Psychometric properties of the Arabic version of the 9-item Shared Decision-Making Questionnaire: the entire process from translation to validation

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ABSTRACT
Objective To translate the German 9-item Shared Decision-Making Questionnaire (SDM-Q-9) to Arabic and assess its psychometric properties for measuring Arabic-speaking patients’ perceptions of the shared decision-making (SDM) process.

Design Multicentre cross-sectional study.

Setting Secondary healthcare settings; outpatient clinics of 10 major hospitals were selected in four emirates in the United Arab Emirates (Abu Dhabi, Dubai, Sharjah and Umm Al Quwain).

Participants Patients with chronic diseases who attended outpatient clinics of participating hospitals.

Measurements The original German SDM-Q-9 was translated to Arabic. International multiphase translation guidelines and the process of cross-cultural adaptation of self-reported measures were used. Various psychometric properties were assessed, including reliability (internal consistency), and construct validity (exploratory factor analysis [EFA] and confirmatory factor analysis [CFA]).

Results The final Arabic version of the SDM-Q-9 was tested among 516 secondary care patients. Internal consistency yielded a Cronbach’s alpha of 0.929 for the whole scale. EFA showed a one-factorial solution, Kaiser-Meyer-Olkin measure of sampling adequacy was 0.907 and Bartlett’s test of sphericity was significant ($\chi^2=3413.69$, df=36, $p<0.0005$). For the CFA, two different models were tested; Model 1 included the nine items and Model 2 was monofactorial that included items 2–9 and thus excluded item 1. Both models were adequate as they produced similar indices.

Conclusions The Arabic version of SDM-Q-9 showed excellent reliability and acceptable validity parameters among secondary care patients. The newly translated Arabic questionnaire is the first psychometrically tested tool that can be used in the member states of the Arab league to assess patients’ perspectives on the SDM process.

INTRODUCTION
The importance of active patient participation during clinical decision-making is gaining increasing emphasis in modern healthcare policy.1 Shared decision-making (SDM) has been advocated as a key model of treatment decision-making.2 The SDM process takes into account patients’ preferences and opinions, and clinicians work collaboratively with patients in making treatment decisions.3 The extent to which SDM is applied in routine medical encounter varies. Research showed that the SDM, when applied, promotes patient autonomy, limits practice variation and ensures that treatment decisions are guided by patient preferences.4–6 Patients are increasingly encouraged to assume active roles as managers of their own health and not merely the recipients of services or advice.7,8 This growing interest in SDM has been driven by several factors including (1) the increasing accessibility of health information facilitates participation by patients in medical decision-making by asking informed questions and expressing their personal values and opinions regarding prescribed treatment, (2) clinicians are increasingly respecting patients’ goals and preferences and willing to use these to guide their recommendations and treatments and (3) rapidly changing societal norms where patients are demanding more autonomy.9–11 However, barriers to use

To cite: Alzubaidi H, Hussein A, Mc Namara K, et al. BMJ Open 2019;9:e026672. doi:10.1136/bmjopen-2018-026672

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Strengths and limitations of this study
► One major strength of this work is the potential for the Arabic version of 9-item Shared Decision-Making Questionnaire to be used by the 407 million people who make up the populations of all the Arab states.
► The convenience sampling may not be representative of the entire population attending secondary healthcare settings.
► The large sample size and the diversity of study participants increases the likelihood of results being representative.
► The use of a self-reported measure in this study does not eliminate the possibility of an inaccurate recall of respondents’ experiences and opinions.
of SDM in routine clinical practice remain extensive. Knowledge alone is insufficient to empower patients to share in decisions—a power imbalance remains between patients and clinicians, and active clinician support for patients to engage in SDM is required. Unfortunately, even when clinicians are open to considering patients’ values and preferences, they typically remain under skilled to do so despite self-perceptions of competency. They believe that they do not have the time to incorporate SDM as a routine practice, and they underestimate patient’s desire and capacity to engage in SDM.

The evidence regarding health benefits of SDM is unclear—this may reflect a variety of factors including an incomplete understanding about how to optimise SDM interventions, the heterogeneity of contexts in which trials were performed (eg, if no treatment option discussed is clearly superior in terms of intended effect) or patients prioritising quality of life over narrow clinical benefits. Despite the lack of clarity around clinical effectiveness, there is a clear ethical imperative to incorporate SDM into practice. It is an essential component of patient-centred care, and there may also be a modest benefit in reducing the quality of care gap for vulnerable patients who are more likely to suffer from a power imbalance in the clinical relationship. Patients’ experiences with the healthcare systems have also improved as a result of SDM, as patients were more likely to attend appointments and had fewer complaints. SDM has been shown to significantly reduce healthcare costs by reducing the length of hospital stays and the rates of invasive procedures, as informed patients often tend to choose more conservative approaches.

With the growing emphasis on patient involvement in clinical decision-making, there is a high need for valid and reliable tools to assess the quality of the SDM process. This is reflected in the emergence of several tools that measure various aspects of the decision-making processes, such as factors surrounding the task of decision-making, the decision-making process itself and decision outcomes. The content, characteristics and perspective assessed by instruments should be considered when choosing the most appropriate instrument. Existing tools evaluate the decision-making process from the perspective of patients, providers or external observers. While most instruments have shown acceptable reliability, there is significant variability in the extent of validity testing. A recent systematic review assessed the measurement quality of existing SDM tools. A total of 40 instruments were included, in this review, and results on the best evidence synthesis were inconclusive or unknown for 50% or more for the measurement psychometric properties mainly due to poor methods. We chose the 9-item Shared Decision Making Questionnaire (SDM-Q-9), as we wanted to have a patient-reported SDM measure in Arabic that has both good psychometric properties and that has been widely used. The SDM-Q-9 has been translated into more languages than any other SDM measure and has been used in a large amount of studies. It is a unidimensional self-report measure that assesses patient perceptions of the decision-making process in a specific medical encounter. The SDM-Q-9 has been translated into several languages from the original German and has consistently demonstrated good reliability and validity. It is a brief tool that consists of nine items, each asking about one step of the SDM process. For each item, respondents indicate their level of involvement in SDM on a six-point Likert scale (from 0=completely disagree to 5=completely agree). The scale was originally developed in German, and no Arabic version exists. A recent review of the literature concluded that the SDM-Q-9 can and has been used to assess interventions aimed at improving the quality of SDM in a wide range of fields.

Conventionally, SDM research has been conducted in western countries; however, recently more research is being undertaken in other regions of the world including Arabic-speaking countries. There appears to be a positive attitude towards SDM among Arabic-speaking professionals and patients, yet further studies are needed to assess the extent to which this model is implemented as a routine daily medical practice. Results of a recent study among 236 Saudi Arabic-speaking patients showed that Saudi patients generally have a positive attitude towards active participation in clinical decision-making. No valid tool was used to assess patients’ preferences for SDM process; participants were given three options to select the most preferred decision-making style. These were (1) ‘consumerist’ style when the final decision is made by the patient and his/her family members without physicians, (2) ‘paternalistic’ approach where the final decision is made by the physician only and (3) SDM style where the decision is jointly made by patient and physician. Results demonstrated that SDM was the most preferred style followed by the paternalistic approach, while the consumerist approach was the least preferred. Patients’ views on participation in SDM were obtained only from one family practice centre in Saudi Arabia, which represents a major limitation of this study. To date, there is no validated Arabic-language tool that measures patients’ perspectives on SDM. The aim of this study was to translate and assess the psychometric properties of an Arabic version of the SDM-Q-9 that measures the process of SDM in medical encounters from Arabic-speaking patient’s perspective.

METHODS

Study design and setting
A cross-sectional survey was conducted at the outpatient clinics of 10 major hospitals in four emirates in the UAE; namely Abu Dhabi, Dubai, Sharjah and Umm Al Quwain. The hospitals were purposefully selected as they are visited by large numbers of Arabic-speaking patients with chronic diseases.

Questionnaire development
Translation and adaptation of SDM-Q-9
To adapt the scale for use in Arabic-speaking populations, the five-step approach described by Beaton et al.
for cross-cultural adaptation of health status self-report measures was used. First, the original German scale was sent to two independent certified professional translators to translate the original questionnaire from German into Arabic. Second, the two Arabic translations were synthesised by HA and WS and consensus was reached on the translation of words, phrases and items. In the third step, content validity and cultural appropriateness testing of the synthesised Arabic version were done by pilot testing the Arabic version of SDM-Q9 with two family medicine physicians, one psychologist and one sociologist. These professionals reviewed the content validity, appropriateness and understandability of each item. In the fourth step, feedback from pilot testing was incorporated and the revised Arabic version was then back-translated to German by a third independent and certified translator. In the final step (equivalence testing), the back-translation was sent to the original author (IS) to review and compare the original German version and the back-translated version in German of the SDM-Q9. Minor discrepancies were identified and resolved by discussion between the researchers and the translators. After minor revisions, the final Arabic version of SDM-Q9 (table 1) was deemed equivalent to the original German tool and was approved by IS. The final version of the Arabic tool was then pilot tested with four members of the target population (Arabic-speaking adults with chronic diseases). This process ensured face and content validity of the questionnaire and the understandability of all items. No further modifications were necessary.

**Study participants and procedure**

Patients attending outpatient clinics in the selected hospitals were approached while waiting for their appointments. Patients were screened for eligibility to participate, and those who met inclusion criteria (self-identified as Arabic-speaking [Arabic was their first language], had at least one chronic disease and were over 18 years of age) were invited to complete the survey. Research objectives were explained to eligible participants, each received a full written explanation of the study and those who agreed to participate signed an informed consent sheet. During pilot testing, participants were asked to complete the survey after attending their medical appointments; however, people were unwilling to wait and complete the survey. Therefore, participants completed an anonymous self-administered questionnaire, while awaiting their medical appointment, without the presence of their treating clinicians. Participants were asked to rate a prior consultation and answered several questions about SDM. The survey had other sections, including (1) sociodemographic section (age, country of birth, sex, marital status, educational level and employment status), (2) health-related data included self-reported health status and comorbidity. Two questions assessed each patient’s preferred sources of information and whether (or not) they had any unanswered questions about their condition/treatment and (3) functional health literacy was assessed using three previously validated items that measured difficulties in reading medical forms or learning about medical conditions. Inadequate health literacy was indicated if the total score of the three items was ≤10 out of a possible total of 15.

**Patient and public involvement**

Patients and/or public were not involved in the design or planning of the study.

**Sample size**

As there are no standard sample size requirements for conducting a validation study, the sample size was obtained using the formula of sample size calculation for a cross-sectional study. The estimated proportion was set at 50% in order to maximise the value of the minimum
sample size needed. Level of confidence was set at 95%, type 1 error at 5% and margin of error at 5%. Sample size calculation yielded a value of 385 subjects. To compensate for potential missing data, this number was increased by 20% resulting in a minimum required sample size of 462.

Data analysis
Item analysis was completed by reporting the descriptive statistics pertaining to each item. Frequencies, percentages, means and SD were reported for each item. Percentage of subjects responding to the ‘completely agree’ option was reported as a ceiling effect for each item. Scale reliability was measured using the internal consistency of subjects’ responses on the scale items and Cronbach’s alpha was reported. Corrected item–total correlations were reported for each item on the SDM-Q-9 scale.

The dimensionality of the SDM-Q-9 scale was assessed by conducting the exploratory factor analysis (EFA) using the principal components analysis (PCA), with oblimin rotation, whereby components with Eigenvalues higher than 1 were extracted. Kaiser-Meyer-Olkin test was used to check for sampling adequacy where a minimum value of 0.5 indicated that factor analysis was appropriate. Bartlett’s test of sphericity was used to check whether the variables were correlated in an identity matrix. A significant p value associated with the Bartlett’s test indicated adequacy of factor analysis.

Confirmatory factor analysis (CFA) was then conducted in order to check how well the factor structure, identified in the EFA, fits the observed data. CFA was performed following the five steps of model specification, identification, estimation, assessment and respecification. The goodness of fit indices, that were used to check whether the data fit with the proposed models, included comparative fit indices (CFI), goodness of fit index (GFI), root mean square error of approximation (RMSEA) and root mean square residual (RMR). GFI and CFI values above 0.90 and RMR and RMSEA values below 0.05 indicated that the CFA model was a good fit. Data were entered, cleaned and analysed using the Statistical Package for Social Sciences (SPSS V.24.0). All statistical analyses were performed using SPSS except for CFA which was conducted using IBM AMOS V.25.0.

RESULTS
Participants’ characteristics
A total of 516 participants were recruited and completed the questionnaire. The vast majority of participants were aged between 31 and 60 years with an estimated mean of 45 (SD±13.8). They were a mix of both Emirati (76%) and Arab expat born in different Arab countries. Of the total sample, 56% were females, 45% had a university degree; however, 61% had inadequate health literacy. Only 42% reported having a full-time job. When participants were asked how often they had unanswered questions regarding their condition/treatment, 48% reported either ‘always’ or ‘sometimes’. Around 91% of participants were interested in finding more information about their condition/treatment (more details in table 2). Regarding the sources of medical and health information, most participants (83%) cited physicians as their main source of information. The Internet and friends and family members were also major sources of information (50% and 38% of participants, 

| Table 2 | Participant’s characteristics (n=516) |
|---|---|
| **Participants’ characteristics** | n (%) |
| Gender | | |
| Male | 225 (43.6) |
| Female | 291 (56.4) |
| Age (years) | | |
| 18–30 | 89 (17.2) |
| 31–45 | 175 (33.9) |
| 46–60 | 177 (34.3) |
| 61–75 | 75 (14.5) |
| Country of birth | | |
| United Arab Emirates | 394 (76.4) |
| Others, Arab expat born in different Arab countries | 122 (23.6) |
| Marital status | | |
| Single | 94 (18.2) |
| Married | 352 (68.2) |
| Widowed | 45 (8.7) |
| Divorced/separated | 25 (4.8) |
| Educational level | | |
| University education | 231 (44.8) |
| High school diploma | 134 (26.0) |
| Primary/middle school | 151 (29.3) |
| Employment status | | |
| Full-time | 216 (41.9) |
| Part-time/business owner | 54 (10.5) |
| Unemployed | 184 (35.7) |
| Retired | 62 (12.0) |
| Health literacy | | |
| Inadequate | 313 (60.7) |
| Adequate | 203 (39.3) |
| Unanswered questions | | |
| Always/sometimes | 247 (47.9) |
| Rarely/never | 269 (52.1) |
| Interest in finding more information | | |
| Yes | 468 (90.7) |
| No | 48 (9.3) |
| Main sources of health information | | |
| Physicians | 428 (82.9) |
| Internet | 260 (50.4) |
| Friends and family | 198 (38.4) |
| Pharmacists | 47 (9.1) |
| Television | 7 (1.4) |
| Magazines | 4 (0.8) |
| Academic background | 01 (0.2) |

*Estimated mean from the age categories using the midrange value.
respectively). The most prevalent chronic diseases were hypertension, diabetes and dyslipidemia (44%, 41% and 32%, respectively). More information regarding chronic disease can be found in figure 1. The mean score for self-reported health status was 75.8 out of 100 (100 being the best possible health) with a SD of 18.3 points.

QUESTIONNAIRE RELIABILITY

Internal consistency reliability for the SDM nine-item scale was measured using the Cronbach’s alpha coefficient, which was 0.929 (the Cronbach’s alpha ranged between 0.915 and 0.929 when deleting items 1 and 5, respectively). The ceiling effect, that is, the percentage of participants completely agreeing, on the SDM scale ranged between 16.5% for item 7 (My doctor and I thoroughly weighed the different treatment options) and 34.5% for item 9 (My doctor and I reached an agreement on how to proceed).

The means of the study participants’ responses on all SDM items were between 3.06 (item 7) and 3.72 (item 1: My doctor made clear that a decision needs to be made). The corrected item–total correlation was lowest for item 1 (0.602) and highest for item 5 (0.831) (table 3).

Factor structure

EFA was conducted to identify the underlying structure of the SDM scale. Kaiser-Meyer-Olkin measure of sampling adequacy was 0.907 and Bartlett’s test of sphericity was significant with a chi-square test value of 3413.69 (df=36, p<0.0005) indicating that factor analysis was adequate to the observed data. Using the PCA, only one factor had an eigenvalue above 1 and explained 64% of the total variance. Factor loadings of the nine scale items ranged between 0.676 (for item 1) and 0.875 (for item 5) (table 4).

CFA was conducted using two different models. Model 1 was a one-factor model, including the nine items of the SDM-Q-9, to confirm the single factor obtained in the EFA. Model 2 was also a monofactorial model that included items 2–9 and thus excluded item 1, which had the lowest factor loading in the EFA. Both models were adequate as they produced similar indices, with model 2 showing slightly better indices (table 5).

DISCUSSION

This study is the first to report the psychometric characteristics of the Arabic version of the SDM-Q-9. To ensure content accuracy, semantic equivalence and construct

**Table 3** Items and contents of the SDM-Q-9, response distribution, means, SD and corrected item–total correlations (n=516)

| Items and content of the SDM-Q-9 | Completely disagree N (%) | Strongly disagree N (%) | Somewhat disagree N (%) | Somewhat agree N (%) | Strongly agree N (%) | Completely agree N (%) | Mean (SD) | Corrected item–total correlation |
|---------------------------------|--------------------------|-------------------------|------------------------|---------------------|---------------------|------------------------|-----------|-------------------------------|
| 1. My doctor made clear that a decision needs to be made | 13 (2.5) | 15 (2.9) | 40 (7.8) | 141 (27.3) | 135 (26.2) | 172 (33.3) | 3.72 (1.226) | 0.602* |
| 2. My doctor wanted to know exactly how I want to be involved in making the decision | 25 (4.8) | 41 (7.9) | 62 (12.0) | 148 (28.7) | 136 (26.4) | 104 (20.2) | 3.24 (1.374) | 0.703* |
| 3. My doctor told me that there are different options for treating my medical condition | 30 (5.8) | 54 (10.5) | 55 (10.7) | 130 (25.2) | 141 (27.3) | 106 (20.5) | 3.19 (1.453) | 0.744* |
| 4. My doctor precisely explained the advantages and disadvantages of the treatment options | 39 (7.6) | 42 (8.1) | 49 (9.5) | 132 (25.6) | 132 (25.6) | 122 (23.6) | 3.25 (1.497) | 0.715* |
| 5. My doctor helped me understand all the information | 18 (3.5) | 31 (6.0) | 44 (8.5) | 136 (26.4) | 128 (24.8) | 159 (30.8) | 3.55 (1.348) | 0.831* |
| 6. My doctor asked me which treatment option I prefer | 30 (5.8) | 57 (11.0) | 84 (16.3) | 112 (21.7) | 121 (23.4) | 112 (21.7) | 3.11 (1.491) | 0.787* |
| 7. My doctor and I thoroughly weighed the different treatment options | 29 (5.6) | 53 (10.3) | 78 (15.1) | 140 (27.1) | 131 (25.4) | 85 (16.5) | 3.06 (1.408) | 0.799 |
| 8. My doctor and I selected a treatment option together | 17 (3.3) | 45 (8.7) | 52 (10.1) | 114 (22.1) | 131 (25.4) | 157 (30.4) | 3.49 (1.409) | 0.775* |
| 9. My doctor and I reached an agreement on how to proceed | 12 (2.3) | 33 (6.4) | 35 (6.8) | 113 (21.9) | 145 (28.1) | 178 (34.5) | 3.71 (1.304) | 0.699* |

*P<0.0005.
validity, international multiphase translation guidelines were followed in the processes of translation and validation of the Arabic version SDM-Q-9. The newly translated Arabic version of the SDM-Q-9 is the first psychometrically tested tool that assesses SDM process from Arabic-speaking patient’s perspective.

Reliability and validity analysis of the Arabic version of the SDM-Q-9 scale revealed that the translated tool was reliable and valid. Cronbach’s alpha (0.929) indicated high internal consistency of the scale with all items showing adequate values for corrected item–total correlations that ranged between 0.602 (for item 1) and 0.85 (for item 5). Results pertaining to scale reliability and corrected item–total correlations were comparable to those reported for the German version by Kriston et al. and the Spanish version by De las Cuevas et al. Both models resulted in very similar indices indicating adequate fit with the data. The bivariate correlation matrix among all scale items showed good correlation coefficient values ranging between 0.402 and 0.810 with the weakest ones being between item 1 and the other items. This observation has been also reported in other studies where item 1 showed lower values for correlations as well as factor loadings.

### Table 4: Factor loadings using the principle component analysis solution

| Item no | Item                                                                 | Component 1 |
|---------|----------------------------------------------------------------------|-------------|
| 1       | My doctor made clear that a decision needs to be made               | 0.676       |
| 2       | My doctor wanted to know exactly how I want to be involved in making the decision | 0.766       |
| 3       | My doctor told me that there are different options for treating my medical condition | 0.802       |
| 4       | My doctor precisely explained the advantages and disadvantages of the treatment options | 0.779       |
| 5       | My doctor helped me understand all the information                   | 0.875       |
| 6       | My doctor asked me which treatment option I prefer                   | 0.840       |
| 7       | My doctor and I thoroughly weighed the different treatment options   | 0.849       |
| 8       | My doctor and I selected a treatment option together                 | 0.832       |
| 9       | My doctor and I reached an agreement on how to proceed               | 0.766       |

### Table 5: Results of the confirmatory factor analysis

| Model   | χ²      | CFI    | GFI    | RMR   | RMSEA   |
|---------|---------|--------|--------|-------|---------|
| Model 1 | 500.8*  | 0.998  | 0.991  | 0.029 | 0.033   |
| Model 2 | 373.0*  | 0.998  | 0.992  | 0.027 | 0.032   |

Model 1—includes all nine items.  
Model 2—excludes item 1.  
*P<0.0005.  
CFI, comparative fit index; GFI, goodness of fit index; RMR, root mean square residual; RMR and RMSEA <0.05; RMSEA, root mean square error of approximations recommended values: CFI and GFI >0.90.

In this study, EFA revealed a one-factor solution explaining 64% of the total variance. This result showed that, unlike the Spanish version of the SDM-Q-9 that resulted in a two-factor-solution, the validation of Arabic version of the SDM scale was consistent with those of the original version and the Hebrew version of the scale that showed a unidimensional structure of the SDM scale. All items of the Arabic version of the SDM scale showed adequate factor loadings that ranged between 0.676 for item 1 and 0.875 for item 5. In our study, two single-factor models were tested in the CFA. Model 1 included all nine items of the SDM scale while model 2 excluded item 1 as it had lowest factor loading in the EFA, similar to what was reported by De las Cuevas et al. Both models resulted in similar indices indicating adequate fit with the data. In general, the bivariate correlation matrix among all scale items showed good correlation coefficient values ranging between 0.402 and 0.810 with the weakest ones being between item 1 and the other items. This observation has been also reported in other studies where item 1 showed lower values for correlations as well as factor loadings.

### Methodological consideration

Some limitations of this study need to be taken into account. The convenience sampling may not be representative of the entire population attending secondary healthcare settings. However, the aforementioned limitation is likely mitigated considering the large sample size and the diversity of study participants (a mix of both Emirati and Arab expat born in different Arab countries, and varying educational characteristics). Caution must be exercised when interpreting results; the use of a self-reported measure in this study does not eliminate the possibility of an inaccurate recall of respondents’ experiences, opinions and behaviour. Another limitation of this study lies in conducting EFA and CFA using the same sample. This could be presenting duplicate analyses that aim to first discover the underlying factors of the SDM9 tool and then confirm these factors using the same sample subjects. EFA and CFA analyses ideally should have been conducted on separate samples, yet, in this study both analyses were run using the same subjects. One major strength of this work is the potential for the Arabic version of SDM-Q-9 (perhaps with minor adaptations to adjust to regional variations in the language) to be used by the 407 million people who make up the populations of all the Arab states. In addition, the Arabic version also can be of use for Arabic-speaking immigrants in other regions of the world, for example, Europe, North America and Australia. The sample size exceeded the minimum needed number, which is another strength of this study.
CONCLUSION
The study results suggest that SDM-Q-9 in its Arabic version is suitable for use in the UAE and the other 21 state members of the Arab League where Arabic is the official language, capitalising on linguistic and cultural similarities between these Arabic-speaking countries. The Arabic version of the SDM-Q-9 may be used to evaluate the effectiveness of intervention and strategies that aim to enhance SDM in healthcare services and research across various settings. The use of the questionnaire in medical encounters could provide a valuable reminder to healthcare professionals to think about SDM in their consultations and monitor their own practice to ensure patients’ preferences and values will guide treatment decisions (where appropriate). Furthermore, the Arabic version of the SDM-Q-9 can be a useful tool in epidemiological and clinical studies, resulting in better insight into how best to implement SDM in clinical practice in Arabic-speaking countries aiming at improving patient care.

Acknowledgements
The authors would like to thank study participants for taking the time to complete the study questionnaire, and sharing their ‘real’ perspectives and opinions. We also would like to acknowledge the support of field research teams for their efforts in data collection (Aisha Ali, Fatima Alzaibi and Alhara Ali).

Contributors
HTA designed the study, supervised data collection process, assisted with data analysis, wrote, reviewed and edited the entire manuscript. KM contributed to the discussion and edited the manuscript. AH assisted significantly with data analysis and edited the manuscript. KM assisted with writing the entire manuscript. KM assisted with data analysis, wrote, reviewed and edited the entire manuscript.

Funding
This work was supported by an internal grant from the Sharjah Institute for Medical Research, University of Sharjah, United Arab Emirates.

Competing interests
None declared.

Patient consent for publication
Not required.

Ethics approval
Ethical approval to conduct the study was obtained from the University of Sharjah Research Ethics Committee (REC-17-09-28-01-S).

Provenance and peer review
Not commissioned; externally peer reviewed.

Data sharing statement
All data relevant to the study are included in the article or uploaded as supplementary information.

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