the patient	0	1	2	3	4	The practitioner was **fully** able to negotiate 'safety netting' strategies with the patient
Comments:						

Fig. 1. Example section from the MRCF Did the practitioner undertake the following activities? 1 = not at all, 2 = touched upon; 3 = adequate; 4 = very good; N/a = not applicable.

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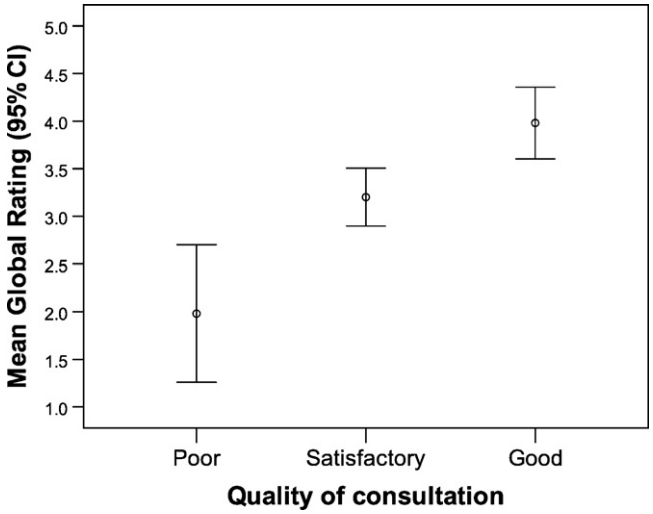

Fig. 2. Differences between mean ratings on the global assessment level.

Table 3
Inter-assessor agreement for the global and section ratings (A to D).

	Kendall's *W*	Chi-square	df	*p*
Global rating	.67	94.23	14	.000
Section ratings				
(A) Scene setting	.56	70.92	14	.000
(B) Data collection and problem ID	.48	66.55	14	.000
(C) Actions and solutions	.51	71.00	14	.000
(D) Closing	.51	71.23	14	.000

3.3.2. Inter-assessor reliability

As shown in Table 3, there was moderate agreement between assessors at the global rating level (*Kendall's W* = 0.67; *df* = 14; $p < .001$) and section rating level (*Kendall's W* = 0.48–0.56; *df* = 14; $p < .001$). At the individual item level, inter-assessor agreement was variable (*Kendall's W* = 0.28–0.67) but the degree of agreement between assessors remained significant ($p < .05$).

3.3.3. Intra-assessor (test–retest) reliability

There was moderate to high intra-assessor reliability at the global level (*rho* = 0.59–0.95). At the section level there was also moderate to high intra-assessor reliability for all sections (*rho* = 0.42–1.00) except section C (*rho* = 00.0–0.94) (see Table 4).

3.3.4. Internal consistency

The alpha coefficients for the activities/behaviors within sections B, C and E were high (above .80), which indicates high internal reliability of these sections. The alpha coefficients for sections A and D were moderate (.60 and .58 respectively), showing lower internal consistencies (see Table 5).

Table 5
Summary of Cronbach's alpha coefficients for items per individual section.

Individual item ratings	Cronbach's alpha (α)
(A) Scene setting (5 items)	0.62
(B) Data collection and problem Identification (14 items)	0.87
(C) Actions/solutions (8 items)	0.88
(D) Closing (3 items)	0.58
(E) Consultation behaviors (11 items)	0.97

Note: Five items were excluded from the analysis as there were too few cases to calculate the Cronbach's alpha coefficients. These were: '(*A6*) *Pays attention to comfort and privacy*'; '(*B8*) *Undertakes appropriate physical assessment (when indicated)*';'(*E9*) *Uses information from test results to inform decision making*'; '(*E10*) *Uses evidence based medicine-type information to inform decision making*'; '(*E14*) *Provides logical and correct documentation*'. These activities/behaviors could not be observed as they were 'not applicable' to be undertaken in the assessed simulated consultation scenarios.

4. Discussion and conclusion

4.1. Discussion

Through a process of literature review and expert consultation, a medication-related consultation framework was developed with established content validity. The framework is designed to facilitate a patient-centered consultation style, where the practitioner is required to consider the patient's perspective of their illness and its treatment, as well as undertake clinically related activities, which serve to inform future care. It incorporates the key principles of pharmaceutical care [20] and the perceptions-practicalities model to explore individual reasons for non-adherence [21]. The framework integrates the assessment of content and process skills, increasing the likelihood of practitioners delivering comprehensive, patient-centered consultations.

Using the MRCF enabled assessors to discriminate between practitioners conducting good, satisfactory and poor consultations. This is important in terms of the framework's construct validity and useabilty as only an assesment instrument that can determine differences in the quality of consultations can be used for teaching and evaluation. MRCF ratings were found to be consistent at the global and section level, both over time and across assessors. This finding indicates that the framework is reliable for evaluating the overall quality of a consultation. The inter-asessor reliability, at the individual item level, was less satisfactory. Lowest levels of reliablity were obtained for more complex items that required a higher degree of professional subjective judgement; for example the behavior "Explores patient's attitudes towards taking medication". It is likely that assessors differed in their understanding of some of the activities and behaviors and that this reflected, in part, their personal skill set. Although the assessors received some standardized training before rating the simulated consultations, more extensive training is required. A training pack (DVD and booklet) has now been developed for this purpose.

Although, no specific consensus development method (e.g. nominal group process technique or Delphi technique) was used to

Table 4
Median intra-assessor correlation coefficients for section and global ratings at Time 1 and Time 2.

Assessor	2	3	4	5	6	7	8	9	10
Global rating	.95	.59	.94	.91	.90	.84	.85	.84	.90
Section ratings									
(A) Scene setting	.75	.77	.99	.71	.83	.85	.68	.76	1.00
(B) Data collection and problem identification	.95	.45	.42	.83	.71	.82	.87	.82	.42
(C) Actions and solutions	.94	.00	.55	.87	.92	.00	.89	.46	.85
(D) Closing	.67	.81	.88	.66	.90	.43	.80	.92	.87

Note: Assessor 1 did not complete follow-up assessment of consultations.

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reach consensus between *all* experts involved in the content validity study, a robust alternative was used [34,41]. Instead, the framework modifications were made by the Framework Development Panel following a review of the expert panel discussions and one-to-one interviews. This method was considered appropriate as reaching a unanimous verdict was not a prerequisite of the study; rather the aim was to assess whether the framework comprehensively included key activities and behaviors that should be addressed when conducting medication-related consultations. Consensus techniques have themselves been criticized as different groups of experts differ in their opinions and consensus is rarely reached on complex issues [42,43]. As the patient-practitioner consultation is a complex area it was thought that the inclusion of pharmacy experts working in different specialties, i.e. academia, community, as well as hospital in and out-patient environments, in addition to involving experts from different healthcare fields would secure a wide range of opinions and experiences to be assessed which is fundamental to the content validity of the framework.

While the framework validation study offers important preliminary indications about this framework's psychometric properties, it is not possible to claim that these findings are generalisable to any medication-related consultation. The study has so far been tested in simulated consultations and not in the practice setting. While the use of simulated consultations for the testing of an instrument's properties is widely accepted and considered useful [44,45], there remains a need to assess whether the activities and behaviors included in the framework are observable in practice. Although medical and nursing consultation experts were involved in the design of the MRCF whether the framework can be used by other health care professionals who consult with patients about their medicines requires exploration.

4.2. Conclusion

The MRCF is a validated tool, developed specifically for the teaching and evaluation of medication-related consultation skills. It meets key criteria for a formative assessment tool and can be used to identify practitioners' strengths and weaknesses in conducting patient-centered, medication-related consultations. The framework was developed specifically for pharmacists who play an increasingly important role in delivering patient-centered clinical services, such as medicines use reviews and prescribing consultations. The framework may also be relevant to other professional groups involved in medication-related consultations, although this requires further investigation. While the MRCF provides a structured approach to the consultation process further research is needed to determine whether this has the desired impact on patient adherence.

4.3. Practice implications

Effective consultation skills are vital if patients' medication-related needs are to be identified and resolved. The importance of such skills has been recognized, as reflected in several initiatives from the government and other professional bodies [3–5,8] and the introduction of consultation skills training programmes on pharmacy courses. The MRCF can be used as a means of structuring consultation skills teaching, which would cover both content and process skills included within the framework. The MRCF can then be used to assess students' consultation performance and suggestions for skills improvement could be tailored to the individual. This approach builds on student-centered teaching and learning approaches already used in training doctors [13,39]. The MRCF has been adopted by postgraduate pharmacy teaching programmes delivered by ten Higher Education Institutions across England and Wales to evaluate the consultation skills of qualified practitioners, including non-medical prescribing courses, with the aim of identifying their training needs. The framework is also currently being used for teaching consultation skills to undergraduate pharmacy students. It can be used as a reflective tool to aid individuals' professional development, during peer assessment or as an observer administered evaluative tool.

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Conflict of interest

None.

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