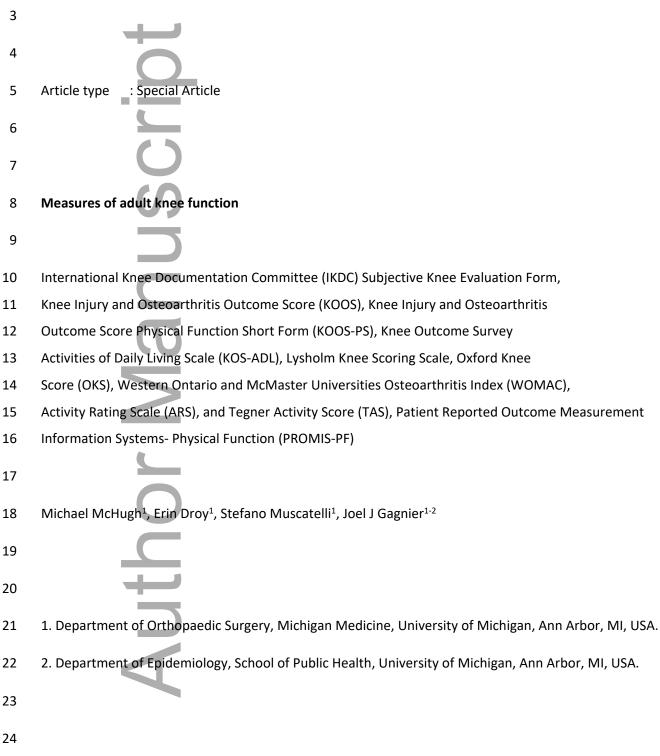
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# 37 INTRODUCTION

Patient reported outcome measures (PROMs) are important to fulfill both clinical and research purposes with regards to assessing knee function in patient with a variety of knee conditions associated with injury, osteoarthritis or rheumatological disorders. For inclusion into this review, measures of knee function were required to be pertinent to rheumatology, orthopaedics, and sports medicine specialties. We identified measures published with scientific analysis and included dimensions that were most important to patients including pain, quality of life, and activity level. A 2011 review of 9 tools was published and focused on much of these issues as they related to rheumatology and orthopaedic surgery.

45

Based on the aforementioned criterion and the goals of this review, we used the same 9 measures developed
specifically for patient reported knee function and perceptions: International Knee Documentation Committee
(IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and
Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily
Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster
Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). This
updated review was conducted by doing a thorough search of new publications for each measure between

January 1, 2010 and March 1, 2020. We also included Patient-Reported Outcomes Measurement Information
System Physical Function (PROMIS-PF) measure based on rising popularity and the amount of research
dedicated for its use in a variety of knee conditions.

56

A basic summary of the properties of the different measures is displayed in table 1. Psychometric data 57 pertaining to the floor and ceiling effects, validity, reliability, responsiveness, and minimum clinically important 58 59 difference of each patient reported outcome is displayed in table 2. Floor and ceiling effects were considered to 60 be absent if no participants scored the bottom or top score, respectively, and acceptable if <15% of the cohort scored the bottom or top score, respectively. Validity was measured by assessing content, face, and construct 61 62 validity. Content validity was present if patients were involved in development. Face validity was present if 63 expert reviewers made a similar assessment and considered the measured items adequate. Construct validity 64 was considered adequate if expected correlations were found with existing measures that assess similar 65 (convergent construct validity) and dissimilar (divergent construct validity) constructs. Internal consistency was 66 considered adequate if Cronbach's alpha was at least 0.7 (1), and test-retest (intrarater) reliability was adequate 67 if the intraclass correlation coefficient was at least 0.8 for groups and 0.9 for individuals. Responsiveness was determined with a measures ability to detect change over a period of time or intervention. Minimum clinically 68 69 important difference is the amount of change of a patient-reported outcome that represents a meaningful 70 change to the patient.

71

Since 2011, there have been numerous studies evaluating the psychometric properties of the above studies.
There has also been ample research assessing the utility and psychometric properties of the PROMIS-PF
function. Extensive work has been performed to add available translations and culturally adapted versions of the
above measures. Our review summarizes the available information about how these measures perform for
different patient populations in different settings.

# 77 INTERNATIONAL KNEE DOCUMENTATION COMMITTEE (IKDC) SUBJECTIVE KNEE EVALUATION FORM

78 Description

Purpose. To detect improvement or deterioration in symptoms, function, and sports activities due to knee
 impairment caused by a variety of knee conditions including ligament injuries, meniscal injuries, articular

81 cartilage lesions, and patellofemoral pain (2).

82 Version. The IKDC was formed in 1987 to develop a standardized international documentation system for knee

83 conditions. The IKDC Standard Knee Evaluation Form, which was designed for knee ligament injuries, was

84 subsequently published in 1993 (3) and revised in 1994 (4). The IKDC Subjective Knee Evaluation Form was This article is protected by copyright. All rights reserved

- 85 developed as a revision of the Standard Knee Evaluation Form in 1997. It has undergone subsequent minor
- 86 revisions since its publication in 2001.
- 87 **Content.** Three domains: 1) symptoms, including pain, stiffness, swelling, locking/catching, and giving way; 2)
- sports and daily activities; and 3) current knee function and knee function prior to knee injury (not included in
- 89 the total score) (2).
- Number of items. 18 (7 items for symptoms, 1 item for sport participation, 9 items for daily activities, and 1 item
   for current knee function).
- 92 **Response options/scale.** Response options vary for each item. Item 6 dichotomizes response into yes/no; items
- 1, 4, 5, 7, 8, and 9 use 5-point Likert scales; and items 2, 3, and 10 use 11-point numerical rating scales.
- 94 **Recall period for items.** Not specified for items 1, 3, 5, 7, 8, and 9; 4 weeks for items 2, 4, and 6. Function prior
- to knee injury for item 10a and current function for 10b.
- 96 Cost to use. Free to use. Cost of administration and information storage not assessed and varies for each
   97 practice.
- 98 How to obtain. https://www.sportsmed.org/aossmimis/Staging/Research/IKDC\_Forms.aspx
- 99

100 Practical Application

- 101 Method of administration. Patient-completed questionnaire. The form has not been validated for
- administration by interview, either in person or via telephone.
- Scoring. The response to each item is scored using an ordinal method (i.e., 0 for responses that represent the
   highest level of symptoms or lowest level of function). The most recent version has assigned scores for each
- 105 possible response printed on the questionnaire. Scores for each item are summed to give a total score
- 106 (excluding item 10a). The total score is calculated as (sum of items)/(maximum possible score) 100, to give a
- 107 total score of 100. An online scoring sheet is available (www.sportsmed.org/tabs/ research/ikdc.aspx) that
- 108 provides a patient's raw score and percentile score (relative to age- and sex-based norms). The item regarding
- 109 knee function prior to knee injury is not included in the total score. The revised scoring method states that, in
- 110 cases where patients have up to 2 missing values (i.e., responses have been provided for at least 16 items), the
- total score is calculated as (sum of completed items)/ (maximum possible sum of completed items) 100.
- 112 **Score interpretation.** Possible score range 0–100, where 100 no limitation with daily or sporting activities and
- 113 the absence of symptoms. Normative data are available from the general US population, stratified for age, sex,
- 114 and current/prior knee problems (5).
- **Respondent burden.** 10 minutes to complete (6). It uses simple language that is suitable for patients.
- 116 Administrative burden. Approximately 5 minutes to score. Training is not necessary. Manual scoring can be
- 117 performed easily using the scoring instructions supplied with the questionnaire. This article is protected by copyright. All rights reserved

Translations/adaptations. Available in English, Arabic, Brazilian Portuguese, traditional Chinese (Taiwan, Hong
 Kong), simplified Chinese (China, Singapore), Czech, Dutch, French, German, Greek, Italian, Japanese, Korean,
 Norwegian, Polish, Spanish, Swedish, Thai, Turkish. Cross-cultural adaptations have been conducted for the
 Arabic (7), Brazilian (8), Chinese (9-11), Danish (12), Dutch (13), German (14), Greek (15), Italian (6), Korean (16),
 Romanian (17), Thai (18), and Turkish (19) translations.

# 123 Psychometric Information

124 Method of development. The initial set of items was developed by the IKDC, considering questions from the 125 Standard Knee Evaluation Form, the MODEMS Lower Limb Instrument, and the Activities of Daily Living and 126 Sports Activity Scales of the Knee Outcome Survey. Pilot testing of the initial version (n 144) resulted in revision 127 or deletion of existing items and the addition of new items. Testing of the second version (n 222) resulted in 128 further revisions and deletions (based on missing data), producing a final version. Item-response theory was 129 used to create the scoring system. Patients were not involved in development; rather, items were selected by 130 the IKDC, a committee of international orthopedic surgeons (2). Following development, validation and 131 implementation of the IKDC, a pediatric form was developed, the Pedi-IKDC, which has been tested for 132 psychometric properties and normative data as well as is electronic use (20-22). 133 Floor and ceiling effects. Studies consistently report no floor or ceiling effects (i.e., no participants scored lowest

134 or highest score) (2, 6, 8, 13, 15, 23, 24).

135 **Reliability.** Internal consistency is adequate for patients with knee injuries and mixed knee pathologies (Table 1). 136 Test–retest reliability is adequate for groups of patients with knee injuries and mixed pathologies and individuals 137 with knee injuries. It also has been shown to be adequate in pediatric populations (20). The test-retest reliability 138 is slightly below adequate for individuals who fall into a broader category of knee pathologies. However, studies 139 have shown superior reliability over other measurement forms. The Chinese IKDC has better reliability than the 140 Chineses KOOS (25). The Dutch IKDC had better reliability than the WOMAC and KOOS for meniscal injury (26). 141 Validity. Face and content validity. The domains covered by the IKDC appear to represent elements that are 142 likely to be important to patients. However, the lack of patient contribution to the selection and revision of items in the IKDC means that content validity cannot necessarily be assumed. 143

144 *Construct validity.* There are consistent reports of high convergent and divergent construct validity, with the 145 IKDC more strongly correlated with the Short Form 36 (SF-36) physical subscales and component summary than 146 with the mental subscales and component summary (2, 8, 11, 13, 23, 24, 27,). Construct validity is acceptable in 147 the pediatric form (20) and improved over the KOOS-Child form (28). Studies have shown the IKDC score to be 148 highly correlated with the Cincinnati Knee Rating System, pain visual analog scale, Oxford 12 Questionnaire,

Western Ontario and McMaster Universities Osteoarthritis Index, Lysholm score, and SF-36 physical component,
physical function, and bodily pain subscales (8, 13, 29).

151 **Responsiveness.** The IKDC has been shown to be adequately responsive (24). In a study comparing

152 responsiveness of the IKDC versus KOOS for ACL injuries, the IKDC was found to be adequately responsive and

the KOOS was not (30). The same finding was found in a Chinese study comparing IKDC versus KOOS (25).

154 Further testing has specifically shown its adequate responsiveness for meniscal injury (31). The Pedi- IKDC has

also been shown to have acceptable responsiveness (20). When directly compared to the KOOS-Child, it has superior responsiveness (28).

157 Minimally Important Differences. The minimal detectable change has been reported to be between 8.8 and

158 15.6, and the standard error of the measure between 3.2 and 5.6. Few studies have shown the minimal

159 important changes. One study shows the minimal important change to be 10.9 for meniscal injuries (31).

160 Another showed it to be 9.8 in the Chinese population (25) and another showed 12.0 for pediatric populations

161 (12). The minimum clinically important difference has been reported to be 6.3 at 6 months and 16.7 at 12

162 months following cartilage repair (32), and 11.5–20.5 (range 6–28 months) in those who have undergone various

surgical procedures for mixed (various) knee pathologies (33). The patient-acceptable symptom state has not
 been determined.

165

#### 166 Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. At face value, the domains covered by the IKDC appear to represent elements that are likely to be important to patients. It shows adequate internal consistency and has no floor or ceiling effects across mixed groups of patients with knee conditions. The IKDC has been shown to be responsive to change following surgical interventions, highlighting its usefulness in this patient population. It has particularly been shown to be a stronger measure for ACL injuries and meniscal injuries. It has also been shown to be a strong measure in the pediatric population.

Caveats and cautions. Despite demonstrating face validity, the lack of patient contribution to item selection indicates that content validity cannot necessarily be assumed and has not been thoroughly investigated. The relatively long recall period associated with 3 of the items may be a problem for some patients. The use of 1 aggregate score to represent symptoms, activities, and function may mask deficits in 1 domain. Psychometric testing is lacking for patients with knee osteoarthritis as an isolated group, as well as responsiveness following nonsurgical management, highlighting areas for future studies.

Clinical usability. The IKDC involves minimal administrative and respondent burden, and can be easily scored in
 the clinic using the online scoring sheet. However, clinicians using the online scoring system need to keep in

181 mind that the normative data provided are from a particular population, and may not be representative of their182 individual patient's population.

183 Research usability. Psychometric evaluation supports the use of the IKDC in research for a variety of knee 184 conditions. As some versions of the IKDC published online contain subtle differences in the wording of 185 instructions and items, researchers should ensure that they utilize the version published as a component of the 186 2000 IKDC Knee Forms to ensure that findings of psychometric properties still apply, and that comparisons can 187 be made with previous studies. Administrative and respondent burden would not limit research use, although 188 researchers should be diligent in checking for missing data.

# 189 KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)

#### 190 Description

191 Purpose. To measure the opinions of young, middle-aged, and elderly patients' with posttraumatic osteoarthritis

192 (OA), and other injuries leading to OA, in regards to their knee and associated problems over short and long-

term follow up (34). Examples of conditions includes knee ligament injury (ACL, posterior cruciate ligament

194 [PCL], medial collateral ligament [MCL]), meniscal tears, knee cartilage lesions, knee OA, and osteochondritis

dissecans. Interventions: ligament reconstruction (ACL, PCL, MCL), meniscectomy, microfracture, osteochondral

autografts, tibial osteotomy, total knee replacement (TKR), exercise (land based, aquatic), intraarticular sodium

197 hyaluronate injection, pharmacologic therapy, and glucosamine supplementation.

198 Content. Five domains: 1) pain frequency and severity during functional activities; 2) symptoms such as the

severity of knee stiffness and the presence of swelling, grinding or clicking, catching, and range of motion

200 restriction; 3) difficulty experienced during activities of daily living (ADL); 4) difficulty experienced with sport and

201 recreational activities; and 5) knee-related quality of life (QOL) (34). The original KOOS remains unchanged,

although there have been other subscales developed including the Koos-12 short form, the KOOS- Joint

203 Replacement form, and the KOOS-Child form

204 Number of items. 42 items across 5 subscales.

205 **Response options/scale.** All items are rated on a 5-point Likert scale (0–4), specific to each item.

206 **Recall period for items.** Previous week for pain, symptoms, ADL, and sport/recreation subscales. Not defined for

207 QOL subscale.

208 **Cost To Use.** Free of Charge. Cost of distribution, collection and data storage not assessed.

209 How to Obtain. Available with associated documentation at www.koos.nu.

# 210 Practical Application

Method of administration. Patient-completed, in-person questionnaire. Can be administered on paper, tablet or
 computer.

- 213 Scoring. Scoring sheets (manual and computer spreadsheets) are provided on the web site. Each item is scored
- from 0–4. The 5 dimensions are scored separately as the sum of all corresponding items.. Scores are then
- transformed to a 0–100 scale (percentage of total possible score achieved)(34). If a mark is placed outside a box,
- the closest box is chosen. If 2 boxes are marked, that which indicates more severe problems is chosen. One or 2
- 217 missing values within a subscale are substituted with the average value for that subscale. If 2 items are missing,
- the response is considered invalid and a subscale score is not calculated.
- Score interpretation. 0 is equivalent to the most severe knee problems and 100 representative of no knee
   problems..Population-based normative data are available, stratified by age and sex (35).
- Respondent time to complete. The KOOS takes 10 minutes to complete (34). It uses simple language and similar
   1-word responses for each item.
- Administrative burden. Approximately 5 minutes to score, if using the scoring spreadsheet. Can be
   automatically calculated with any time of data management software

#### 225 Translations/adaptations.

226 Arabic (Egypt), Arabic (Saudi Arabia), Austria-German, Bengali (India), Czech, Chinese (Hong Kong), Chinese 227 (Singapore), Croatian, Danish, Dutch, Estonian, English, Finnish, Filipino (Philippines), French, German, Greek, 228 Hindi (India), Icelandic, Italian Japanese, Kannada (India), Korean, Latvian, Lithuanian, Malayalam (India), Malay, 229 Marathi (India), Norwegian, Persian, Portuguese, Portuguese (Brazil), Polish, Romanian, Russian, Singapore, 230 English, Slovakian, Slovenian, Spanish, Spanish (US), Spanish (Peru), Swedish, Tamil (India), Telugu (India), Thai, 231 Turkish, Ukrainian, Urdu (India), Vietnamese, Welsh, Zulu. Validation of the cross-cultural adaptations have been 232 conducted and found adequate in the following languages (36,37), Mainland Chinese (38, 39), Singapore Chinese (40), Greek (41), Icelandic (42), Spanish (43,44), Dutch (45), French (46), Saudi Arabic (47), Hong Kong (48), 233 234 Japanese (49), Persian (50), Portuguese (51), Russian, Singapore English (40), Thai (52), and Turkish (53) 235 translations.

236

# 237 **Psychometric Information**

- 238 Floor and ceiling effects. Studies consistently report no or acceptable floor or ceiling effects in knee injury
- cohorts (36, 50, 54) and in patients with mild or moderate knee OA (37, 40, 46, 51). In those with severe OA
- awaiting TKR (37, 40, 45, 46, 51), there are consistent reports of floor effects for the sport/recreation subscale
- 241 (16–73.3% scored lowest score), and ceiling effects have been reported for the pain (15–22%), sport/recreation This article is protected by copyright. All rights reserved

(16%), and QOL (17%) subscales up to 12 months following TKR (37). Comparatively, it has been shown to have
lower ceiling effects in all categories except for pain against the Knee Society Function score (55). Studies have
shown that the original KOOS was not well understood by children and subsequently the KOOS-Child was
formed (56). The KOOS-Child was found to have no floor or ceiling effects (57).

246 **Reliability.** For patients with knee injuries, the pain, ADL, and sport/recreation subscales have adequate internal consistency in all reports, while the symptom and QOL subscales have had reports of lower as well as adequate 247 248 internal consistency (Table 1). In patients with knee OA, the ADL, sport/recreation, and QOL subscales have 249 adequate internal consistency, while the pain and symptoms subscales have reports of lower as well as adequate internal consistency. Test-retest reliability is adequate for group evaluation in all reports on the pain, 250 251 symptoms, and QOL subscales for patients with knee injuries, while there are reports of lower and adequate 252 reliability, respectively, for the ADL and sport/recreation subscales. Recent meta-analysis has shown adequate 253 test-retest reliability for age and condition relevant subscales (58). Across the 5 subscales, the minimal 254 detectable change ranges from 6–12 for knee injuries and from 13.4–21.1 for knee OA. For the five KOOS 255 subscales, the pooled smallest detectable change (SDC) for individuals ranged from 15.7 (ADL) to 25.1 (Sport/ 256 Rec). The SDC was greater for older adults and those with knee OA than for younger and ACL cohorts (58). The standard error of the measure is reported to be lower for knee injuries than for OA. 257

258

Validity. Face and content validity. As well as exhibiting face validity, the direct involvement of patients with
knee conditions in the development of the KOOS facilitates content validity (34, 37).

*Construct validity.* Multiple studies report that the KOOS demonstrates convergent and divergent construct 261 262 validity, with the KOOS more strongly correlated with subscales of the Short Form 36 (SF-36) that measure 263 similar constructs (e.g., ADL with physical function, sport/ recreation with physical function, pain with bodily 264 pain), and less strongly with SF-36 subscales that measure mental health (34, 36, 37, 40, 45, 50, 51, 54, 58, 59). 265 Rasch analysis conducted using patient data 20 weeks post-ACL reconstruction showed that only the 266 sport/recreation and QOL subscales exhibited unidimensionality, not the 3 subscales that were based on the 267 WOMAC (60). A more recent study reported that the KOOS subscales had acceptable dimensionality (59). 268 Further meta-analysis more recently found the hypothesis of superior convergent and divergent construct 269 validity were supported when all data were pooled, and when split by age group and knee condition for pain, 270 symptoms, ADL, sports/recreation and QoL(58). They found that further testing was necessary for the short form 271 as well as needed structural validity in all categories (58).

Responsiveness. The KOOS appears to be responsive to change in patients with a variety of conditions that have
 been treated with nonsurgical and surgical interventions (Table 2). In patients who have undergone partial
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274 meniscectomy 3 months previously, large effect sizes are seen on all but the ADL subscale. Large effect sizes are 275 seen in all subscales 6 months after ACL reconstruction. Three years following autologous chondrocyte 276 implantation or microfracture, large effect sizes are seen for the pain, sport/recreation, and QOL subscales, and 277 moderate effects on the symptoms and ADL subscales. In those with knee OA who have undergone physical 278 therapy treatment, large effect sizes are seen at 4 weeks on the pain, symptoms, and ADL subscales, while the 279 sport/recreation and QOL subscales show moderate effects. Larger effect sizes are found following TKR than 280 with non-operative treatment (58). Large effect sizes are consistently reported on all subscales 3–12 months 281 after TKR, but without increasing effect sizes over these periods (58). Large effect sizes have been shown to be a strength of the KOOS as opposed to other parameters (61). 282

Minimally important differences. The minimum clinically important difference (MCID) of the KOOS short form
 and KOOS QoL has been reported in one study (62). MCID and moderate improvement estimates for KOOS-QOL
 were 8.0 and 15.6, respectively (62).

#### 286 Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. The KOOS has undergone a substantial amount of psychometric testing. Over the last decade, the 287 288 creation of subscales paired with psychometric testing has expanded as well as cultural adaptation testing. 289 Establishment of the KOOS as a reliable and valid measure across multiple languages highlights its usefulness as 290 a patient-reported measure of knee function for people with knee OA and various combinations of sports and 291 trauma related injuries. This has been expanded to include a child form of the test. The use of individual scores 292 for each subscale, rather than an aggregate score, enhances clinical interpretation and in research acknowledges 293 the impact of different interventions on different dimensions (e.g., exercise therapy is likely to have more 294 impact on ADL and sport/recreation, while pharmacology may impact more on pain and symptoms) and ensures content validity in groups of different ages and functional activity levels (e.g., the sport/ recreation subscale is 295 296 more important in patients with a high physical activity level, while the ADL subscale is more important in 297 subjects with a lower physical activity level).

298 **Caveats and cautions.** The KOOS has not been validated for interview administration, meaning that it may not 299 be appropriate for patients who are unable to read or write, or where telephone follow-up is necessary. When 300 administering the KOOS in older or less physically active individuals, higher level components of the ADL and 301 sport/recreation subscales may not be applicable, and could result in missing data. It may be appropriate to 302 leave out the sport/ recreation subscale in those with more advanced disease or disability; however, doing so 303 omits the ability to measure improvements seen in these more demanding functions following treatment (37). 304 The MCID has been minimally examined.

Clinical usability. The KOOS is freely available online. Administration and scoring burden are minimal when
 online score sheets are utilized. Clinicians should bear in mind that the sport/recreation subscale may not be
 applicable for less physically active patients, and may not have adequate test-retest reliability in individuals with
 knee injuries.

309 Research usability. The KOOS fulfills desired criteria for research outcomes, demonstrating adequate reliability 310 for use in groups and validity when used in those with knee injuries and knee OA. The inclusion of the 3 WOMAC 311 subscales facilitates comparison of findings with studies that have utilized the WOMAC as a primary measure. 312 The minimal amount of MCID evidence continues to weaken research usability.

# 313 KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE PHYSICAL FUNCTION SHORT FORM (KOOS-PS)

314 Description

Purpose. Patients' opinions about the difficulties they experience with physical activity due to their knee
problems.

317 **Content.** Measure of physical function derived from the activities of daily living and sport/recreation subscales

of the KOOS (63). Patients rate the degree of difficulty they have experienced over the previous week due to

their knee pain, with respect to: 1) rising from bed, 2) putting on socks/stockings, 3) rising from sitting, 4)

bending to the floor, 5) twisting/pivoting on injured knee, 6) kneeling, and 7) squatting.

321 Number of items. 7 items.

Response options/scale. All items are scored on a 5-point Likert scale (none, mild, moderate, severe, extreme)
 scored from 0–4.

324 **Recall period for items.** Previous week.

325 **Cost to use.** Free to use. Cost of administration and data storage is unique to each practice.

326 How to obtain. The KOOS-PS and associated documentation are freely available at www.koos.nu.

327

328 **Practical Application** 

329 Method of administration. Patient-completed questionnaire. Can be completed in paper form or electronic330 form.

331 Scoring. Each question is scored from 0–4. The raw score is the sum of the 7 items. The interval score from 0–

100 is obtained using a conversion chart (63). No instructions on how to handle missing values.

**Score interpretation.** Possible raw score range: 0–28. Scores are then transformed to a score from 0–100, where

334 0 no difficulty.

335 *Normative values.* Not available.

336 **Respondent burden.** Based on findings for the KOOS, no more than 2 minutes to complete. Uses simple

language and the same 1-word responses for each of the 7 items. As the items relate to everyday tasks, it is not
 considered that they would have an emotional impact on the individual.

Administrative burden. Less than 5 minutes to score, using the conversion table provided (63). Training is not
 necessary, as the questionnaire and scoring instructions are self-explanatory.

- 341 Translations/adaptations. Available in Arabic, Chinese, Danish, Dutch, English, French, German, Hindi, Italian,
- 342 Korean, Norwegian, Polish, Portuguese, Russian, Spanish, Swedish, and Turkish. Can easily be compiled by
- 343 extracting the 7 items needed from the full KOOS forms in all languages in which the KOOS is available. Cross-
- 344 cultural adaptations have been conducted for the French (64), Portuguese (65) and Turkish (66) translations.

#### 345 **Psychometric Information**

346 **Method of development.** Rasch analysis was conducted on KOOS and Western Ontario and McMaster

347 Universities Osteoarthritis Index (WOMAC) data from individuals with knee OA from Sweden, Canada, France,

348 Estonia, and The Netherlands. Patient data from 13 data sets were used (age 26–95 years, male:female ratio

1:1.4). This included community and clinical samples, such as those who had undergone previous meniscectomy,

tibial osteotomy, or anterior cruciate ligament repair, as well as those scheduled to undergo TKR (63).

351 Acceptability. Rates of missing data have not been reported. Findings of 1 study indicate no floor or ceiling

352 effects when used in patients with knee OA (i.e., no patients had lowest or highest score, respectively) (64).

353 Reliability. The KOOS-PS has adequate internal consistency and test–retest reliability for groups of patients with

knee OA; however, its reliability is lower than adequate for use in individuals with knee OA (Table 1). The

355 minimal detectable change and standard error of the measure have not been reported.

Validity. Face and content validity. As items are taken directly from the KOOS, which has face and content
validity, this can also be assumed for the KOOS-PS although no studies have evaluated content validity solely for
KOOS-PS (58).

359 *Construct validity.* The KOOS-PS shows evidence of convergent and divergent construct validity. Higher

360 correlations have been shown with the Short Form 36 (SF-36) physical function, role physical, and bodily pain

361 subscales; WOMAC function subscale (excluding KOOS-PS items); and Osteoarthritis Knee and Hip Quality of Life

362 questionnaire (OAKHQOL) physical activity domain (64, 65, 67). Conversely, lower correlations have been

reported with KOOS pain, symptoms, and quality of life subscales; SF-36 mental health subscales; mental health

questionnaires (e.g., Profile of Mood States, Hospital Anxiety and Depression Scale); and OAKHQOL social

support (64, 65, 67). One study found that, in patients with knee OA, KOOS-PS had a unidimensional structure

366 when evaluated using principal component analysis (68)

367 **Responsiveness.** In patients with knee OA, the KOOS-PS shows moderate to large effect sizes following 4 weeks 368 of physical therapy, and moderate effects 4 weeks after intraarticular hyaluronic acid injection (Table 2). The 369 KOOS-PS is also able to discriminate groups of patients based on use of walking aids (65). When compared 370 directly to the WOMAC physical function subscale, the WOMAC physical function subscale was better able to 371 detect changes over time in physical function categories (69). One study found the minimum clinically important 372 difference (MCID) for patients undergoing non-operative treatment for OA to be 12 (70). For KOOS-PS, MCID 373 and moderate improvements were 2.2 and 15.0.

# 374 Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. The KOOS-PS is one of the few knee-related patient-reported outcomes that utilized Rasch analysis in its development. Its inclusion of only 7 items facilitates use with short measures of other dimensions, such as pain visual analog scales, and makes it ideal for those for which long questionnaires may be onerous (e.g., older populations).

- 379 **Caveats and cautions.** The KOOS-PS was intended for use in those with knee OA, and limited evaluation for
- other conditions is available. Also, utilizing the Rasch analysis, data suggests that a 12 item short form for
- 381 physical function may lead to a more optimal measurement (68).
- 382 **Clinical usability.** The minimal administration and scoring burden associated with the KOOS-PS make it ideal for
- 383 clinical use, particularly considering that the included items are frequently asked in the standard clinical
- examination. However, clinicians should bear in mind that the reliability has been shown to be less than
- 385 adequate for individuals.
- 386 **Research usability.** Psychometric testing shows the KOOS-PS to be valid and reliable for use in groups with knee
- 387 OA, making it an ideal tool for measuring knee related function in research.

# 388 KNEE OUTCOME SURVEY ACTIVITIES OF DAILY LIVING SCALE (KOS-ADL)

- 389 Description
- **Purpose.** To determine symptoms and functional limitation in usual daily activities caused by various kneepathologies (71).
- 392 Intended populations/conditions. Patients undergoing physical therapy for various knee pathologies, such as
- ligament/meniscal injury, osteoarthritis (OA), and patellofemoral pain (71-73). It is applicable for patients
- undergoing a variety of orthopedic knee procedures and young athletic subjects as well as older adults (74, 75).

*Version.* Although originally described as a single index with 17 items (71), shorter versions have been widely
used. A version using Likert-type scales is also available (76).

397 Content or domains. Single index with 2 sections pertaining to symptoms (pain, crepitus, stiffness, swelling,

instability/ slipping, buckling, and weakness) and functional limitations (difficulty walking on level surfaces, use
 of walking aids, limping, going up and down stairs, standing, kneeling, squatting, sitting, and rising from a sitting

400 position) (71,76). A separate scale has been developed to assess sporting activities (71).

401 Number of items. The original version comprised 17 items (7 for symptoms, 10 for function), but a 14-item
402 version (6 for symptoms, 8 for function) is also used (71,76).

403 Response options/scale. Patients rate items using descriptive responses, which are translated to a numerical
404 ordinal scale for scoring. Responses for each item are scored from 0–5, with the exception of item 9 (0–3) and
405 item 10 (0–2) in the 17-item questionnaire.

406 **Recall period for items.** 1–2 days.

- 407 **Cost to use.** Free
- 408 How to obtain. Presented in full as an appendix in the original publication (71).
- 409

410 Practical Application

- 411 **Method of administration.** Patient-completed questionnaire. It has not been validated for interview
- 412 administration (in person or via telephone).
- 413 **Scoring.** The total score is calculated as the sum of scores from the responses to each item, and then
- 414 transformed to a percentage score by dividing by the maximum total possible score and multiplying by 100415 (71,76).
- 416 *Missing values.* While there are no instructions provided as to handling missing data, the original publication 417 only analyzed questionnaires with no missing data (71).
- **Score interpretation.** Possible transformed score range 0–100, where 100 means no knee-related symptoms or
- 419 functional limitations.
- 420 *Normative values.* Not available.
- 421 **Respondent time to complete.** It takes approximately 5 minutes to complete the KOS-ADLS questionnaire (71).
- 422 No training or assistance is required as the KOS-ADLS is self-explanatory.
- 423 **Administrative burden.** The total score can be calculated in 5 minutes. No training is required for interpretation. This article is protected by copyright. All rights reserved

- 424 Translations/adaptations. The KOS-ADLS instrument has been validated after translation to Arabic (77,78),
  425 Chinese (79), French (80) German (81), Portuguese (82), Polish (83), Turkish (84), and Greek (85).
- 426

#### 427 Psychometric Information

Floor and ceiling effects. No floor effects have been detected (74,75). Acceptable ceiling effects have been
reported in people with a variety of knee pathologies undergoing physical therapy and orthopedic surgeon
evaluation (71,75). However, high ceiling effects have been reported 6 months after TKR (74).

- 431 **Reliability.** In patients with mixed knee pathologies, the KOS-ADLS has demonstrated adequate internal
- 432 consistency across multiple languages, as well as adequate test-retest reliability for use in groups and

433 individuals (Table 1). There has been shown to be high test-retest reliability in patients with patellofemoral pain

- 434 syndrome (PFPS) (86). Reliability decreases as the time increases between baseline and follow up measurements
  435 in patients undergoing physical therapy for knee OA (87).
- 436 Validity. Face and content validity. During development, the KOS-ADLS was examined by orthopedic surgeons
- 437 and physical therapists, who thought that it adequately covered the range of functions/painful activities
- 438 performed in daily life, ensuring face validity (71). However, since item selection did not involve patient input,
- this instrument may lack content validity if the instruments from which items were drawn were not themselves
  derived from patient input (71).

441 *Construct validity.* The KOS-ADLS shows good correlation with other knee-specific scales, such as the Lysholm
 442 Knee Scoring Scale (71), WOMAC subscales (74), and global assessment of function (71). Higher correlations with
 443 the physical than mental component score of the Short Form 12 indicates convergent and divergent construct
 444 validity (74).

Responsiveness. The KOS-ADLS demonstrates an ability to detect change in patients with a variety of knee disorders (Table 2). Among patients undergoing physical therapy for various knee pathologies, small effect sizes were reported at 1 week, and large effect sizes were reported at 4 and 8 weeks (71). Moderate effect sizes were reported among patients with PFPS (73). Large effect sizes have been reported following TKR (74). The responsiveness has been shown to decrease over time in patients undergoing physical therapy for knee OA (87). The patient acceptable symptom state has not been reported.

Minimally important differences. Among patients with PFPS, the minimum clinically important difference has
been determined to be 7.1 (73) and a minimal detectable change of 8.3% (86). In patients undergoing physical
therapy for knee OA, there is an increase in the minimum clinically important difference from 2.2 at 2 months to
5.0 at 12 months (87)

455 **Generalizability.** The KOS-ADLS has been used in a variety of knee pathologies. It is likely generalizable to many

456 knee conditions and many different populations due to the consistent reliability, validity, and responsiveness

457 that is found in the literature.

458 Use in clinical trials. None reported.

# 459 Critical Appraisal of Overall Value to the Rheumatology Community

460 Strengths. The KOS-ADLS is a reliable and valid instrument that is responsive to change in patients with a variety
 461 of knee conditions who are undergoing physical therapy or orthopedic procedures.

462 **Caveats and cautions.** The lack of direct patient input into item selection means that content validity cannot be

463 assumed. The KOS-ADLS uses more descriptive responses to each item as compared to other patient-reported

464 outcomes, which may be confusing or overwhelming for some patients, particularly those with reading

difficulties. By design, the KOS-ADLS does not include items pertaining to athletic activities, such as running and
 jumping.

467 **Clinical usability.** The KOS-ADLS is sufficiently reliable to allow use in individuals with a variety of knee disorders.

468 **Research usability.** The KOS-ADLS is reliable, valid, and appropriate for measuring change following nonsurgical 469 and surgical interventions in a variety of knee conditions. However, researchers should be aware that if subjects 470 being evaluated are highly physically active, this instrument is not necessarily valid. Researchers should also be 471 consistent with which version of the scale they are utilizing.

# 472 LYSHOLM KNEE SCORING SCALE (LKS)

473 Description

474 **Purpose.** To evaluate outcomes of knee ligament surgery, particularly symptoms of instability (88).

475 Intended populations/conditions. Patients with knee ligament injury and anteromedial, anterolateral, combined

476 anteromedial/anterolateral, posterolateral rotatory, or straight posterior instability (88).

477 Version. First published in 1982 (88). The revised version (1985) added an item regarding knee locking, removed

items regarding pain on giving way, swelling with giving way, and the objective measure of thigh atrophy, and

- also removed the reference to walking, running, and jumping above the sections regarding instability, pain, andswelling (89).
- 481 **Content.** The original scale included 8 items: 1) limp; 2) support; 3) stair climbing; 4) squatting; 5) walking,
- running, and jumping; and 6) thigh atrophy (88). The revised scale also includes 8 items: 1) limp, 2) support, 3)
- 483 locking, 4) instability, 5) pain, 6) swelling, 7) stair climbing, and 8) squatting (89).

484 Number of items. 8 items.

- 485 **Response options/scale.** Individual items are scored differently, using individual scoring scales. The revised scale
- 486 modified the original scoring slightly: 1) limp (0, 3, 5), 2) support (0, 2, 5), 3) locking (0, 2, 6, 10, 15), 4) instability
- 487 (0, 5, 10, 15, 20, 25), 5) pain (0, 5, 10, 15, 20, 25), 6) swelling (0, 2, 6, 10), 7) stair climbing (0, 2, 6, 10), and 8)
- 488 squatting (0, 2, 4, 5) (89).
- 489 **Recall period for items.** Not specified.
- 490 **Cost of use.** The revised version is freely available in the publication (89).
- 491 How to obtain. <u>https://stfsportsmed.com/wp-content/uploads/Lysholm-Knee-Scale.pdf</u>
- 492
- 493
- 494 Practical Application
- 495 Method of administration. Original and revised scales were intended for in-person clinician administration 496 (administered by the orthopedic surgeon with the patient's collaboration) (88,89), although subsequent studies 497 have documented using the scale as a patient-completed questionnaire (90). While significantly lower scores 498 have been found for questionnaires versus interview administration, suggesting interview bias (91), 1 study 499 reported a high level of agreement between patients and physiotherapists using a modified version of the 500 Lysholm scale (item for swelling removed) in patients with knee chondral damage (92). Most recently, several 501 studies have shown that telephone interviews (as opposed to face-to-face) and electronically delivered 502 questionnaires are indeed reliable modes of administration, with the perceived advantage of fostering multi-503 center collaborations and potential for more accurate comparisons of outcomes between patient groups 504 (93,94).
- Scoring. Each possible response to each of the 8 items has been assigned an arbitrary score on an increasing
   scale. The total score is the sum of each response to the 8 items, of a possible score of 100. Computer scoring is
   not necessary.
- 508 *Missing values.* No instructions provided.
- 509 **Score interpretation.** Possible score range: 0–100, where 100 no symptoms or disability. Scores are categorized 510 as excellent (95–100), good (84–94), fair (65–83), and poor (<64) (89).
- 511 *Normative values.* Normative data are available with and without stratification by sex (95,96).
- 512 **Respondent burden.** Time to complete has not been reported, but is expected to vary depending on the
- administration method (i.e., patient completed versus clinician administered). The Lysholm scale generally uses
- simple language in its questioning. However, it does use some specific medical terms such as locking, catching,
- and weight bearing. Administration of this scale as it was intended (i.e., clinician administered) would ensure
- adequate explanation of such terms, although this may vary between clinicians. As the items relate to everyday
- tasks, it is not considered that they would have an emotional impact on the individual.

518 Administrative burden. Less than 5 minutes to score. Training is not necessary, as the scale provides the 519 corresponding score next to each possible response for each item.

Translations/adaptations. Since its original publication in English, several other translations have been accepted for use. An Arabic translation has been validated for OA, ligamentous, and meniscal injuries (97). Cross-cultural adaptations specifically for ACL injuries have been translated and validated in the Chinese and Dutch languages (98, 99) An Italian version demonstrates equivalence to the English version for assessing patellofemoral pathology (100). A German translation was found to be valid and reliable in assessing patients following total knee arthroplasty (101). Turkish and Spanish adaptations have also been accepted for use in assessing ligamentous pathology (102).

527

# 528 **Psychometric Information**

529 Method of development. Items pertaining to limp, support, stairs, squatting, and thigh atrophy were selected, 530 and items for pain and swelling were adapted from the modified Larson scoring scale (103). The authors added 531 the item for instability, as they deemed this to be an important component of the disability associated with ACL 532 injury (88). The revised scale does not report how the item for locking was selected (89). Four groups of patients were used to compare the original scale to the modified Larson scoring scale: 1) knee ligament injury and 533 534 anteromedial, anterolateral, and combined anteromedial/anterolateral instability; 2) knee ligament injury and 535 posterolateral rotatory or straight posterior instability; 3) meniscus tears; and 4) chondromalacia patellae (88). 536 Item-response theory was not used in the development of the Lysholm scale.

Acceptability. Rates of missing data have not been reported. There are consistent reports of no floor or ceiling
effects (i.e., 15% of patients score the lowest or highest score, respectively) (75, 90, 104-107).

539 **Reliability.** The Lysholm scale appears to have inadequate internal consistency in patients with a variety of knee

540 conditions (Table 1). Test–retest reliability is adequate for use in groups with knee injuries, but is less than

adequate for groups with mixed knee pathologies. Reliability may be inadequate for use in individuals. The

542 minimal detectable change has been reported as between 8.9 and 10.1 for knee injuries, while the standard

error of the measure is reported to range from 3.2 to 3.6 for knee injuries and from 9.7 to 12.5 for mixed kneepathologies.

545 **Validity.** *Face and content validity.* The Lysholm scale has been reported as having face validity, as evaluated by

546 5 orthopedic surgeons with sports medicine experience (75). Because the items in the Lysholm scale are surgeon 547 derived, content validity from the patient's perspective cannot be assumed.

548 *Construct validity.* Multiple studies have reported convergent construct validity for the Lysholm score, finding

significant correlations with the Hospital for Special Surgery modified knee ligament rating system, Cincinnati

550 Knee Ligament Score, International Knee Documentation Committee Subjective Knee Evaluation Form,

- 551 Fulkerson and Kujala scores, and Western Ontario and McMaster Universities Osteoarthritis Index (106-108).
- 552 Two studies have reported evidence of convergent and divergent construct validity, finding the Lysholm score to
- 553 correlate more highly with the Short Form 12 and Short Form 36 physical components than mental components
- 554 (75, 90). The Lysholm score was shown to satisfy the Rasch model after removal of the item for swelling in
- 555 patients awaiting surgery for knee chondral damage (92).
- 556 **Ability to detect change.** Large effect sizes have been reported following ACL reconstruction (6–9 months
- 557 postoperative), meniscal repair (1 year postoperative), and microfracture (1–6 years postoperative) (Table 2).
- Large effect sizes are also reported following 1 month of physical therapy in a group of patients with mixed knee pathologies.
- 560 **Minimal Important Difference**. The minimum clinically important difference (MCID) and patient-acceptable
- 561 symptom state (PASS) have not been calculated in any patient population. Specifically, when comparing
- responsiveness following autologous chondrocyte implantation (ACI), The Lysholm and IKDC were the most
- 563 sensitive to detecting changes when compared with MCKRS, KOOS, and SF-36 (109).

# 564 Critical Appraisal of Overall Value to the Rheumatology Community

- 565 **Strengths.** The Lysholm scale is a freely available measure that is able to detect change following nonsurgical 566 and surgical intervention. It is considered to have face validity by orthopedic surgeons. Because the Lysholm 567 scale assesses everyday activities as opposed to higher functional activity, delayed return to sport has little 568 impact on the LKS. Therefore, LKS may be ideal for assessing short term outcomes, or outcomes in patients not 569 intending to return to a specific sport (109).
- 570 Caveats and cautions. Content validity cannot be assumed, as the items included in the Lysholm scale were 571 surgeon derived. The Lysholm scale was developed as a clinician-administered tool, which increases the 572 potential for interviewer bias if the patient-reported outcome is applied as intended. Despite this, there are 573 inconsistencies between methods of administration of the Lysholm scale in published studies. The MCID and 574 PASS are lacking in psychometric analysis.
- 575 Clinical usability. Minimal administrative and respondent burden makes the Lysholm scale attractive for clinical 576 use. The lack of floor and ceiling effects across different knee conditions suggests that the Lysholm scale is useful 577 for tracking improvement with intervention as well as deterioration over time in patients with various knee 578 pathologies. However, clinicians should consider the impact of inadequate reliability in evaluation of individuals.
- 579 **Research usability.** The Lysholm scale is reliable for use in research on ligamentous injuries of the knee,
- 580 chondral injuries, and patellar dislocation. The use of Lysholm and IKDC together has proven to represent a
- responsive combination for efficiently evaluating treatment effects following autologous chondrocyte
- 582 implantation (109). It is important that researchers consistently utilize the same scale version (89). Researchers
- should be aware that the psychometric properties may change between different administration methods,

- ensure consistent administration within and between studies, and be aware that clinician and patient ratings
- 585 may differ substantially. Lack of known MCID is a weakness.
- 586

# 587 TEGNER ACTIVITY SCORE (TAS) Description

- 588 **Purpose.** To provide a standardized method of grading work and sporting activities (89). Developed to
- 589 complement the Lysholm scale, based on observations that limitations in function scores (Lysholm) may be
- 590 masked by a decrease in activity level (89).
- 591 *Intended populations/conditions.* Intended for use in conjunction with the Lysholm Knee Scoring Scale, originally 592 in patients with anterior cruciate ligament (ACL) injury (89).
- 593 Version. Although in some circumstances it has been modified slightly to accommodate different populations,
- 594 the standard TAS remains in its original format.
- 595 **Content.** Graduated list of activities of daily living, recreation, and competitive sports. The patient selects the
- 596 level of participation that best describes their current level of activity.
- 597 Number of items. One item is selected from a list of 11.
- 598 **Response options/scale.** A score of 10 is assigned based on the level of activity that the patient selects. A score
- 599 of 0 represents "sick leave or disability pension because of knee problems," whereas a score of 10 corresponds
- to participation in national and international elite competitive sports (89). Activity levels 6–10 can only be
- achieved if the person participates in recreational or competitive sport.
- 602 **Recall period for items.** Current ability.
- 603 **Cost to use.** Freely available in the original publication (89).
- 604

# 605 Practical Application

606 **Method of administration.** Originally established as an in-person, clinician-administered tool (110), but has been 607 used more recently as a patient-completed questionnaire (90, 111).

- 608 **Scoring.** A score of 10 is assigned based on the level of activity that the patient selects as best representing their
- 609 current activity level. Computer scoring is not necessary. *Missing values.* Not applicable (single score).
- 610 **Score interpretation.** Possible score range: 0–10. Higher scores represent participation in higher-level activities.
- 611 *Normative values.* Normative data have been presented by sex and age group (95).
- 612 **Respondent burden.** Reported to take mean SD 3.3 0.6 minutes to complete in those who have undergone
- total knee replacement (112). The scale classifies work, recreational, and sport activities in a graded activity
- 614 scale, using common terminology. As such, patients should not have difficulty selecting which level corresponds
- to their current activity. Degree of difficulty (measured on a visual analog scale) has been reported to increase
- 616 with age (r 0.25, P 0.03) (112).

Administrative burden. Scoring time is negligible, as the score is based on a single selected item. Training is notnecessary.

- 619 Translations/adaptations. Available in English. Cross-cultural translations are now validated for use in the
- 620 Swedish, Dutch, German, Chinese, and Iranian populations for use in ACL injuries, and a German translation has
- been validated for use in the TKA population (99,101,113-115). Use in other rheumatology populations has
- 622 consisted of ankle and shoulder disorders.

623 Psychometric Information

624 **Method of development.** Orthopedic surgeons selected items they believed to be difficult for patients with ACL

625 injury. Forty-three patients with ACL-deficient knees then completed a questionnaire in which they graded these

626 activities according to how difficult they were. This formed the basis of item selection for the TAS. Both paper

and electronic forms have found to be reliable methods of administration (93).

628 Acceptability. Studies consistently report no floor or ceiling effects in those with knee injury or OA (i.e., 15%

629 scored lowest or highest score, respectively)

630 (90, 101, 104, 112).

631 **Reliability.** The TAS has adequate test–retest reliability for groups with knee injuries and knee OA, although

reliability is less than adequate for use in individuals (Table 1). For knee injuries, the minimal detectable change
is 1, while the standard error of the measure ranges from 0.4–0.64.

634 Validity. Face and content validity. At face value, the TAS covers a wide variety of activity levels that may be 635 applicable to patients with ACL and other knee injuries. However, as initial activity selection was conducted by 636 orthopedic surgeons, with patient input afterward regarding the difficulty of these selected activities, content 637 validity cannot necessarily be assumed.

638 *Construct validity*. Evidence for convergent and divergent construct validity is provided by studies that found

higher correlations with the physical component of the Short Form 12 than the mental component (90, 101,

640 112). The TAS has also shown significant correlations with the International Knee Documentation Committee641 Subjective

642 Knee Evaluation Form, Knee Society Score function score, Western Ontario and McMaster Universities

643 Osteoarthritis Index pain and function subscales, and Oxford Knee Score (90, 101, 104, 112).

644 **Generalizability.** The Tegner Score was found to be reliable in both adult and pediatric populations (116).

645 Ability to detect change. Following meniscal surgery, moderate effect sizes are seen 12 months postoperatively

646 in those with isolated meniscal lesions, and large effect sizes are seen in those with combined lesions (Table 2).

647 In those who have undergone ACL reconstruction, effect sizes are reported to be moderate at 6 months and

648 large at 9 months, 1 year, and 2 years. The minimum clinically important difference (MCID) and patient-

649 acceptable symptom state have not been determined.

650

- 651 Critical Appraisal of Overall Value to the Rheumatology Community 652 Strengths. The TAS is a simple freely available measure of activity level that spans work, sporting, and 653 recreational activities. It is one of the few patient-reported outcomes that were developed to consider the 654 influence of activity level on other symptoms, such as pain alleviation when aggravating activities are avoided. 655 The Tegner score was found to have clear benefits over other PROMs, and is the preferred PROM for ACL 656 injuries in the UK (117). 657 **Caveats and cautions.** The TAS was originally intended and developed for patients with ACL injury as an adjunct 658 to the Lysholm scale, not as a stand-alone measure. The MCID is missing from psychometric analysis. Studies 659 suggest that TAS data need to be adjusted for age and sex 660 (118). 661 **Clinical usability.** Clinicians should note that its reliability may be inadequate for use in individuals. 662 **Research usability.** Although valid and reliable for use in groups, use of the TAS in research may need to be applied with caution. Given its intent to measure change within patients, the TAS may be more appropriate for 663 664 within-subject repeated measures studies rather than between-group comparisons. 665 666 667 **OXFORD KNEE SCORE (OKS)** 668 Description 669 Purpose. Brief questionnaire for patients undergoing total knee replacement (TKR) that reflected the patient's 670 assessment of their knee-related health status and benefits of treatment (119). 671 Intended populations/conditions. Patients undergoing TKR.
- 672 Version. A new version was proposed on the basis that some surgeons believed that the scoring of the original
- 673 version was non-intuitive (i.e., lower scores represented better outcome, higher scores represented worse
- outcome), where the original 12 items are used but the scoring is different (120). 674
- 675 Content or domains. Single index pertaining to knee pain and function (pain severity, mobility, limping, stairs,
- 676 standing after sitting, kneeling, giving way, sleep, personal hygiene, housework, shopping, and transport). The
- 677 questionnaire can be separated into pain and function subscales with good validity and responsiveness (121).
- 678 Number of items. 12 items.

- 679 **Response options/scale.** Each item is followed by 5 responses (scores ranging from 1–5), where 1 is the best and
- 5 is the worst outcome. The modified version also has 5 responses to each item, but the scoring is from 0–4,
- 681 where 0 is the worst and 4 is the best outcome.
- 682 **Recall period for items.** Previous 4 weeks.
- 683 Cost to use. Free.
- How to obtain. The original version can be found in its original publication (119). The modified version is freely
   available online (<u>http://www.orthopaedicscore.com/scorepages/oxford\_knee\_score.html</u>) (120).
- 686
- 687 Practical Application
- 688 Method of administration. Patient-completed questionnaire.
- 689 Scoring. Originally, each response to each item was assigned a score from 1–5 (where 1 no problem and 5
- 690 significant disability). The modified version assigns a score from 0–4 (where 4 no problem and 0 significant
- disability). The total score is calculated as the sum of scores from responses to all 12 items.
- 692 *Missing values.* No instructions provided.
- 693 Score interpretation. In the original version, the total score ranges from 12–60 (119), while in the modified 694 version the total score ranges from 0–48 (120). Higher scores in the original version reflect poor outcome and 695 lower scores reflect better outcomes. In the modified version, this is reversed.
- 696 *Normative values.* Not available.
- 697 Respondent time to complete. Reported to involve minimal respondent burden (119). It takes approximately 5-
- 698 10 minutes to complete the questionnaire. No training or assistance is required since the questions are self699 explanatory.
- Administrative burden. Scoring is simple and quick (119). Calculation of the total score takes 1–5 minutes. No
   training is necessary.
- 702 **Translations/adaptations.** Translated and validated in many languages, including Arabic (122, 123), Chinese
- 703 (124-126), Finnish (127), German (128), Japanese (129), Korean (130), Persian (131, 132), Portugese (133),
- 704 Spanish (134), Swedish (135), and Thai (136), Turkish (138).
- 705

706 Psychometric Information

Floor and ceiling effects. A study reported no floor or ceiling effects prior to TKR (74). Six months
postoperatively, although there were no floor effects, there were ceiling effects reported (27% of patients
scored the top score). Conversely, one study found large floor effects at an average of 18 months postoperatively, with no ceiling effect (138). Furthermore, the ceiling effect has been shown to increase from 6
months to 2 years post operatively from TKR, while no floor effect was found at either time point (139). Another
study found no floor or ceiling effects in patients with knee OA (134).

713 Reliability. The OKS has adequate internal consistency across multiple languages (119, 124, 128, 129, 135, 136)

714 (Table 1). The original study reported adequate test–retest reliability for use in groups and individuals (119).

There test-retest reliability was confirmed in patients with OA being managed non operatively (140).

716 Validity. Face and content validity. Extensive input from patients in the development of the OKS ensures content
717 validity.

718 Construct validity. The OKS shows good correlation with knee-specific and general health questionnaires, such as 719 the Western Ontario and McMaster Universities Osteoarthritis Index, American Knee Society Score, Knee 720 Outcome Survey Activities of Daily Living Scale, and pain and physical function components of the Short Form 36 721 and Health Assessment Questionnaire (119, 141). Internal and external validity is adequate post-operatively 722 (138). Convergent and divergent construct validity is demonstrated by higher correlations with the Short Form 723 12 physical than mental component (74). Convergent and divergent validity has also been confirmed when the 724 pain and function subscales of the OKS has been separately compared to other outcome scores (140). The OKS 725 has been shown to fit Rasch models following rescoring of some items (142), and removal of items for limp and 726 kneeling (143).

727 **Responsiveness.** The OKS demonstrates good sensitivity and responsiveness to change (Table 2).

Responsiveness is consistent whether using raw OKS data or after Rasch analysis (139). Large effect sizes have been reported 6–12 months after TKR (119, 144) and 1 year after high tibial osteotomy (145). The OKS has also been found to be a good predictor of revision TKR within 6 months (146), and is also a predictor of range of motion after TKR (147). The effect size is larger in patients who report positive changes in their knee symptoms over time compared to patients who report a negative progression in symptoms (134).

Minimally important differences. The minimum detectable change (MDC95) after high tibial osteotomy was
reported to be 8.29 (145). The minimum detectable change (MDC90) and minimal important change (MIC) 6
months after TKR were found to be 4.15 and 9.22, respectively (148). In patients with knee OA, the MDC90 after
3 months of non-operative management was 6 and the minimum important difference was 6.4 (140). In this

- same patient cohort, the MIC for the total OKS was 7.1, the MIC for OKS the pain subscale was 17.3, and the MIC
- for the function subscale was 10.6. Patient acceptable symptom state has not been reported.
- 739 **Generalizability.** The OKS was intended for use in patients with knee OA before and after TKR. It is likely
- 740 generalizable to many knee conditions and many different populations due to the consistent reliability, validity,
- and responsiveness that is found in the literature.
- 742 Use in clinical trials. None reported.
- 743 Other: Patients are able to recall their pre-operative health status in regards to the OKS with good consistency
  744 (149), even up to 1 year post-operatively (150).
- 745 Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. The OKS is a self-administered questionnaire developed to measure outcome following TKR. Due to simplicity and ease of administering, it has been used widely, especially in the UK, and is available in languages other than English. For the same reasons, it can be used as a cost-effective screening tool in short-term (2 years) followup of TKR compared to physician administered instruments, such as the American Knee Society Score, as reported by 1 study (151). It may be separated into pain and function subscales.

- Caveats and cautions. Although simple, some items are "double barreled" and may be confusing to patients (e.g., trouble getting in and out of a car or using public transportation). Some response options potentially overlap with others, which may also cause confusion. The use of an aggregate score combining pain and function may mask changes in 1 domain, particularly given that only 1 of the 12 items relates solely to pain. If separated into pain and function subscales, must be aware of the complex interaction between pain and function and therefore patient interpretation of the questions. The floor and ceiling effects post-operatively make post-operative comparisons and distinctions more difficult.
- Clinical usability. Psychometric testing suggests that the OKS is sufficiently reliable for use in individuals with knee OA. The ease of administration and scoring makes it a useful tool for clinical use. However, clinicians should be aware that some patients may require explanation of individual items, which could introduce interviewer bias.
- 762 **Research usability.** The OKS is a knee OA–specific measure that is reliable, valid, and responsive to change 763 following TKR. Researchers should be aware of the different scoring methods when interpreting findings of 764 previous research. It is correlated with the American Knee Society Score, and therefore these scores can be 765 directly compared (152).
- 766

#### 767 WESTERN ONTARIO AND MCMASTER UNIVERSITIES OSTEOARTHRITIS INDEX (WOMAC)

- 768 Description
- 769 **Purpose.** To assess the course of disease or response to treatment in patients with knee or hip osteoarthritis
  770 (OA) (153, 154).
- 771 Intended populations/conditions. Patients with knee and hip OA (153,154).
- 772 *Version.* Initially developed in 1982, the WOMAC has undergone multiple revisions (most recent version 3.1). It
- is available in 5-point Likert, 100-mm visual analog scale (VAS), and 11-box numerical rating scales (155, 156).
- Reduced and modified versions of the WOMAC have been validated but are not endorsed on the WOMAC web
  site (157-159, 160).
- Content or domains. Three subscales: 1) pain severity during various positions or movements, 2) severity of
   joint stiffness, and 3) difficulty performing daily functional activities.
- 778 **Number of items.** 24 items.
- 779 **Response options/scale.** In the Likert version, each item offers 5 responses: "none" scored as 0, "mild" as 1,
- 780 "moderate" as 2, "severe" as 3, and "extreme" as 4. Alternatively, the VAS and numerical rating scale versions
- 781 permit responses to be selected on a 100-mm or 11-box horizontal scale, respectively, with the left end marked
- as "none" and the right end marked as "extreme" (153,154).
- 783 Recall period for items. 48 hours.
- 784 **Cost to use.** Not free, cost depends on research project.
- 785 **How to obtain.** Available from Professor Nicholas Bellamy (Australia, e-mail: n.bellamy@uq.edu.au). To obtain
- 786 licensing and fee information and permission to use the WOMAC for clinical or research purposes a request
- needs to be submitted to http://www.womac.com.
- 788

#### 789 Practical Application

- Method of administration. Self-administered or interview-administered questionnaire. It has been validated for
   use in person, over the telephone, or electronically via a computer or mobile phone (154, 161-164). Electronic
   and paper questionnaires show high agreement (165).
- 793 **Scoring.** The total score for each subscale is the sum of scores for each response to each item, and can be
- calculated manually or using a computer. The range for possible subscale scores in the Likert format are: pain
- 795 (0–20; 5 items each scored 0–4), stiffness (2 items, 0–8), and physical function (17 items, 0–68). In the VAS

- format, the ranges for the 3 subscale scores are: pain, 0–500; stiffness, 0–200; and physical function, 0–1,700
  (153,154).
- 798 Missing values. If 2 or more pain items, both stiffness items, and 4 or more physical function items are missing,
- the response should be regarded as invalid and the deficient subscale(s) should not be used in analysis (153).
- 800 Score interpretation. Higher scores indicate worse pain, stiffness, or physical function.
- 801 *Normative values.* Australian population-based normative data have been reported, stratified by age and sex802 (166).
- 803 **Respondent time to complete.** 5–10 minutes to complete.
- 804 Administrative burden. Approximately 5 minutes to score. Training is not necessary.
- 805 **Translations/adaptations.** WOMAC version 3.1 is available in over 100 languages (155), and has validated
- 806 language translations for Arabic (167), Arabic reduced (168), Bangladesh (169), Chinese (170, Symonds 2015
- 807 171), Finnish (172), German (173), Greek (174), Hebrew (175), Italian (176), Japanese (177), Korean (178),
- Moroccan (179), Nepali (180) Persian (131), Portuguese-Brazil (181) Singapore (182), Spanish (183), Swedish
  (184, 185), Thai (186), and Turkish (187,188).

#### 810 **Psychometric Information**

- Floor and ceiling effects. Reports of floor and ceiling effects have differed between studies (74, 170, 186, 188, 189). The stiffness subscale has been reported as having floor and ceiling effects prior to intervention (74, 170, 188), as well as up to 1 year postoperatively from TKR (190). Ceiling effects have been reported by various
  studies for all subscales 6 months and 2 years after TKR (74, 189).
- 815 **Reliability.** The stiffness and function subscales have consistently demonstrated adequate internal consistency 816 in knee OA (Table 1). Studies have generally reported adequate internal consistency for the pain subscale, 817 although there have been reports slightly lower than adequate. There have been mixed findings regarding 818 adequacy of test=retest reliability in knee OA for all subscales. Test- retest reliability for the stiffness subscale 819 may not be adequate for use in individuals with knee OA. One study that investigated test-retest reliability in 820 patients with chondral defects found that all subscales had adequate reliability for use in groups, but only the 821 function subscale was adequate for individual use. However, the "putting on socks" item of the physical function 822 subscale may present problems in stability and variance when analyzed with the Rasch model (191). 823 Additionally, the physical function subscale may have a stronger association with pain than performance (192,

193) The minimal detectable change and standard error of the measure vary according to condition and

subscale. These measures tend to increase over time, and the reliability decreases over time (87).

826 Validity. Face and content validity. Since the WOMAC was developed with extensive input from patients with

827 OA, as well as input from academic rheumatologists and epidemiologists experienced in clinical assessment of

828 rheumatologic diseases, the WOMAC can be considered to have face and content validity.

829 *Construct validity*. Multiple studies have shown that the WOMAC subscales demonstrate good construct validity. 830 Moderate to strong correlations with measures of similar constructs (e.g., Short Form 36 [SF-36] physical 831 subscales, pain/handicap VAS) suggest convergent construct validity (170, 175, 176, 179, 187, 188, 194, 195), 832 while lower correlations with measures such as the SF-36 mental subscales indicate divergent construct validity 833 (170, 176, 187, 188, 195). Convergent validity was also demonstrated with strong correlation with the 30 second 834 chair stand and 50 foot timed walk tests (196). Although Rasch analyses have largely utilized mixed knee and hip 835 OA cohorts, it has been reported that there is no differential item functioning based on affected joint (197). 836 While 1 study found the pain subscale to demonstrate good item separation and unidimensionality in patients 837 with knee or hip OA (198), a subsequent study found that a reduced pain subscale (night pain and pain on 838 standing removed) fit the Rasch model and provided more stable results over time and between patients with 839 knee or hip OA and those who have undergone joint replacement (197). The function subscale demonstrates 840 more variability. Although found to have good item separation and unidimensionality in knee/ hip OA, function items for performing light chores, getting in/out of a car, and rising from bed were found to be redundant (198). 841 842 Similarly, Davis et al (197) suggested a 14-item function subscale, with items for heavy domestic duties, getting in/out of the bath, and getting on/off the toilet removed. There is a strong correlation with psychological 843 844 measures and total WOMAC score, indicating poor divergent validity (199). Hip abductor and knee extensor 845 strength are not correlated with WOMAC function subscale (200)

846 **Responsiveness.** The WOMAC appears to be responsive to change following surgical and nonsurgical 847 interventions for knee OA and chondral defects (Table 2, 201). A recent study has confirmed the high 848 responsiveness in patients undergoing TKR with a mean change in score of 29 at 3 months post operatively 849 (202). In particular, the physical function domain has been suggested to be the best choice for detecting changes over time compared to other measures (203). However, in patients undergoing exercise therapy, the total 850 851 WOMAC was found to be more responsive than the physical function subscale (204). In patients with knee OA, 852 large effect sizes are consistently reported on all 3 subscales up to 2 years post-TKR. This was recently confirmed 853 at one 1 year postoperatively, however the stiffness subscale has a smaller effect size than pain or function 854 (205). Furthermore, effect size decreases over time up to 2 year after TKR (190). Following exercise intervention, 855 the stiffness subscale shows small effect sizes at 2 weeks compared to moderate to large effect sizes for the pain

856 and function subscales; however, these also are small at 6 months. Acupuncture has shown small to moderate 857 effect sizes in the short term (3 weeks), but large effect sizes after 8 weeks. Drug intervention tends to show 858 different patterns across 12 weeks for the 3 subscales. Effect sizes for pain tend to be large initially (1 week), and 859 become more variable at 6 weeks (moderate to large) and 3 months (small to large). In comparison, the stiffness 860 subscale tends to show small to moderate effect sizes over the initial 4 weeks, becoming moderate to large by 3 861 months. Similarly, effect sizes for function also gradually increase, starting at moderate at 2 weeks, and 862 becoming moderate to large at 6 and 12 weeks. Following surgery for chondral defects, large effect sizes are 863 seen for pain and function 6 and 12 months postoperatively, while moderate effect sizes are seen on the 864 stiffness subscale. Using composite WOMAC outcomes by combining the subscales improves responsiveness and 865 reduces the necessary sample size (206). The reduced WOMAC has been shown to have similar responsiveness to the original WOMAC (207). 866

Minimally important differences. The minimum clinically important difference has been calculated for TKR (up to 2 years postoperatively; range for pain 22.9–36, range for symptoms 14.4–21.4, range for function 19–33) and nonsteroidal antiinflammatory use (4 weeks; function 9.1). At 3 months post operatively, the MCID was determined to be 10.21 (202). The patient-acceptable symptom state has been determined to be 31.0 (95% confidence interval 29.4–32.9) for the function subscale in people with knee OA (208). The minimum important change has also been determined for the short WOMAC, 7.9 and 9.8 points for small change, 8.4 and 9.8 points for medium change, and 12.1 and 10.1 points for large change (209).

Generalizability. The WOMAC has been mainly used for OA and TKR, however it has been used in other knee
pathologies. Due to the consistent reliability, validity, and responsiveness that is found in the literature it can be
inferred that it is generalizable to many knee conditions and many different populations.

877 Use in clinical trials. The WOMAC was used to assess efficacy of the addition of oxygen therapy to usual therapy 878 in patients experiencing a flare of knee arthritis (210). The effect of patellofemoral overstuffing on clinical 879 outcomes was also investigated with the WOMAC as the primary outcome (211). The WOMAC was a primary 880 outcome measure in a trial investigating tanezumab for hip and knee arthritis (212). It has also been used as the 881 primary outcome measure in a trial assessing the impact of change in physical activity on pain and physical 882 function (213). A trial of aqueous extract of Terminalia chebula fruit as a dietary supplement in overweight, 883 healthy adults used the modified WOMAC as a primary outcome (214). Pain progression evaluated using the 884 WOMAC was associated with radiographic and MRI evaluation of cartilage loss in symptomatic knee 885 osteoarthritis (215).

#### 886 Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. The WOMAC is one of the most commonly used patient-reported outcomes for knee OA. It is simple and quick to administer and score using guidelines provided. The utilization of patients in development ensures content validity. In addition, the WOMAC has undergone validated translations into multiple languages. The use of individual scores for each subscale, rather than an aggregate score, enhances interpretation.

Caveats and cautions. The need to obtain permission and pay licensing fees prior to use may encourage researchers and clinicians to seek alternatives. The inclusion of tasks in the function subscale that may not be performed regularly by all patients (e.g., stair climbing, taking a bath) may result in missing data. Content validity is not ensured for more physically active patients since the function scale does not include more difficult functional tasks. Rasch analysis suggests that the function subscale contains redundant items. The physical function domain has a stronger association with pain compared to performance. Patients have to recall symptoms during specific movements. There is a correlation between patient psychological status and WOMAC

898 score. Reliability and responsiveness decrease with time.

899 **Clinical usability.** The variability in administration methods makes the WOMAC a good choice for clinical use, 900 particularly when dealing with patients with communication difficulties. Minimal floor effects means that the 901 pain and function subscales are able to monitor deterioration in condition over time, while ceiling effects have 902 only been reported following TKR. However, clinicians should consider that the stiffness subscale may not be 903 sufficiently reliable for use in individuals. An additional physical function measure may be employed to ensure 904 that this construct is fully measured due to its association with pain.

905 Research usability. Psychometric testing indicates that the WOMAC is sufficiently reliable and valid for use in 906 research. The variety of validated language translations and methods of administration is a major strength for 907 WOMAC use in research. A body of research supports the responsiveness to change of the WOMAC following 908 surgical and nonsurgical interventions. Extensive use of the WOMAC in previous research facilitates comparison 909 of new findings.

# 910 ACTIVITY RATING SCALE (ARS) Descriptive

911 **Purpose.** Developed as a short, simple, knee-specific questionnaire to evaluate the activity level of patients with

various knee disorders who participate in different sports. Intended to provide data on an athlete's highest
activity level within the past year (i.e., at a time when they were most active) (216).

914 *Intended populations/conditions*. Various knee conditions, including ligament, meniscus, and chondral injury;

- 915 patellofemoral pain; osteochondritis dissecans; trabecular fracture; and iliotibial band syndrome (216).
- 916 *Version.* No modifications to the original version. This article is protected by copyright. All rights reserved

- 917 **Content.** Single index pertaining to frequency of athletic activities: 1) running, 2) cutting, 3) decelerating, and 4)
- 918 pivoting.
- 919 Number of items. 4 items.
- 920 **Response options/scale.** Each item is followed by 5 responses for the frequency of each functional component
- 921 within the past year.
- 922 Recall period for items. 1 year.
- 923 Endorsements. None.
- 924 **Examples of use.** Conditions: anterior cruciate ligament (ACL) injury, cartilage injury, and knee osteoarthritis.
- 925 Interventions: ACL reconstruction, autologous chondrocyte implantation, microfracture, high tibial osteotomy,
- 926 and total knee replacement.
- 927 Practical Application
- 928 **How to obtain.** The ARS can be found as an appendix in the original publication (216).
- 929 Method of administration. Patient-completed questionnaire, either paper or electronically administered, with
- particularly high rates of agreement for the Activity Rating Scale (ARS) (217). ARS not yet been validated for
- 931 interview administration (telephone, in person).
- 932 **Scoring.** Each item is scored from 0–4, where 0 "less than 1 time a month," 1 "one time in a month," 2 "one
- time in a week," 3 "two to three times in a week," and 4 "four or more times in a week." The total score is the
- sum of scores from responses to each of the 4 items (216). *Missing values*. No specific instructions for handlingmissing values.
- **Score interpretation.** The total possible score range is 0–16, where 16 represents more frequent participation.
- 937 *Normative values.* Not available.
- 938 **Respondent burden.** Approximately 1 minute to complete. Respondent burden was intentionally minimized
- 939 through the inclusion of only 4 items (216).
- 940 Administrative burden. Less than 5 minutes to score. No training is required.
- 941 Translations/adaptations. A Cross-cultural adaptation has been conducted for the Swedish translation (218),
- and a Persian version has been translated and validated specifically for ACL injuries (219).
- 943 **Psychometric Information**
- 944 Method of development. Items were selected by literature review, expert opinion (orthopedic surgeons who
- 945 specialized in sports medicine, physical therapists, and athletic trainers), and surveying patients with knee
- 946 disorders. Item reduction involved 50 patients with a variety of knee disorders who were physically active who
- 947 rated the importance and difficulty associated with each functional task on the preliminary list. The top 4, as
- agreed by the panel of clinicians, were retained in the final version (216).
- 949 Acceptability. Information on missing data and floor/ ceiling effects is not available.

- **Reliability.** One study has evaluated the test-retest reliability of the ARS, finding adequate reliability for use in
   groups and individuals (216) (Table 1). The internal consistency has not been reported.
- 952 Validity. Face and content validity. The use of patients with knee disorders in both item selection and reduction
  953 ensures content validity. Final item selection also involved the opinion of clinicians to ensure face validity
- 954 (216).
- 955 *Construct validity*. The ARS has been reported to have moderate to strong correlation with other knee-related 956 scales that measure activity levels, such as the Tegner Activity Score, Cincinnati Knee Ligament Score, and Daniel 957 Score, suggesting good convergent construct validity (216).
- 958 **Generalizability.** Previously, the ARS had only been validated for adult use. However, a study published in 2015
- 959 found ARS to be reliable in patients younger than the age of 18 in knee injuries, with decreasing reliability in
- 960 patients younger than 14. Test-retest data confirmed its reliability in all but 1 of the questions in the age >14<18
- 961 cohort. While the questionnaire may prove useful in this pediatric population, its usefulness may be limited by
- 962 the significant ceiling effect observed, as more than half of the patients had maximum scores of 16 (50.6%)
- 963 (220).
- Ability to detect change. The responsiveness, minimum clinically important difference, and patient-acceptable
   symptom state have not been reported (Table 2). Rasch analysis was not performed.
- 966 Critical Appraisal of Overall Value to the Rheumatology Community
- 967 Strengths. The ARS is a short simple measure that represents minimal administrator or respondent burden. As it 968 assesses 4 common components of various sporting activities, rather than nominating specific sports, it is 969 generalizable across a wide range of elite and recreational athletes. In addition, to the extent that activities such 970 as running, stopping, and changing direction are also needed for nonsport activities, it could be applicable to 971 other situations (e.g., work tasks).
- 972 Caveats and cautions. Since its focus is limited to specific activities, it is important to assess activity related 973 scales, in conjunction with questionnaires used to evaluate pain and function, as activity level may be 974 particularly important as a potential confounding variable when evaluating patient outcomes following knee 975 injuries. Often, an inverse relationship is observed when administered together. Some patients may report pain 976 and functional limitations, but are able to return to a higher level of activity. Or perhaps, the higher level of 977 activity is associated with increased pain and perceived limitations. Inversely, patients may report better 978 outcomes in pain and function, but report lower ARS scores as a result of lifestyle changes made to avoid 979 symptoms and risk of re-injury (221). Therefore, the utility of an activity rating scale is maximized as an adjunct 980 to scales that assess other domains of knee function (222).
- 981

982 Other activities such as swimming and jumping cannot be evaluated by this scale. Furthermore, since the ARS 983 does not focus on current ability, but on baseline activity frequency perhaps prior to injury, the validity of the

984 instrument depends on the subject's accurate recollection of this frequency. The accuracy of such recollection

985 may be influenced by the time since injury and by the current state of activity. Lack of evidence for

responsiveness to change/sensitivity is also a limitation. The ARS should be used as an adjunct to other kneeinstruments assessing symptoms and difficulty (216).

988 Clinical usability. The ARS is a short activity-specific questionnaire, making it good for clinical use. It would be
 989 suitable for patients who participate in land-based sports or activities that do not involve jumping as a primary
 990 movement. Clinicians should consider that the 1-year recall period may be difficult for some patients.

991 Research usability. The lack of psychometric data for the ARS limits its use in research. As the scale measures 992 the highest level of activity over the past year, without taking into account time of injury, it may be more suited 993 for within-subject study designs, rather than comparing ratings between subjects.

994

#### 995 PATIENT REPORTED OUTCOME MEASUREMENT INFORMATION SYSTEMS- PHYSICAL FUNCTION (PROMIS-PF)

996 **Description** 

Purpose. To measure self-reported capability rather than actual performance of physical activities. This includes
 the functioning of one's upper extremities (dexterity), lower extremities (walking or mobility), and central
 regions (neck, back), as well as instrumental activities of daily living, such as running errands (223).

1000 **Content.** The Patient-Reported Outcome Measurement Information Systems (PROMIS), funded by the NIH, was 1001 developed to be a tool for both clinicians and researchers to access efficient, precise, valid and responsive adult

1002 and pediatric PROMs in health and well-being. (224). This tool is unique as it is useful in various disciplines in

1003 measuring physical, mental, and social health in individuals with chronic conditions (**223**). There are multiple

1004 subscales specific to the goals of measurement and patient population. The physical function form of PROMIS

specifically measures the ability to carry out various activities that require capability, ranging from self-care to more vigorous activities of mobility, strength and endurance (**223**).

Number of items. Form 10a has 10 items. The first 5 focus on the degree to which the patient's health limits their activities: vigorous, walking, climbing stairs, carrying groceries, bending or kneeling. The second 5 focus on difficulty in carrying out ADLs: vacuuming or yard work, dressing, shampoo hair, wash and dry body, and use the toilet.

1011 **Recall period for items.** There is no specification of recall period

1012 Cost to use. The PROMIS forms are free to use in the single use forms. Integrated data collection and

1013 computerized scoring are priced independently and will vary based on chosen system and needs.

- 1014 How to Obtain. <u>https://www.assessmentcenter.net/PromisForms.aspx</u>,
- 1015 <u>http://www.healthmeasures.net/index.php?option=com\_content&view=category&layout=blog&id=71&Itemid=</u>
- 1016 <u>817</u>
- 1017 <u>Practical Application</u>
- 1018 Method of Administration. PDF forms are available as well as integrated data collection tools through
- 1019 HealthMeasures (<u>http://www.healthmeasures.net/resource-center/data-collection-tools</u>).
- 1020 Scoring. Scoring. Creators of the PROMIS intended the measurement to be scores according to response pattern
- 1021 scoring with item-level calibrations using the Health Measures Scoring Service
- 1022 (33TU33TUhttps://www.assessmentcenter.net/ac\_scoringservice). However, there is also a table to be used.
- 1023 Each question has five response options, Likert, ranging 1-5. A score of 5 is equivalent to no limitation or
- 1024 difficulty and a score of 1 is equivalent to being unable to complete.
- 1025 **Scoring Interpretation.** The raw score ranges 10-50 and the scaled score ranges from 13.5 to 61.9. With 50 or
- 1026 61.9 representing optimal physical function. The T-score rescales the raw score into a standardized score with a
- mean of 50 and a standard deviation (SD) of 10. Therefore, a person with a T-score of 40 is one SD below the
- 1028 mean.
- 1029 Respondent time to complete. 5 Minutes
- Administrative Burden. Multiple integrative data options for all the PROMIS measures exist that would alleviate
   any significant administrative burden, but come with variable price points. However, it takes about 3-5 minutes
   to score manually on the single use PDFs.
- 1033 **Translations and adaptations.** PROMIS physical function 10a is available in the following languages: English,
- 1034 Spanish, Danish, Dutch, French, German, Hungarian, Italian, Polish, Russian, Simplified Chinese (Mandarin),
- 1035 Traditional Chinese, and Ukranian.
- 1036

#### 1037 Psychometric Information

Floor and ceiling effects. Studies have shown no floor or ceiling effects with meniscal injuries, patellofemoral
 malalignment, multi-ligamentous injuries, and chondral disease (225, 226, 228). In a study of 204 patients,

- 1040 PROMIS-PF was found to have no floor effect, while one patient scored the highest possible score (227). When
- 1041 compared to the KOOS-ADL, KOOS- sport and SF-36 PF, the PROMIS-PF had the lowest ceiling effect of the
- instruments with 1.4% at 6 months and 9.0% at 2 years in patients with ACL injuries, well below the 15% cutoff(229).
- 1044 Reliability. Few studies have demonstrated reliability in the PROMIS-PF form. One study showed high reliability
   1045 in patients with rheumatoid arthritis (230). Hung and colleagues, when attempting to validate the lower

1046 extremity physical function computer adaptive test based on PROMIS PF items found the items to demonstrate1047 high reliability (231).

Validity. Hung and colleagues, when attempting to validate the lower extremity physical function computer 1048 1049 adaptive test based on PROMIS PF items, found the item bank to be unidimensional and free of item bias with high content and construct validity (231). Another study by the same group showed adequate face validity as 1050 1051 well as construct validity (232). Good construct validity of the PROMIS-PF form in patients with rheumatoid 1052 arthritis has also been shown (230, 233). Content validity was further shown in patients with patients with 1053 Tenosynovial Giant Cell Tumors of the knee (234). Strong validity of comparisons for the PROMIS-PF items was shown in patients with different musculoskeletal disorders namely chronic pain, rheumatoid arthritis and 1054 1055 osteoarthritis and there is high correlation with SF-36 scores (227, 235). Good convergence has been found

1056 between the PROMIS-PF, KOOS and IKDC scales (236).

1057 Responsiveness. The PROMIS assessments collectively have been shown to be very responsive to change (237).
1058 When compared to the KOOS-ADL, KOOS- sport and SF-36 PF, the PROMIS-PF showed equal responsiveness and
1059 excellent utility in the postoperative ACL course (229). The PROMIS-PF was specifically found to have high
1060 responsiveness to patients with OA, while pain, depression and anxiety PROMIS forms only have moderate
1061 responsiveness (238). It has also been shown to compare well with disease specific scales in regards to knee
1062 arthroscopy patients (236).

# 1063 Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. The PROMIS-PF can be used not only for a variety of conditions in the knee, but also a variety of musculoskeletal and rheumatologically conditions. Further, with regards to the knee, it is comparable in psychometric properties to disease-specific scales. There is low burden to the patient as well as low administrative burden. There are also a lot of resources available to integrate scoring and maintaining data.

Caveats and cautions. PROMIS has multiple subscales and forms that can be used. It is important to use the best
 subscale for a given need. Psychometric properties have not been assessed for all knee conditions and the
 PROMIS-PF score was not developed specifically to knee conditions.

1071 Clinical Usability. The PROMIS-PF is easy to use and has low respondent burden and administrative burden. It1072 can be used for many conditions.

1073 Research Usability. Easy to use in the research setting and has been shown to be comparable to other scales
 1074 that are specific to knee conditions. May allow for comparing similarities in physical function changes between
 1075 patients of varying conditions.

1076

#### 1077 SUMMARY / RECOMMENDATIONS

1078 We reviewed nine of instruments that have been developed to measure patient reported knee function and one 1079 measure that has been used for overall physical function, but has been adequately tested for assessment of 1080 knee related conditions. Since the last review of some of these knee measures was published in 2011, there has 1081 been an enormous body of research evaluating their psychometric properties in patients with varying knee 1082 conditions. Further, many tools have also been cross-culturally translated into multiple languages and adapted 1083 where needed. While other measures may be useful (e.g., 239), this extensive review provides researchers with 1084 the necessary information for the nine most commonly used instruments in trials in the last 10 years as well as 1085 information for the PROMIS Physical Function. When seeking to use knee measures it might be useful to refer to 1086 core outcome sets or minimum standard sets of outcomes (e.g, 240).

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1090	REFERENCES	σ

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# Table 1: Practical applications

	<b>-</b>	•			_	/			<b>•</b> • • •
	Number	Content/	Method of		Response	Range of	Score	Availability of	Cross-cultural
Measure	of items	Domains	administration	Recall period	format	scores	interpretation	normative data	validation
									Chinese,
	()								Greek,
									Icelandic,
	U)								Spanish,
									Dutch, French,
									Saudi Arabic,
									Japanese,
Knee Injury		5: pain,		Previous					Persian,
and		symptoms,		week for all				Population	Portuguese,
Osteoarthritis		ADIs,	Patient	except QoL,			0= worse,	based	Russian,
Outcome		recreation,	completed	no	5 point		100= no	normative data	English, Thai,
Score	42	QoL	questionnaire	specification.	Likert, 0-4	0-100	problems	available	Turkish.
									Specific
	$\mathbf{O}$								adaptation is
Knee Injury									found in
and									French,
Osteoarthritis									Portuguese
Outcome								Population	and Turkish
Score-			Patient					based	although
Physical		Single	completed	Previous	5 point		28 = no	normative data	KOOS has
Function	7	Domain	questionnaire	week	Likert, 0-4	0-28	problems	available	been validated

									as a whole by
									more.
									Arabic,
_									Portuguese,
-				Not specified					Chinese,
International				for some, 4					Danish, Dutch,
Knee				weeks for					German,
Documentation	<b>S</b>			some	Yes/no;				Greek, Italian,
Committee		3:Symptoms,		questions,	Likert 5				Korean,
Subjective		sports and	Patient	and function	point			Available from	Romanian,
Knee		ADLs, knee	completed	before and	scale; 11		100 is no	the general US	Thai, and
Evaluation	18	function	questionnaire	after surgery	point scale	0-100	limitation	population	Turkish
	U					Each item			
						has been			
						assigned			
		Categories				an			
		of limping,				arbitrary			
	$\bigcirc$	support,				score on			
		locking,			Individual	an			
		instability,			items are	increasing	Possible		
		pain,			scored	scale.	score range:	Normative data	Arabic,
		swelling,			differently,	The total	0–100,	are available	Chinese,
		stair			using	score is	where 100 =	with and	Dutch, Italian,
Lysholm Knee		climbing,	Patient		individual	the sum	no	without	German,
Scoring Scale		and	completed		scoring	of each	symptoms or	stratification by	Turkish and
(LKS)	8	squatting.	questionnaire	Not specified	scales.	response,	disability.	sex.	Spanish

					of a			
					possible			
					score of			
					100.			
	Graduated							
	list of							
$\overline{\mathbf{O}}$	activities of							
	daily living,					Possible		
()	recreation,					score range:		
	and					0–10. Higher		
	competitive					scores		
	sports that					represent	Normative data	Swedish,
	described			One item		participation	have been	Dutch,
	their current	Patient		is selected		in higher-	presented by	German,
Tegner Activity	level of	completed	Current	from a list		level	sex and age	Chinese, and
Score (TAS) 11	activity.	questionnaire	ability	of 11.	0-10	activities.	group.	Iranian
				Each item				
				is followed				
$\mathbf{O}$				by 5				
				responses		Possible		
				for the		score range:		
				frequency		0–16, where		
	Single index			of each		16		
	pertaining to			functional		represents		
	frequency of	Patient		component		more		
Activity Rating	athletic	completed	1-year recall	within the		frequent		Swedish and
Scale (ARS) 4	activities.	questionnaire	period	past year.	0-4	participation.	Not available.	Iranian

									Arabic,
									Chinese,
									Finnish,
									German,
_									Japanese,
		Single index;							Korean,
	$\overline{\mathbf{O}}$	can be							Persian,
		separated			5 point		Higher		Portuguese,
	<b>(</b> )	into pain and	Patient		Likert; 1 is		scores		Spanish,
Oxford Knee		function	completed	Previous 4	best and 5		reflect poor		Swedish, Thai,
Score	12	subscales	questionnaire	weeks	is worst	12-60	outcomes	No	Turkish
							Higher		
		Single index;			Descriptive		scores		Arabic,
_		2 sections			response		reflect less		Chinese,
Knee Outcome		pertaining to			translated		knee-related		French,
Survey		symptoms			to		symptoms		German,
Activities of		and	Patient		numerical		and less		Portuguese,
Daily Living		functional	completed		ordinal		functional		Polish, Turkish
Scale	17	limitations	questionnaire	1-2 days	scale	0-100	limitations	No	Greek
		Three	Self-		Likert	Likert			Arabic,
		subscales;	administered		version 0-	format 0-	Higher		Bangladesh,
Western		pain severity	or interview		4. VAS	20 pain,	scores		Chinese,
Ontario and		during	administered		and	0-8	indicate	Yes, for	Finnish,
McMaster		various	questionnaire;		numerical	stiffness,	worse pain,	Australian	German,
Universities		positions or	in person,		rating	0-68	stiffness or	population,	Greek,
Osteoarthritis	7	movements,	over the		scale	physical	physical	stratified by	Hebrew,
Index	24	severity of	telephone, or	48 hours	versions	function.	function	age and sex	Italian,

	joint	electronically		with 0-100	VAS			Japanese,
	stiffness,	via computer		or 11 box	format			Korean,
السباب	and difficulty	or mobile		scale	pain 0-			Moroccan,
	performing	phone			500,			Nepali,
	functional				stiffness			Persian,
	activities				0-200,			Portuguese,
$\overline{\mathbf{O}}$					physical			Singapore,
					function			Spanish,
()					0-1700			Swedish, Thai,
								Turkish
						50 or 61.9		
						representing		
						optimal		
()						function. T-		
						score		
Ma						rescales the		English,
						raw score		Spanish,
Patient		Patient			Raw	into a		Danish, Dutch,
Reported		completed			score	standardized		French,
Outcome	5 questions	questionnaire.			ranges	score w/		German,
Measurement	on limitation	Paper format,			10-50.	mean of 50		Hungarian,
Information	of activities,	computer			Scaled	and a		Italian, Polish,
Systems-	5 questions	adaptive		Likert	score	standard		Russian,
Physical	on difficulty	testing	No specific	scoring	13.5 to	deviation of		Chinese,
Function 10	of ADLs.	options	recall period	from 1-5	61.9.	10.	Yes	Ukranian.

# Table 2: Psychometrics

					Minimally		
					important		
	Floor, ceiling				differences		
Measure	effects	Reliability	Validity	Responsiveness	(MCID)	Generalizability	Used in RCTs
						May be useful	
	()					for a variety of	
						conditions and	
	0)					populations, but	
						its intent was	
	Little or no					OA focused and	
	floor or ceiling					results may be	
	effects for					less than	
	knee injury or					optimum in	
	mod. OA.		Good content			other conditions.	
Knee Injury	Floor effects		and face validity,		MCID and	Recreational	
and	for severe OA	Adequate internal	superior	Very responsive	moderate	subscale may	
Osteoarthrit	is and ceiling	consistency,	convergent and	to change for OA.	improvement	not be	
Outcome	effects	adequate test-	divergent	Limited research	is 8.0 and	appropriate for	
Score	following TKA	retest reliability	construct validity,	for other injuries.	15.6 for QoL	some groups	Yes
Knee Injury		Adequate internal	Assume good			Use was	
and		consistency,	content and face		Only one	intended for	
Osteoarthrit	is	adequate test-	validity since		study showed	knee OA and	
Outcome	None found in	retest reliability in	items taken from		MCID for non-	studies largely	
Score-	1 study of	mild to moderate	KOOS.	Moderate to large	op OA to be	focus on this	
Physical	knee OA	OA. May be less	Convergent and	effect sizes	12	without many	Yes

Function		adequate for	divergent			studies on other	
		severe OA	construct validity,			conditions.	
_			good correlation				
			with physical				
_			domains of other				
=			measures.				
	$\overline{\mathbf{O}}$	Superior reliability				Generalizable to	
		over other				most	
	C)	measurements				populations	
I	_	have been shown.	No patient			including	
International		Adequate internal	contribution	Adequate		pediatric	
Knee		consistency,	weakens content	response to		population.	
Documentation		adequate test-	validity. Good	change.	Has been	Strongest	
Committee		retest reliability for	face validity.	Particularly in	shown to be	psychometric	
Subjective		knee injuries and	High convergent	injuries as well as	anywhere	properties in	
Knee		some mixed	and divergent	the pediatric	from 8.8 to	injury related	
Evaluation	None	pathologies.	construct validity.	population.	15.6	conditions.	Yes
		Test-retest	The Lysholm	When comparing			
	$\bigcirc$	reliability is	scale has been	responsiveness			
	Č	adequate for use	reported as	following			
		in groups with	having face	autologous			
-		knee injuries, but	validity, content	chondrocyte			
		is less than	validity from the	implantation	The MCID has		
		adequate for	patient's	(ACI),The	not been		
Lysholm Knee	Little to no	groups with mixed	perspective	Lysholm and	calculated in	Generalizability	
Scoring Scale	floor or ceiling	knee pathologies.	cannot be	IKDC were the	any patient	has not been	
(LKS)	effects.	Reliability may be	assumed. Two	most sensitive to	population.	reported.	Yes

	inadequate for use	studies have	detecting			
	in individuals.	reported	changes when			
		evidence of	compared with			
		convergent and	MCKRS, KOOS,			
		divergent	and SF-36.			
		construct				
		validity.				
	The TAS has	Content validity				
S	adequate test-	cannot be				
	retest reliability for	assumed, but			The Tegner	
Information	groups with knee	evidence for			Score was	
on missing	injuries and knee	convergent and			found to be	
data and	OA, although	divergent			reliable in both	
floor/ceiling	reliability is less	construct validity		The MCID has	adult and	
Tegner Activity effects is not	than adequate for	has been	Has not been	not been	pediatric	
Score (TAS) available.	use in individuals.	provided.	reported.	determined.	population.	Yes
	One study has					
Studies	evaluated the test-					
consistently	retest reliability of					
report no floor	the ARS, finding				ARS was found	
or ceiling	adequate reliability	Face, construct,			to be reliable in	
effects in	for use in groups	and content			both adult and	
those with	and individuals.	validity have			pediatric	
Activity Rating knee injury or	Also reliable in	been	Has not been	MCID has not	population ages	
Scale (ARS) OA.	patients 14-18.	demonstrated.	reported.	been reported.	14-18.	No

	Nama with t		Operatorial - Poly				
	None prior to		Content validity;				
	TKR; ceiling		internal and	Good sensitivity	MDC90 and		
-	effect		external validitiy	and	MIC after		
	increases		post-operatively;	responsiveness	TKR: 4.15 and	Useful in OA	
	post-		correlates well	to change; large	9.22; non-op	before and after	
_	operatively;	Adequate internal	with other knee-	ES post-op;	knee OA MIC:	TKR; likely	
	controversial	consistency,	specific and	predicts revision	total 7.1, pain	applicable to	
Oxford knee	post-op floor	adequate test-	general health	TKR and range of	17.3, function	multiple knee	
score	effect	retest reliability	questionnaires	motion after TKR	10.6	conditions	No
	5		Good face				
1			validity, may lack	Good			
			content validity;	responsiveness			
			correlates well	for a variety of			
Knee Outcome	No floor		with other knee-	knee pathologies			
Survey	effects;	Adequate internal	specific scales;	in various stages	MCID after PT		
Activities of	ceiling effects	consistency and	convergent and	of treatment, but	for knee OA:	Useful for a	
Daily Living	present after	test-retest	divergent	may decrease	2.2 at 2 mo, 5	variety of knee	
Scale	TKR	reliability	construct validity	over time	at 12mo	pathologies	No
	Floor and	Stiffness and	Has face and	High			
	ceiling effects	function subscales	content validity;	responsiveness			
	exist for the	have adequate	Good construct	in knee OA and			
Western	stiffness	internal	validity due to	chondral defects	MCID after		
	subscale pre	consistency, may	strong	post-op; large ES	TKR: for pain	Useful in OA	
Ontario and					00 0 00	and TKD, likely	
1	and post-op	lower than	correlations with	all subscales	22.9-36,	and TKR; likely	
McMaster		lower than adequate for pain	correlations with other measures,	all subscales post-op, smaller	22.9-36, symptoms	applicable to	
Ontario and McMaster Universities Osteoarthritis	and post-op				,		

	subscales	retest reliability for		knee OA and			
		all subscales		chondral defects			
٦	None for						
	meniscal						
	injuries,						
	patellofemoral						
	malalignment,			PROMIS	MCID has not		
	multi-			assessments	been fully	Can be use	
	ligamentous			collectively have	determined for	among a variety	
Patient	injuries and			been shown to be	knee specific	of conditions,	
Reported	chondral			responsive.	conditions.	but measure is	
Outcome	disease.		Unidimensional	PROMIS-PF	One study	not specific to	
Measurement	Ceiling effects	Few studies have	with high content	compared to	showed 2.45	the knee and	
Information	noted in ACL	demonstrated	and construct	KOOS, SF-36 in	to 21.55 in	further	
Systems-	injuries, but	reliability although	validity.	ACLs. High	orthopaedic	psychometric	
Physical	below 15%	one showed high	Adequate face	responsiveness	patients w/	analysis is	
Function	cutoff.	reliability in RA	validity.	in OA.	OA.	necessary.	Yes