

ORIGINAL ARTICLE

# Development of a questionnaire for identification of the risk factors for osteoarthritis of the knees in developing countries. A pilot study in Iran and Bangladesh. An ILAR–COPCORD phase III study

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## Abstract

**Background:** Knee osteoarthritis (OA) is one of the most prevalent rheumatic disorders in the Asia-Pacific region. Identification of modifiable risk factors is important for development of strategies for primary and secondary prevention of knee OA.

**Objective:** Developing a core questionnaire for identification of risk factors of knee OA at the community level.

**Methods:** Steps performed: (1) item generation from literature, existing knee OA questionnaires and patient focus group discussions; (2) development of a preliminary APLAR-COPCORD English questionnaire; (3) translation into target language, back translation and development of a pre-final target language version; (4) adaptation of the pre-final target language version through tests of comprehensibility, content validity, test–retest reliability; and (5) finalization of the English questionnaire. Investigators in Bangladesh, Iran, China, Philippines and Indonesia participated in steps 1 and 2. Subsequent steps were carried out by Bangladeshi and Iranian investigators.

**Results:** Fifty-three items were generated. Fourteen were obtainable from physical examination and placed in an examination sheet. Two radiological items were not included. A preliminary English questionnaire comprising the remaining 37 items was constructed and translated into Bengali and Persian. The preliminary Bengali and Persian versions were adapted as a result of tests of comprehensibility, content validity and test–retest reliability. The English questionnaire was adapted through repeated exchange of ideas and experiences among participating investigators. A 35-item English core questionnaire was finally developed.

**Conclusion:** The questionnaires may be used to identify risk factors of knee OA in Asia-Pacific communities after validation and further adaptation. From these data strategies for primary and secondary prevention of knee OA can be developed.

**Key words:** knee osteoarthritis, prevention, questionnaire, risk factors.

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## INTRODUCTION

The aim of the Community Oriented Program for Control of Rheumatic Disorders (COPCORD) program is reduction of the community burden of rheumatic disorders, particularly in developing countries. Stage I entails estimation of prevalence and incidence of musculoskeletal pain and rheumatic disorders. Stage II is dedicated to education of health workers, patients and the community. The aim of stage III is to identify risk factors.<sup>1</sup> This study comprises the third phase of a collaborative research program to decrease rheumatic disorders in the Asia-Pacific region.

A stage I survey has been completed in a number of countries in the Asia-Pacific region. Osteoarthritis (OA) of knees was found to be one of the commonest rheumatic disorders in most of these studies. Within the Asia-Pacific region, the reported prevalence of knee OA was 5.8% in rural India,<sup>2</sup> 22–28% in urban and 25% in rural populations of north Pakistan,<sup>3</sup> 7.5%, 9.2% and 10.6% respectively in Bangladeshi rural, urban slum and urban affluent communities,<sup>4</sup> 7.5% in China<sup>5</sup> and 15.3% in Iran.<sup>6</sup>

Management of knee OA is often difficult and therapeutic options are limited; for that reason the best strategies to reduce the burden of knee OA are primary and secondary prevention.<sup>1</sup> For primary prevention, the etiologic or risk factors for this condition should first be identified. For secondary prevention identification of risk factors for progression and disability will have to be detected. Questionnaires are commonly used instruments for collecting health-related information in clinical and research studies for their ease and simplicity of use.<sup>7</sup> Development of a reliable and valid questionnaire for identification of risk factors for knee OA will be the first, but very important, step toward achieving the goal of precise identification of the risk factors, development of preventive strategies and intervention programs and finally reduction of the incidence and associated morbidity of knee OA in the Asia-Pacific region. The wide range of socio-cultural diversity, linguistic and lifestyle differences among the inhabitants in the Asia-Pacific make the task of development of a common questionnaire a difficult one. It needs involvement and active participation of representative researchers from different countries. The Asia-Pacific League of Associations of Rheumatology (APLAR) realized the unmet need of one valid and reliable core English questionnaire for the identification of risk factors for knee OA. The basic argument for a

common questionnaire was that it would stimulate epidemiologists to take up studies on identification of risk factors and at the same time it would ensure uniformity of data, and if pooled, identification of the risk factors with high power and precision. To be applicable across different communities and cultures in the Asia-Pacific region, the language of the questionnaire had to be English. For that reason, researchers from five different countries, namely, Bangladesh, China, Indonesia, Iran and Philippines organized a core group to develop the APLAR-COPCORD core English questionnaire based on which each country would develop their own version, reflecting and incorporating the changes satisfying socio-cultural and ethnic differences.

## MATERIALS AND METHODS

COPCORD Study Groups in five different Asia-pacific countries, namely, Bangladesh, China, Indonesia, Iran and Philippines, participated in the present study. Investigators in each country worked separately and exchanged their views and opinions through frequent communications. A partial modification of the method used by Chassany *et al.*<sup>8</sup> for the development of a questionnaire for functional digestive disorders was used for development of the core English questionnaire and Beaton's method<sup>9</sup> for translation and validation of the target language versions. This combination resulted in the following successive steps.

Step 1. Item generation

Step 2. Development of a preliminary APLAR-COPCORD English questionnaire

Step 3. Translation into target language, back-translation and development of pre-final target language versions

Step 4. Adaptation and validation of the pre-final target language versions

Step 5. Development of the final English questionnaire

It was decided that the participating groups would make a common checklist of items, and develop a common preliminary core questionnaire in English. Subsequently, the groups would develop their own target language versions simultaneously and separately. After testing of the target language versions, necessary modifications would be made in the core English questionnaire. Different core questionnaires would then be combined and amalgamated through frequent communications and exchanges of views

and ideas for the development of the final questionnaire.

### Step 1: Item generation

The items were gathered from the following sources: systematic review of current knee OA literature, existing knee OA questionnaires, meeting of authors and clinical experts and their departments, consisting of rheumatologists, orthopedic surgeons and epidemiologists, in Iran and Bangladesh. In Bangladesh a patient focus group was formed of five consecutive knee OA patients in outpatient clinics, mainly of an urban background; the discussions in this group contributed to item generation from the patient point of view.

### Step 2: Development of a preliminary APLAR-COPCORD English questionnaire

In order to keep the task manageable, the investigators from five countries decided that those of two countries (Bangladesh and Iran) would perform steps 2–5. All generated items were grouped according to clinical and functional similarity (e.g., weight-lifting, trauma, occupational overuse). Questions were developed for each of the items in English by a panel of experts. The questions were formulated in easily understandable language, quoting familiar words and activities. Wherever appropriate items/wording/phrases were adopted from knee osteoarthritis questionnaires, e.g., the Lequesne questionnaire,<sup>10</sup> WOMAC,<sup>11</sup> the comprehensive osteoarthritis test,<sup>12</sup> arthritis impact measurement scales health status questionnaire,<sup>13</sup> the Dutch-AIMS2,<sup>14</sup> short-form arthritis impact measurement scales 2,<sup>15</sup> and the knowledge questionnaire PKQ-OA.<sup>16</sup> In discussion with patients and local experts, check-recheck and discussions, familiar words were found and relevant activities selected. By the inputs and repeated exchange of ideas and discussion a full-length common preliminary APLAR-COPCORD English questionnaire was developed. Since some of the items were only identifiable through physical examination, the composite questionnaire comprised an interview questionnaire and a physical examination sheet.

### Step 3: Translation into target language, back-translation and pre-final target language versions

Beaton's 'forward backward' procedure was followed to translate the interview part of the English questionnaire into Bengali and Persian languages and for their cultural adaptation.<sup>8</sup>

#### Stage 1: Forward translation

Translators whose mother tongue was Bengali or Persian (target language) did this forward translation. Working independently, the Bengali and Persian translators produced two initial target language versions of the questionnaire in each language. The first and second translations were marked as T1 and T2. Each of the translators submitted a written report of the translation, including additional comments about challenging phrases or uncertainties and the rationale for their choices.

#### Stage 2: Synthesis of target language version (Ts)

Working from the original questionnaire and the translators' (T1 and T2) versions and with some changes depending upon local customs, habits, usage of words, understandability, etc., a synthesized (Ts) target language version was developed.

#### Stage 3: Back-translation

The Ts version of the questionnaire was back-translated into English by two translators (BT1 and BT2) fluent in the source language and totally blind to the original version. These two translators, without medical background, were neither aware nor informed of the concepts explored, to avoid information bias and to elicit unexpected meanings of the items in the translated questionnaire (Ts), thus increasing the likelihood of 'highlighting the imperfections.'

#### Stage 4: Expert committee review

Two expert committees in Bangladesh and Iran, including rheumatologists, methodologists and translators, consolidated all the versions of the questionnaire and developed the pre-final (SI) version for field-testing. Materials at disposal of the committees were:

- Original COPCORD core English questionnaire;
- Two forward-translated Bengali/Persian versions of COPCORD core English questionnaire (T1, T2);
- Synthesized Bengali/Persian versions (Ts);
- Two backward-translated English version of synthesized Bengali/Persian questionnaires (BT1, BT2);
- Corresponding written reports (which explained the rationale of each decision at earlier stages).

The committees reviewed and compared all the translations and the original COPCORD English questionnaire. They verified the semantic, idiomatic, experiential and conceptual equivalence between the source and Bengali/Persian versions. Consensus was reached on the items, and when necessary, the translation and back-translation processes were repeated to clarify how

another wording of an item would work. Thus, the 'pre-final' Bengali/Persian questionnaires were developed.

#### **Step 4: Adaptation and validation of the pre-final target language versions**

This step was accomplished through three successive tests of comprehensibility, validity and test-retest reliability. The expert committee met at the end of each test. Poorly performing questions were either rephrased or deleted. When rephrasing was necessary the process of translation was repeated. The questionnaire thus evolved at the end of one test was subjected to the next test.

#### **Comprehensibility**

In Bangladesh, a non-probability sample of 30 knee OA patients fulfilling American College of Rheumatology 1986 criteria<sup>17</sup> residing in the COPCORD villages, and in Iran, a convenience sample of 22 subjects attending outpatient clinics of the General Rheumatology Clinic of the Rheumatology Research Center, were enrolled for comprehensibility testing. The questionnaire was administered by interviewers and each subject was interviewed for probing about what they thought is meant by each item and about the chosen response in an open-ended manner. The participant was also encouraged to describe his/her way of expressing the items and any suggestions on them. This ensured that the items and the response choices were understood as having a meaning equivalent to that of the source version. Participants' relevant views were recorded separately and in every case the amount of time required to fill in the forms was also kept in record. Opinion was sought from the interviewers, whether they faced any difficulty in questioning, and whether interviewers had to ask questions differently to express the aim of the question.

In Bangladesh, a general recommendation for questionnaires is that they should be understood by the equivalent of a 12-year-old (roughly a Grade 6 level of reading).<sup>9</sup> The questionnaire was administered to an additional ten 12-year-old children. Each of the questions was presented to the subjects who were asked to describe what they understood by the question and how they would answer if the condition were present in them.

#### **Content validity**

The content validity of the questionnaire was assessed by an expert committee composed of three experts in the field of rheumatology in Bangladesh and the rheu-

matology professors from four Medical Universities in Tehran as per method of Beaulieu *et al.*<sup>18</sup> They were supplied with the English questionnaire and an evaluation script to evaluate each question on three aspects. First: to what degree was the question relevant to assess the risk factors of knee osteoarthritis? The gradation was as follows: (i) not relevant at all; (ii) relatively relevant; (iii) relevant; and (iv) fully relevant.

Second: do the questions in this section completely evaluate every aspect of the item (obesity, life style, etc.) as a risk factor for knee OA? The gradation was as follows: (i) good; (ii) average; and (iii) poor.

Third: does the expert think that the number of questions evaluating the item (such as obesity, life style, etc.) as a risk factor for OA was enough? The expected response was a dichotomy between 'yes' and 'no'. The percentages of the rheumatologists' opinions on each question were calculated, including the grades of relevance and of good, average and poor. They were also requested to provide any additional comments or views, including missing risk factors for knee OA if considered appropriate.

#### **Test-retest reliability**

Forty-three consecutive patients of knee OA in Bangladesh and 35 in Iran were administered the questionnaire. Participants were requested to fill in the questionnaire excluding the examination sheet again after 7–15 days. The patients were requested to give an approximate or average number where specific data were difficult to recall. The individual items were calculated.

#### **Step 5. Development of the final English questionnaire**

The Bengali and Persian pre-final questionnaires developed as a result of comprehensibility, validity and reliability tests and were matched with the English questionnaire. The groups in these two countries exchanged their experiences and made the necessary changes in the English version. This final English version was circulated among the participating COPCORD investigators with explanations for the changes from the preliminary questionnaire. A consensus among them led to the development of the APLAR-COPCORD core questionnaire for identification of risk factors for knee OA.

#### **Ethics**

The study was approved by the Ethics Committee of the Bangabandhu Sheikh Mujib Medical University

**Table 1** Checklist of items (items 1–37 are part of the questionnaire, items 38–51 are part of the physical examination and items 52–3 are based on radiological examination)

Socio-demographic	
1.	Age
2.	Gender
3.	Race
4.	Educational level
Disease and family history	
5.	Past history of major or acute knee injury
6.	History of repetitive minor knee injury
7.	Nutrition/diet/antioxidant (fresh fruits, vegetables, milk, meat ...)
8.	Parity
9.	Number of children reared
10.	Age of menopause
11.	Mental stress
12.	Past history of painful swelling of knees
13.	Positive family history of knee or other joint disease
14.	DM
15.	HTN
16.	Other chronic disease(s)
Occupational activity	
17.	Recent occupation
18.	Previous occupations
Leisure and physical activities	
19.	Current recreational activities (climbing, running, soccer, volleyball, martial art...)
20.	Previous recreational activities
21.	Religious activities (praying and other sitting religious worships) Squatting
22.	Sustained knee bending
23.	Sustained knee twisting at job
24.	Going uphill
25.	Riding bicycle
26.	Stair climbing
27.	Level of physical activity
28.	Duration of heavy physical activity
29.	Prolonged standing
30.	Prolonged walking at a stretch
31.	Bare foot walking
32.	Use of high heeled shoes
33.	Regular weight bearing
34.	Type of toilet
35.	Sitting on the floor (criss-cross, lotus or applesauce, for home activities such as eating, watching TV, reading, etc.)
Drugs and medication	
36.	Hormone replacement therapy
37.	Smoking†

**Table 1** (continued)

Physical examination	
38.	Height, weight, BMI
39.	Nodes: Heberden's, Bouchard's
40.	Knee alignment
41.	Laxity
42.	Lower extremity muscle mass
43.	Flexion and extension of knees
44.	Dorsiflexion and plantar flexion of ankles
45.	Quadriceps strength
46.	Hamstring strength
47.	Varus/valgus
48.	Hypermobility
49.	Congenital anomaly of hip and knee joints (including unusual range of joint movement)
50.	Neuropathy (diabetic, syphilitic)
51.	Proprioceptive inaccuracy
Radiological examination	
52.	Chondromalacia patellae
53.	Chondrocalcinosis

†There is no tobacco-chewing in BD and Iran.

Shahbagh, Dhaka, Bangladesh. The study proposal was approved by the national Ethics Committee on Medical Research of the Ministry of Health and Medical Education in Iran.

The study was performed following the Declaration of Helsinki principles and informed consent was obtained from all participants before enrolment.

## RESULTS

### Step 1. Item generation

A systemic review of knee OA literature<sup>1–3,19–57</sup> generated several items: epidemiologic association of pain in OA knee<sup>19</sup> and prognostic factors of cartilage loss,<sup>20–22</sup> obesity,<sup>23–32</sup> level of regular physical activity and high physical workload,<sup>33–37</sup> sex and sex hormone,<sup>38,44</sup> squatting and knee-bending,<sup>45</sup> occupational physical activity,<sup>46,47,48</sup> and progression of primary generalized OA to secondary OA of knee.<sup>49</sup> In total, 53 items were generated (Table 1).

### Step 2. Development of the preliminary English questionnaire

A preliminary APLAR-COPCORD English questionnaire including items 1 through 37 was developed through repeated exchange of ideas and discussion. The 'level of physical activity' was classified by



metabolic equivalents (METs)<sup>33–37</sup> as used in the guidelines for the data processing and analysis of the ‘International Physical Activity Questionnaire’ (short form).<sup>50</sup>

In the absence of an accepted definition in the literature, the investigators from five countries agreed to define ‘repeated minor injury’ as injuries sustained in daily (occupational or non-occupational) activities that did not warrant treatment on their own and occurred more than once in a week.

Items 38 through 51, and 52 and 53 required physical and radiological examinations, respectively. The 14 physical items were sorted in a separate examination sheet through repeated exchange of ideas and phrases. Items detectable through radiological examination, that is, chondromalacia patellae and chondrocalcinosis, were excluded since the real risk factor identification studies are expected to be of case control design that will not permit a follow-up of a cohort of patients with these two conditions.

### **Step 3. Translation into target language, back-translation and pre-final target language versions**

Pre-final Bengali and Persian versions were developed through translation, back-translation and expert committee meetings within the country groups.

### **Step 4. Adaptation and validation of the pre-final target language versions, regarding the questions 1–37 of the questionnaire**

#### *Comprehensibility test*

In Bangladesh, a random sample of 16 men (53.3%) and 14 women (46.7%) with knee OA residing in the COPCORD villages completed the pre-final Bengali questionnaire. Mean age was  $60.2 \pm 9.2$  years (range 45–78 years). Seven (23.3%) subjects never attended school, two (6.7%) could only write their names, 10 (33.3%) had primary and 11 (36.7%) had more than primary-level education. Eleven (36.7%) of the participants were either housewives or retired persons. Seventeen (56.7%) and seven (23.3%) participants were engaged in two and three occupations, respectively. All questions were answered by all participants. The participants found the questionnaire simple and comprehensible. Twenty-four subjects commented it as long and exhausting and suggested the use a shorter version with a simpler format. In Iran and Bangladesh it took an average 35–40 min to complete the questionnaire.

In Iran a random sample of 22 subjects, five men (23%) and 17 women (77%) attending the outpatient

clinic of the General Rheumatology Clinic of the Rheumatology Research Center of Teheran, completed the pre-final Persian questionnaire. All questions were answered by all participants. The mean age was 39.3 years (range 16–66 years). One (4%) subject never attended school, five (23%) had primary level of education, 11 (50%) subjects had middle- and high-school education and five (23%) college/university degrees. All questions were answered by all participants. Of the respondents 37.5% had difficulty in comprehending ‘twisting of the knees’. ‘Level of physical activity’ and ‘psychological stress’ were not comprehended by most respondents. Further, as the levels of participants’ physical activities were different in the course of their lives, the Iranian team faced more recall bias with this compared to other questions. A few respondents found it a long and exhausting interrogation.

The question on ‘other chronic diseases’ generated widely variable responses in both countries. Many patients responded yes with some sort of vague and non-specific chronic complaints.

While testing comprehensibility among a random sample of 12-year-old children in Bangladesh, six respondents failed to understand the word ‘race’. The word became comprehensible after giving an example to four of the children. Examples were also necessary for words like ‘recreational activity’, ‘mental stress’ and ‘anxiety’. Six respondents found difficulty comprehending ‘twisting of the knees’, but all of them could understand after demonstration of the position. Six respondents interpreted the question ‘did you suffer from pain in your knee(s) at an early age during climbing stairs up and down and sports?’ as ‘suffering from pain due to injury sustained during going up or downstairs or playing’. All other questions appeared equally understandable.

On the basis of the feedback from the comprehensibility test, the investigators agreed on two decisions. ‘Mental stress’ and ‘other chronic diseases’ were deleted because of uniformly low comprehensibility, reducing the number of items to 35. To reduce the length of the questionnaire, as many questions as possible were put in a tabulated form.

The older the respondent, the more difficult it was to recall previous jobs and the time spent on each daily activity or posture. To minimize the problem of recall inaccuracy the lifetime occupations and leisure time activities of the participants were recorded on a life grid, including the start and end date of jobs and periods of unemployment or home-making, or periods

spent on recreational activities. This grid was a source of reference for the trained interviewers to remind the participants to fill in the tables regarding the time participants spent on each daily activity. Based on this experience, the investigators in Bangladesh and Iran agreed to design two separate tables for daily activities to help participants to recall the time spent during his/her occupation or non-occupational time in the past. In this way, 12 questions were repeated in two separate tables.

### Content validity (of the 37 questions)

In Bangladesh, in the test of relevance of the questions, the responses were 'completely relevant', 'relevant' and 'relatively relevant' 53%, 6.4%, and 39.7%, respectively. None of the questions was judged 'not relevant at all'. According to the Iranian rheumatologists, the questions were assessed as follows: 'completely relevant' 66%, 'relatively relevant' 30%, 'not relevant at all' 5%. The response of 'not relevant at all' was proposed for some questions with controversial evidences in the literature (questions 6, 10, 14, 16, 17, 21, 24–25, and 26 in supplementary Fig. S1, the core questionnaire). These questions were discussed in an expert meeting and were kept in the core questionnaire.

The 5% not relevant was calculated as follows: on a total of 273 answers question 6 was found to be 'not relevant' by one person, question 10 by four persons, question 14 by one person, 16 by one, 17 by one, 21 by one, 24 and 25 by two, and 26 by one: a total of 12 answers, that is, 5% of the 273 answers.

In Bangladesh, the question of 'whether the questions in the questionnaire evaluate every aspect of a risk factor': 50% scored 'good', 46.2% 'average' and 3.8% 'poor'. In the Iranian part, 87% scored them as good, evaluating every aspect of the proposed risk factor and 13% as poor (questions 6, 10, 11, 13, 16, 20, 21, 22, 24–26 in supplementary Fig. S1, the core questionnaire). The 13% 'Poor' was calculated as follows: on a total of 273 answers, question 6 was found 'Poor' by six persons, question 10 by one person, question 11 by five persons, 13 by six, 16 by one, 20 by four, 21 by six, 22 by one, 24 and 25 by two, and 26 by two: a total of 34 answers, that is, 13% of the 273 answers. All those questions were included because not everyone classified them as poor.

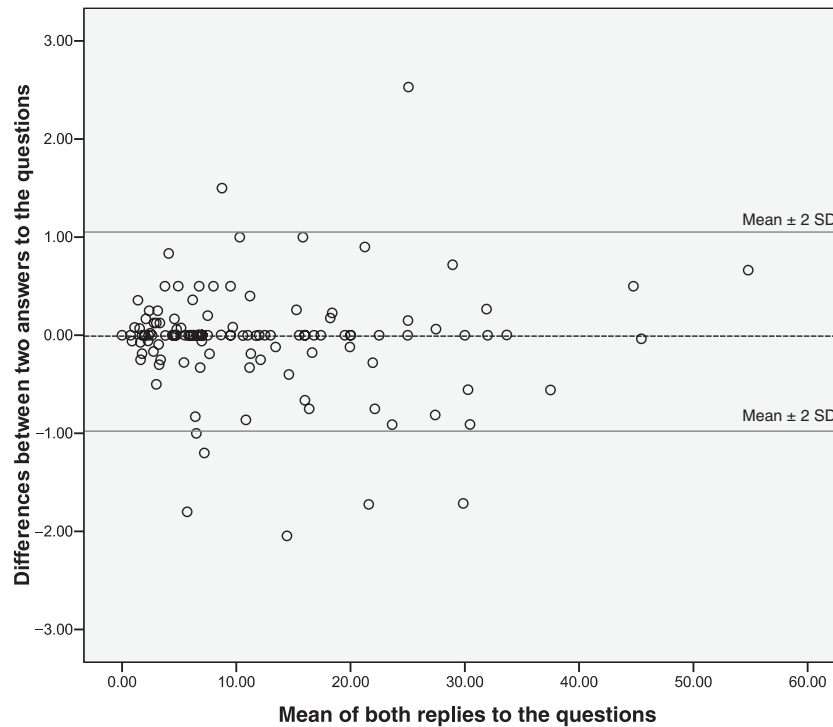
The evaluators found that the number of the questions in the questionnaire evaluating the risk factors of OA was sufficient in 85.7%, according to Bangladeshi rheumatologists, and 81% according to Iranian rheumatologists.

### Test-retest reliability (of the 37 questions in the questionnaire)

In Bangladesh, 43 patients with knee OA were interviewed during the test and 30 of them attended after 7 days for retest. Exposures during current and past occupational and non-occupational activities were recorded and tested as separate variables. To evaluate agreement between two measurements, qualitative questions were analyzed using the kappa test. Twenty-five questions were tested, of which 23 (92%) showed high agreement (Kappa = 0.8–1.0). Two questions (8.4%) showed good agreement (Kappa = 0.6–0.79). All questions showed high or good agreement (Kappa agreement > 0.6). Paired *t*-test was used to evaluate whether the difference between two measurements was significant in quantitative questions. The differences between two measurements were not significant. Approximately 89% of variables showed a high correlation of 0.8–1.0, and 5% showed a good correlation of 0.6–0.8, while 1.4% showed medium correlation (0.4–0.6), and 4.1% had a poor correlation below 0.4. Paired answers to 150 quantitative questions were assessed and the differences between two answers in 142 (95%) questions were within the  $\pm 2$  standard deviations of the mean differences (mean = 0.0373, SD = 0.507). Only 8/150 (5%) questions had large deviations beyond  $\pm 2$  SDs (Fig. 1).

In Iran, 35 participants were interviewed during the test and all were re-tested after 15 days. Exposures during current and past occupational and non-occupational activities were recorded and tested as separate variables. To evaluate agreement between two measurements, qualitative questions were analyzed using the Kappa test. Twenty-two questions were tested of which 11 (50%) showed high agreement (Kappa = 0.8–1.0). Eight questions (36.4%) showed good agreement (Kappa = 0.6–0.79). Only in three questions (13.6%) was Kappa < 0.6. In total, 86.4% of questions showed high or good agreement (Kappa agreement > 0.6). Paired *t*-test was used to evaluate whether the differences between two measurements were significant in quantitative questions. The differences between two measurements in 93% of questions were not significant. Approximately 29% of variables showed a high correlation of 0.8–1.0, and 18% showed a good correlation of 0.6–0.8, while 20% showed medium correlation (0.4–0.6) and 33% had a poor correlation < 0.4.

In addition to the paired *t*-test, the correlation between the test responses, particularly regarding the



**Figure 1** Bland-Altman plot for paired quantitative questions in Bangladesh.

length of time of exposure to a risk factor, and the retest responses, was analyzed by Bland Altman plot (Fig. 2). A Bland Altman plot was used to describe agreement between two quantitative measurements. The difference of the paired measurements is plotted against the mean of two measurements. It is recommended that 95% of data points should lay within  $\pm 2$  SDs of the mean differences. In our data, paired answers to 269 quantitative questions were assessed and the differences between two answers in 261/269 (97%) questions were within the  $\pm 2$  SDs of the mean differences (mean = 0.032, SD = 5.2). Only 8/269 (3%) questions had large deviation beyond  $\pm 2$  SDs. The correlation is 0.908,  $P = 0.000$ .

### Step 5. Finalization of the English questionnaire

A rephrased 35-item Bengali and a 34-item Persian version resulted from the adaptation and validation procedure. The changes and reasons for the changes were communicated to investigators from other countries. Consensus was reached on corresponding changes in the English version. The core English questionnaire finally developed through successive steps from the preliminary English questionnaire, translated

into target languages and tested for their validity and reliability, is shown in supplementary Fig. S1 and the annexed examination sheet in supplementary Fig. S2.

There was no test-retest done on the physical examination part of the questionnaire. As this is already the general way patients are screened and investigated in many COPCORD studies performed by this group, we felt this would be superfluous.

## DISCUSSION

The aim of this study was to develop a tool to identify risk factors for knee OA. This work is unique because there are no standardized questionnaires that address risk factors for knee OA and none that is culturally appropriate for countries in the Asia-Pacific region. We restricted our study to OA of the knees, and this can be used as a model for developing questionnaires for identifying risk factors for other rheumatic disorders and OA elsewhere.

The use of the questionnaire is a common practice in health research. With the increase in the number of multinational and multicultural research projects, the need for adapting questionnaires for use in other than the source language has also grown rapidly.<sup>51,52</sup> Most



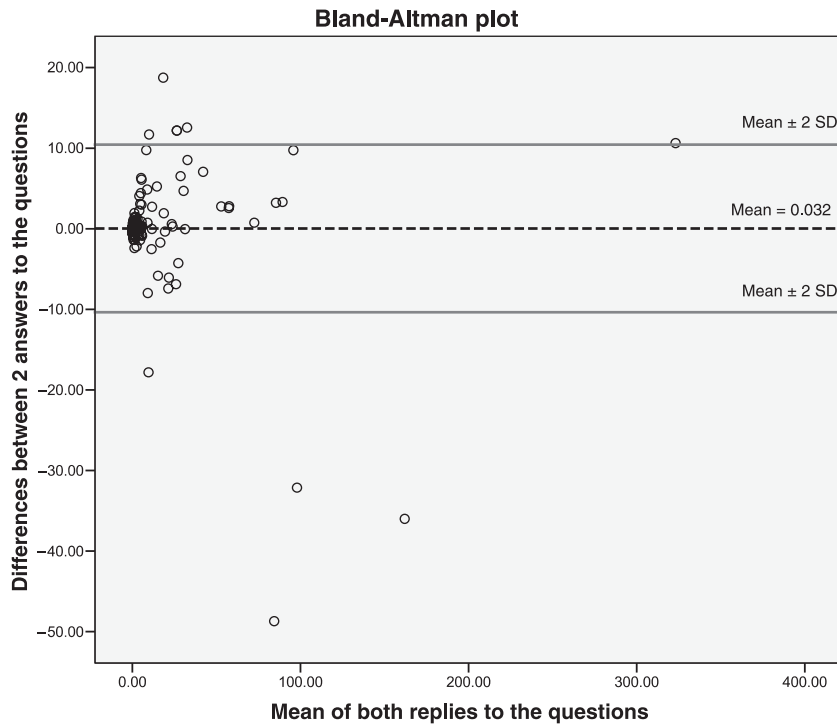


Figure 2 Bland-Altman plot for paired quantitative questions in Iran.

questionnaires were developed in English-speaking countries.<sup>53</sup> The cross-cultural adaptation of a questionnaire for use in different countries, cultures and/or languages necessitates use of methods to reach equivalence between the source and target versions of the questionnaire. It is now recognized that if questions are to be used across cultures, the items must not only be translated well linguistically, but also must be adapted culturally to maintain the validity of the instrument at a conceptual level across different cultures.<sup>54–56</sup> So far, the issue of adaptation and validation of questionnaires across cultures has mainly revolved around quality of life questionnaire. Several studies have paid attention to the identification of risk factors making use of questionnaires,<sup>57</sup> but to our knowledge no questionnaires to identify risk factors for knee OA have been used across cultures. The need for development of a common core questionnaire was felt in the Asia-Pacific region after emergence of data on common rheumatic diseases. The basic argument for a common questionnaire was that it would stimulate epidemiologists to take up studies on identification of risk factors and at the same time it would ensure uniformity of data, and if pooled, identification of the risk factors with high power and precision. To

be applicable across different communities and cultures in the Asia-Pacific region, the language of the questionnaire had to be English. But only few of these populations are native English speakers. So, the original English version could not be tested for comprehensibility and validity in the local communities we selected. A simultaneous local language version had to be developed. This approach of simultaneously developing country-specific questionnaires and then identifying elements common among them to form the core of a cross-cultural instrument has been recommended and used by the WHO.<sup>58</sup> Participation of researchers from varied socio-cultural background ensured the representation and reflection of social and cultural factors that might influence the development of knee OA.

The basic difference of risk factor identification questionnaires from health status or quality of life measurement questionnaires was that the items were not measuring tools. That is why construct validity and internal consistency were not applicable to these items. Estimation of criterion validity was also impossible since a set of standard criteria was absent. However, we examined the questionnaire by content validity, comprehensibility and reliability test, and we

showed that this questionnaire is both a valid and reliable questionnaire to evaluate the risk factors of knee OA.

The first study has been performed using this questionnaire in Iran, showing its usefulness and validity.<sup>59</sup> It proved that two activities were risk factors for knee OA: prolonged squatting (OR1.51) and cycling (OR2.06). Housewives were at greater risk of developing knee OA than women whose main occupation was outside the home.

By making use of the questionnaire described in this article, after adaptation for other developing countries, it will be possible to compare these data in different countries in the Asia-Pacific region.

The questionnaire has some restrictions and shall be adapted accordingly. It is long and if possible can be shortened in the future. For example ACR clinical criteria are 'pain in the knee for most days or prior months', and this specific question should be added.<sup>17</sup> As in the Asia-Pacific region many subjects are not able to read or write, this questionnaire was generally applied by using interviewers and was not always self-administered. As the samples studied in this article may not be representative for the whole population, further studies are needed where the questionnaire is used. The fact that the study could be used in Iran shows that this is not a big issue.

Inaccuracies in recalling what happened in the past are inherent in this kind of questionnaire. Despite this, the method appears to give useful data.<sup>58</sup>

The fact that we did not perform a test-retest study of the physical examination part of the study is also a restriction, as in large studies one may expect some error in these measures. In any case, the examiners should be trained in physical examination procedures and tested and re-tested in order to minimize inter-observer variability.

It may be concluded that the developed core knee OA risk factor identification questionnaire is a valid and reliable instrument. This preliminary study in two populations in the APLAR region is a start, but the questionnaire and probably the discussion about the questionnaire will need broader audience participation before it can be used elsewhere. For practical reasons the COPCORD group performing this study was restricted to some researchers already cooperating in epidemiological studies and convening regularly, but it does not represent the full breadth of APLAR and the people who do work in OA. In the future, input from researchers from other countries will be necessary, such as Australia, New Zealand, other parts of

India, Japan, Korea, Hong Kong and so on, and they should participate in further studies to improve and shorten the questionnaire.

This questionnaire may also be used as a template for development of similar instruments for other diseases, such as low back pain. However, as per the statements of the participants, there is some scope for making it shorter and simpler, as well as for further conceptual and methodological development.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

**Figure S1.** The APLAR-COPCORD Core Questionnaire for Identification of Risk Factors for Osteoarthritis of the Knees.

**Figure S2.** Knee risk factors examination sheet.

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