Patient questionnaires in osteoarthritis: what patients teach doctors about their osteoarthritis on a multidimensional health assessment questionnaire (MDHAQ) in clinical trials and clinical care

T. Pincus, J. Schmukler, I. Castrejon

Department of Internal Medicine, Division of Rheumatology, Rush University Medical Center, Chicago, IL, USA.

Theodore Pincus MD
Juan Schmukler
Isabel Castrejon MD, PhD

Please address correspondence to: Dr Theodore Pincus, Division of Rheumatology, Rush University Medical Center, 1611 West Harrison Street, Suite 510, Chicago, IL 60612, USA.
E-mail: tedpincus@gmail.com

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ABSTRACT

A patient history generally provides the most important information in diagnosis and management of patients with most rheumatic diseases, including osteoarthritis (OA). Patient history components can be expressed as quantitative, structured, "scientific" data, rather than "subjective" narrative descriptions, using patient self-report questionnaires. The Western Ontario McMaster (WOMAC) questionnaire is used in all OA clinical trials, and the health assessment questionnaire (HAQ) in all rheumatoid arthritis (RA) clinical trials, as "disease-specific" questionnaires. However, both questionnaires include scores for physical function function and pain; physical function scores are correlated highly significantly at r=0.78 in both RA and OA patients, while WOMAC pain scores are correlated with HAQ visual analogue scale (VAS) pain scores at r=0.73 in OA and r=0.71 in RA. Therefore, the WOMAC and HAQ may be regarded as largely "generic" questionnaires, at least for people with arthritis. Since it is not feasible to ask patients with different diagnoses to complete different care questionnaires in busy clinical settings, a single multidimensional HAQ (MDHAQ), derived from the HAQ and largely similar and informative in all rheumatic diseases, has been used in all rheumatology patients in several settings. The MDHAQ also has been incorporated into two OA clinical trials, with virtually identical results to the WOMAC. In routine clinical care, MDHAQ scores have documented that the disease burden of OA is comparable to RA in terms of scores for pain, physical function, and RAPID3 (routine assessment of patient index data) an index of pain, function and patient global assessment. Further observations indicate capacity of the MDHAQ to recognise fibromyalgia similarly to formal fibromyalgia criteria, as well as the ineffectiveness of opioids in OA, and similar prevalence of depression and other psychological issues in OA to RA. These findings also illustrate the value of a database of MDHAQ data for retrospective analysis of serendipitous observations from routine clinical care.

Introduction

A patient history generally provides the most important information in diagnosis and management of patients with most rheumatic diseases. In a survey of 313 physicians (154 rheumatologists and 159 primary care physicians), rheumatoid arthritis (RA) was the only disease among 8 for which a patient history among 5 elements of a clinical encounter – the others were vital signs, physical examination, laboratory tests, and ancillary studies – was noted to account for 50% of clinical decisions in diagnosis and management (1). [Hypertension was dominated by vital signs, diabetes and hyperlipidaemia by laboratory tests, and pulmonary fibrosis, ulcerative colitis, congestive heart failure and lymphoma by ancillary studies (1)].

Osteoarthritis (OA) was not included in the physician survey (1). Nonetheless, patient history information may be even more prominent in the management of OA than of RA for at least 2 reasons: a) Most people develop radiographic OA with aging, which often is asymptomatic (2) or not explanatory of patients symptoms, as seen with radiographic changes in the cervical spine in patients with fibromyalgia. b) No biomarker has been shown to be informative in routine patient management of OA (3), while biomarkers are of value in management of some patients with

RA. Of course, biomarkers clearly are required to better understand pathogenesis and develop new treatments for all rheumatic (and other) diseases, but are quite limited at this time to recognise clinical improvement or worsening in OA (3) [and overrated in RA (4, 5)].

The patient history traditionally has been regarded as "subjective," and less informative than physician-generated and high-technology "objective" data (6). However, patient history information may be transformed from narrative descriptions to quantitative, protocol-driven data as scores on patient self-report questionnaires (7, 8). This process applies the "scientific method," the basis for modern medical care, to components of the patient history. Patient self-report questionnaire scores provide "scientific" data, similar to laboratory tests, but as informative and often more informative for clinical decisions in diagnosis and management (1, 7).

Patient self-report questionnaire physical function scores and comorbidities are significant prognostic variables for mortality in OA (9), as in RA (10), reflecting clinical similarities of OA and RA (11-13), as discussed in detail in another article in this supplement (13). Poor physical function scores are as significant as smoking to predict premature mortality in an elderly normal population (14). Improvement of physical function may be regarded as an important public health agenda, more amenable to change than smoking cessation and weight control, for which the rheumatology community may be an important source of information and advocacy.

Many patient questionnaires have been developed over the last 30 years initially as "disease-specific" instruments for assessment of RA, OA, and other conditions. The health assessment questionnaire (HAQ) was developed to assess RA (15) and the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire was developed to assess OA (16) as disease-specific questionnaires. Both questionnaires include 2 scores for physical function and pain among 3 measures; the third score is a patient global assessment on the HAQ and stiffness on the WOMAC. The WOMAC has been incorporated into most OA clinical trials and clinical research, and the HAQ into most RA clinical trials and clinical research over the last 3 decades.

Although developed as "disease-specific" patient questionnaires, scores for WOMAC function and HAQ function are correlated highly significantly at r=0.78 in both RA and OA patients, and WOMAC pain scores with HAQ visual analogue scale (VAS) pain scores at r=0.73 in OA and r=0.71 in RA (17). These correlations are quite high for any two clinical measures [for reference, a correlation of erythrocyte sedimentation rate (ESR) with C-reactive protein (CRP), two biomarkers that are often used interchangeably in RA clinical trials is 0.50 (18)]. The data indicate "generic" properties of the WOMAC and HAQ in patients with many rheumatic diseases (19), a property that appears to apply to derivatives of the HAQ, such as HAQii (20) and multidimensional HAQ (MDHAQ) (21-23) (which are largely identical to the HAQ other than some physical function items). Furthermore, the results of two OA clinical trials indicate virtually identical results according to the MDHAQ and WOMAC (24, 25). The MDHAQ, as well as the HAQ, appears informative in all rheumatic diseases in which it has been studied (23, 26-29), including in OA (13).

This review presents 3 sections: a) A summary of 3 patient questionnaires used in OA research, the WOMAC, used in all OA clinical trials and most OA clinical research, as well as the HAQ, used in all RA clinical trials and most RA clinical research, and MDHAQ, used in routine care for most reported evidence that disease burden in OA is similar in OA and RA (11, 12, 29). b) Data from clinical trials which illustrate the value of the MDHAQ to assess and monitor patients with OA (24-26). c) Some further applications of the MDHAQ in routine care to recognise similar burden of disease in OA and RA (11-13), clues to fibromyalgia (30), the relative ineffectiveness of opioids in OA (31), and similar prevalence of depression and other psychological issues in OA and RA (21).

I. Self-report questionnaires widely-used in clinical trials, clinical research and clinical care of patients with OA

A brief description of questionnaires which have been used in clinical trials, clinical research, and clinical care of patients with OA, the WOMAC, HAQ, and MDHAQ, is presented below (Figs. 1-3, Table I):

a. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

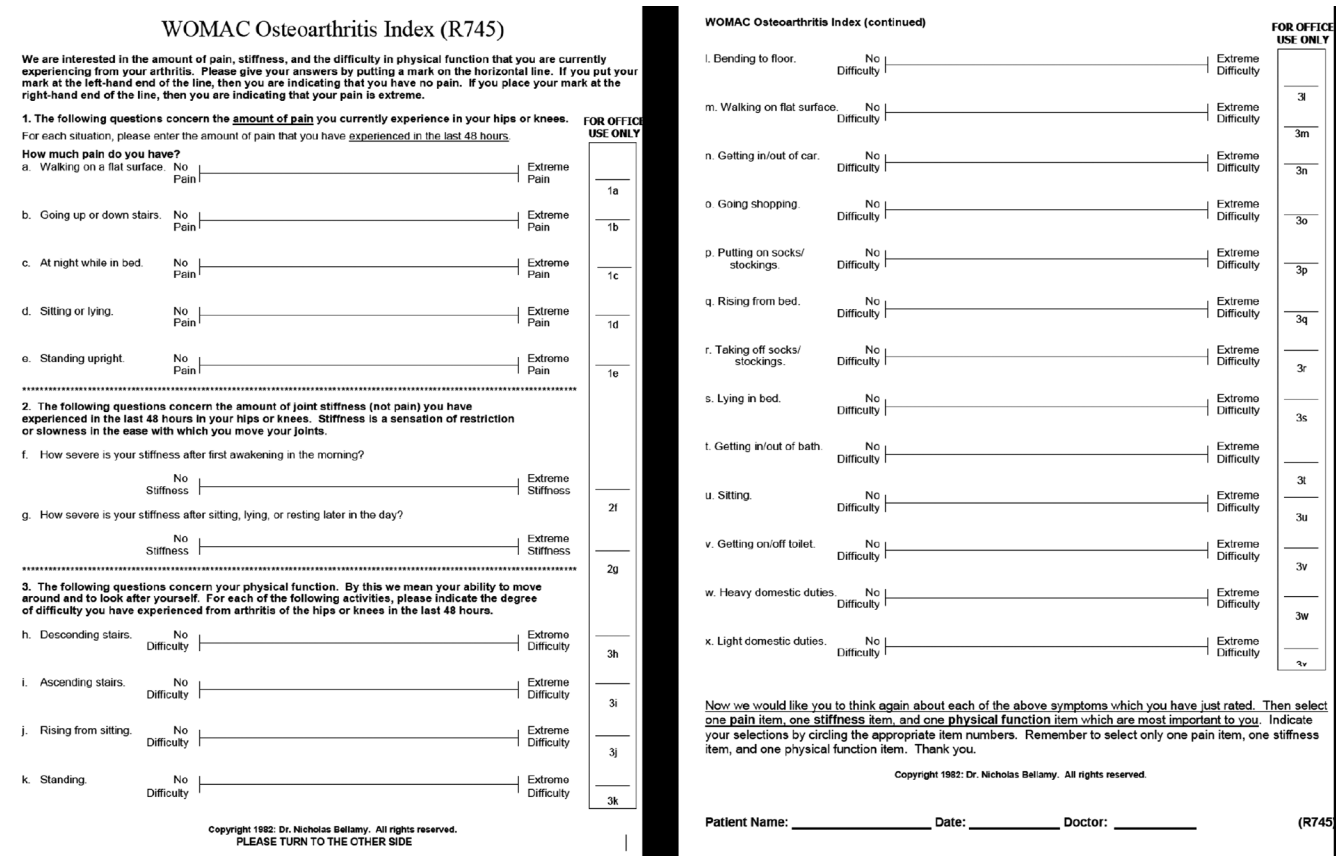
The WOMAC (16) (Fig. 1, Table I) was reported in 1988 and has become the "gold standard" for assessment of patients with OA. The WOMAC scores 3 dimensions: pain, stiffness, and physical function with 5, 2, and 17 queries, respectively. A Likert version of the WOMAC is rated on an ordinal scale of 0 to 4, with lower scores indicating lower levels of symptoms or physical disability. Each subscale is summated to a maximum score of 20, 8, and 68, respectively.

An index score or global score may be calculated by summing the scores for the 3 subscales. A visual analogue scale (VAS) version of the WOMAC is also available, as in Figure 1. The questionnaire is self-administered, requires about 5 to 10 minutes to complete, and has been translated into many languages.

b. The health assessment questionnaire (HAQ)

The health assessment questionnaire (HAQ) (15) (Fig. 2, Table I) was reported in 1980, and has been incorporated into almost all clinical trials and most clinical research in RA over the last 3 decades. The HAQ physical function scale includes 20 activities of daily living (ADL), grouped into 8 categories of 2 or 3 each, scored on a 0–3 scale (0 = without any difficulty, 1 = with some difficulty, 2 = with much difficulty, 3 = unable to do). The physical function score is the mean 0-3 score of the highest ADL score for each of the 8 categories, termed the HAQ disability index (HAQ-DI).

The short, or 2-page HAQ comprises only the HAQ-DI and two 0–10 cm visual analogue scales (VAS) for pain and



WOMAC Osteoarthritis Index (R745)

We are interested in the amount of pain, stiffness, and the difficulty in physical function that you are currently experiencing from your arthritis. Please give your answers by putting a mark on the horizontal line. If you put your mark at the left-hand end of the line, then you are indicating that you have no pain. If you place your mark at the right-hand end of the line, then you are indicating that your pain is extreme.

1. The following questions concern the amount of pain you currently experience in your hips or knees.
For each situation, please enter the amount of pain that you have experienced in the last 48 hours.

How much pain do you have?

a. Walking on a flat surface. No Pain — Extreme Pain — 1a
b. Going up or down stairs. No Pain — Extreme Pain — 1b
c. At night while in bed. No Pain — Extreme Pain — 1c
d. Sitting or lying. No Pain — Extreme Pain — 1d
e. Standing upright. No Pain — Extreme Pain — 1e

2. The following questions concern the amount of joint stiffness (not pain) you have experienced in the last 48 hours in your hips or knees. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

f. How severe is your stiffness after first awakening in the morning? No Stiffness — Extreme Stiffness — 2f
g. How severe is your stiffness after sitting, lying, or resting later in the day? No Stiffness — Extreme Stiffness — 2g

3. The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced from arthritis of the hips or knees in the last 48 hours.

h. Descending stairs. No Difficulty — Extreme Difficulty — 3h
i. Ascending stairs. No Difficulty — Extreme Difficulty — 3i
j. Rising from sitting. No Difficulty — Extreme Difficulty — 3j
k. Standing. No Difficulty — Extreme Difficulty — 3k

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WOMAC Osteoarthritis Index (continued)

l. Bending to floor. No Difficulty — Extreme Difficulty — 3l
m. Walking on flat surface. No Difficulty — Extreme Difficulty — 3m
n. Getting in/out of car. No Difficulty — Extreme Difficulty — 3n
o. Going shopping. No Difficulty — Extreme Difficulty — 3o
p. Putting on socks/ stockings. No Difficulty — Extreme Difficulty — 3p
q. Rising from bed. No Difficulty — Extreme Difficulty — 3q
r. Taking off socks/ stockings. No Difficulty — Extreme Difficulty — 3r
s. Lying in bed. No Difficulty — Extreme Difficulty — 3s
t. Getting in/out of bath. No Difficulty — Extreme Difficulty — 3t
u. Sitting. No Difficulty — Extreme Difficulty — 3u
v. Getting on/off toilet. No Difficulty — Extreme Difficulty — 3v
w. Heavy domestic duties. No Difficulty — Extreme Difficulty — 3w
x. Light domestic duties. No Difficulty — Extreme Difficulty — 3x

Now we would like you to think again about each of the above symptoms which you have just rated. Then select one **pain** item, one **stiffness** item, and one **physical function** item which are most important to you. Indicate your selections by circling the appropriate item numbers. Remember to select only one pain item, one stiffness item, and one physical function item. Thank you.

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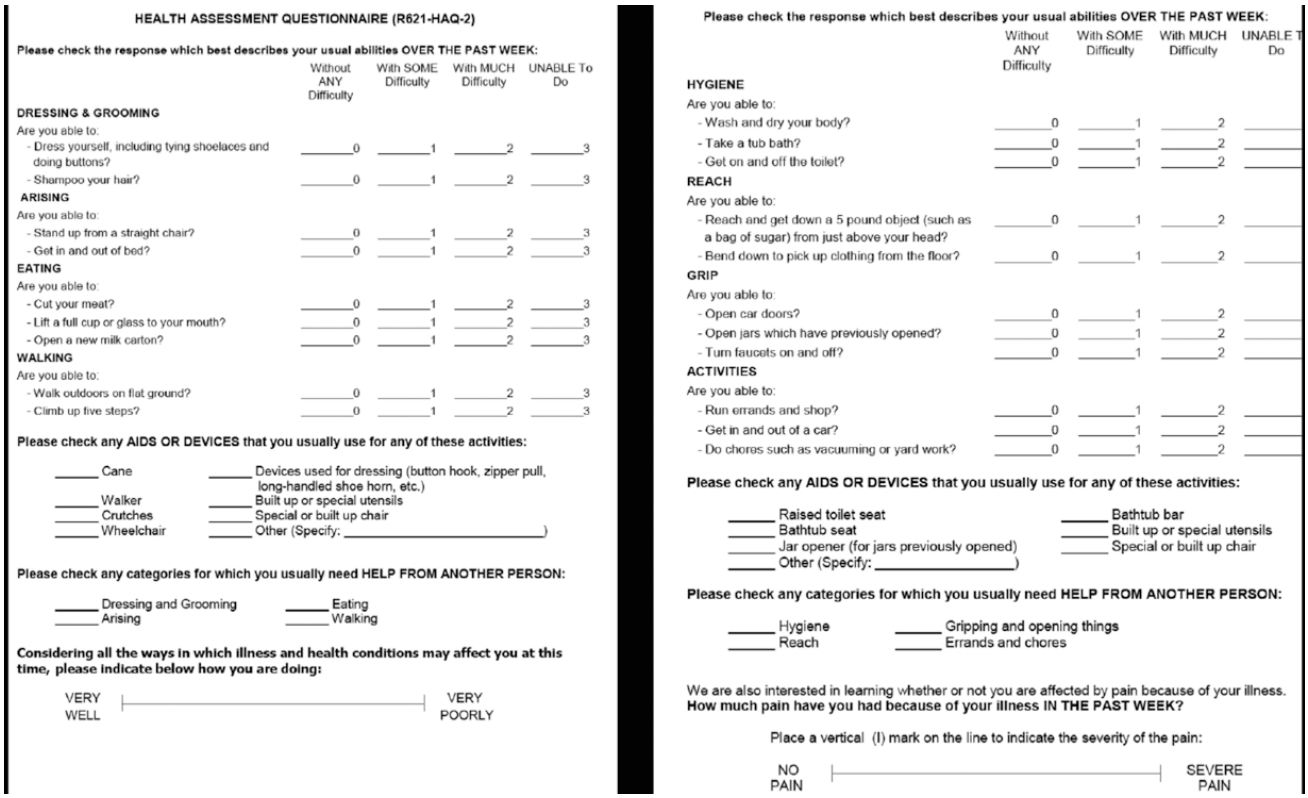
Patient Name: _____ Date: _____ Doctor: _____ (R745)

Fig. 1. WOMAC osteoarthritis index used in all clinical trials in patients with osteoarthritis.
Source: ref. (16) Bellamy *et al*.: Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee.
WOMAC queries may be presented to patients as a Lickert scale or visual analogue scale (VAS). This version involves VAS.



HEALTH ASSESSMENT QUESTIONNAIRE (R621-HAQ-2)

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	UNABLE To Do
DRESSING & GROOMING				
Are you able to:				
- Dress yourself, including tying shoelaces and doing buttons?	0	1	2	3
- Shampoo your hair?	0	1	2	3
ARISING				
Are you able to:				
- Stand up from a straight chair?	0	1	2	3
- Get in and out of bed?	0	1	2	3
EATING				
Are you able to:				
- Cut your meat?	0	1	2	3
- Lift a full cup or glass to your mouth?	0	1	2	3
- Open a new milk carton?	0	1	2	3
WALKING				
Are you able to:				
- Walk outdoors on flat ground?	0	1	2	3
- Climb up five steps?	0	1	2	3

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Cane
_____ Walker
_____ Crutches
_____ Wheelchair
_____ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
_____ Built up or special utensils
_____ Special or built up chair
_____ Other (Specify: _____)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

_____ Dressing and Grooming
_____ Arising
_____ Eating
_____ Walking

Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL — VERY POORLY

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	UNABLE T Do
HYGIENE				
Are you able to:				
- Wash and dry your body?	0	1	2	
- Take a tub bath?	0	1	2	
- Get on and off the toilet?	0	1	2	
REACH				
Are you able to:				
- Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?	0	1	2	
- Bend down to pick up clothing from the floor?	0	1	2	
GRIP				
Are you able to:				
- Open car doors?	0	1	2	
- Open jars which have previously opened?	0	1	2	
- Turn faucets on and off?	0	1	2	
ACTIVITIES				
Are you able to:				
- Run errands and shop?	0	1	2	
- Get in and out of a car?	0	1	2	
- Do chores such as vacuuming or yard work?	0	1	2	

Please check any AIDS OR DEVICES that you usually use for any of these activities:

_____ Raised toilet seat
_____ Bathtub seat
_____ Jar opener (for jars previously opened)
_____ Other (Specify: _____)
_____ Bathtub bar
_____ Built up or special utensils
_____ Special or built up chair

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

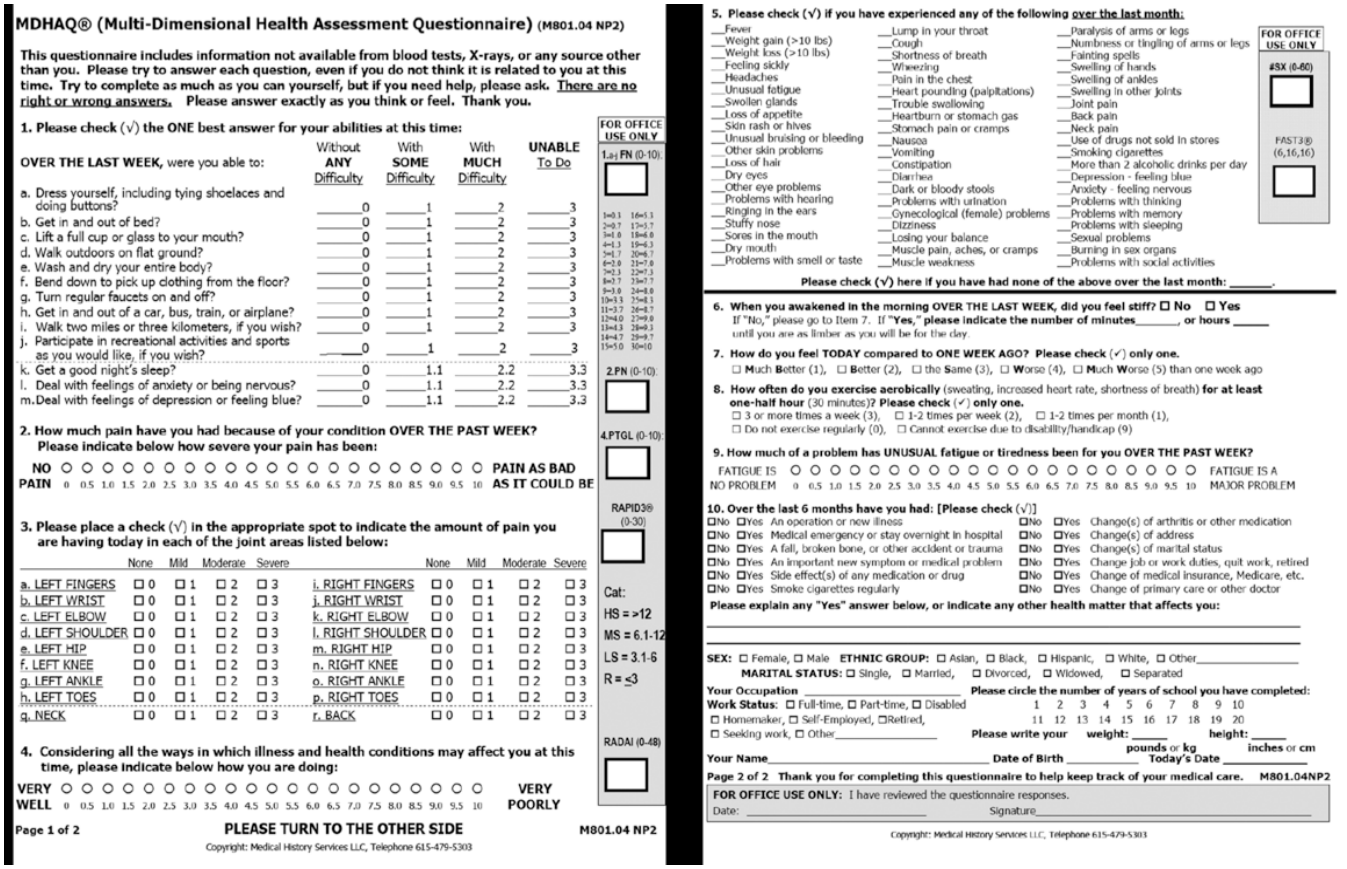
_____ Hygiene
_____ Reach
_____ Gripping and opening things
_____ Errands and chores

We are also interested in learning whether or not you are affected by pain because of your illness. How much pain have you had because of your illness IN THE PAST WEEK?

Place a vertical (I) mark on the line to indicate the severity of the pain:

NO PAIN — SEVERE PAIN

Fig. 2. Health Assessment Questionnaire (HAQ). Source: ref. (15) Fries *et al*.: Measurement of patient outcome in arthritis.



MDHAQ® (Multi-Dimensional Health Assessment Questionnaire) (M801.04 NP2)

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

1. Please check (√) the ONE best answer for your abilities at this time:

OVER THE LAST WEEK, were you able to:	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	UNABLE To Do
a. Dress yourself, including tying shoelaces and doing buttons?	0	1	2	3
b. Get in and out of bed?	0	1	2	3
c. Lift a full cup or glass to your mouth?	0	1	2	3
d. Walk outdoors on flat ground?	0	1	2	3
e. Wash and dry your entire body?	0	1	2	3
f. Bend down to pick up clothing from the floor?	0	1	2	3
g. Turn regular faucets on and off?	0	1	2	3
h. Get in and out of a car, bus, train, or airplane?	0	1	2	3
i. Walk two miles or three kilometers, if you wish?	0	1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	0	1	2	3
k. Get a good night's sleep?	0	1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	0	1.1	2.2	3.3
m. Deal with feelings of depression or feeling blue?	0	1.1	2.2	3.3

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1.4+ FN (0-10):
1=0.1 16=4.3 2=0.7 17=5.7 3=1.0 18=6.0 4=1.3 19=6.3 5=1.7 20=6.7 6=2.0 21=7.0 7=2.3 22=7.3 8=2.7 23=7.7 9=3.0 24=8.0 10=3.3 25=8.3 11=3.7 26=8.7 12=4.0 27=9.0 13=4.3 28=9.3 14=4.7 29=9.7 15=5.0 30=10
2.PN (0-10):
4.PTGL (0-10):
RAPID3® (0-30)
Cat:
HS = >12
MS = 6.1-12
LS = 3.1-6
R = ≤3
RADAI (0-48)

2. How much pain have you had because of your condition OVER THE PAST WEEK? Please indicate below how severe your pain has been:

NO PAIN 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 PAIN AS BAD AS IT COULD BE

3. Please place a check (√) in the appropriate spot to indicate the amount of pain you are having today in each of the joint areas listed below:

	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe
a. LEFT FINGERS	☐ 0	☐ 1	☐ 2	☐ 3	i. RIGHT FINGERS	☐ 0	☐ 1	☐ 2	☐ 3
b. LEFT WRIST	☐ 0	☐ 1	☐ 2	☐ 3	j. RIGHT WRIST	☐ 0	☐ 1	☐ 2	☐ 3
c. LEFT ELBOW	☐ 0	☐ 1	☐ 2	☐ 3	k. RIGHT ELBOW	☐ 0	☐ 1	☐ 2	☐ 3
d. LEFT SHOULDER	☐ 0	☐ 1	☐ 2	☐ 3	l. RIGHT SHOULDER	☐ 0	☐ 1	☐ 2	☐ 3
e. LEFT HIP	☐ 0	☐ 1	☐ 2	☐ 3	m. RIGHT HIP	☐ 0	☐ 1	☐ 2	☐ 3
f. LEFT KNEE	☐ 0	☐ 1	☐ 2	☐ 3	n. RIGHT KNEE	☐ 0	☐ 1	☐ 2	☐ 3
g. LEFT ANKLE	☐ 0	☐ 1	☐ 2	☐ 3	o. RIGHT ANKLE	☐ 0	☐ 1	☐ 2	☐ 3
h. LEFT TOES	☐ 0	☐ 1	☐ 2	☐ 3	p. RIGHT TOES	☐ 0	☐ 1	☐ 2	☐ 3
q. NECK	☐ 0	☐ 1	☐ 2	☐ 3	r. BACK	☐ 0	☐ 1	☐ 2	☐ 3

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 VERY POORLY

Page 1 of 2 PLEASE TURN TO THE OTHER SIDE M801.04 NP2

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5. Please check (√) if you have experienced any of the following over the last month:

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#SX (0-60)
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__Fever	__Lump in your throat	__Paralysis of arms or legs
__Weight gain (>10 lbs)	__Cough	__Numbness or tingling of arms or legs
__Weight loss (>10 lbs)	__Shortness of breath	__Fainting spells
__Feeling sickly	__Wheezing	__Swelling of hands
__Headaches	__Pain in the chest	__Swelling of ankles
__Unusual fatigue	__Heart pounding (palpitations)	__Swelling in other joints
__Swollen glands	__Trouble swallowing	__Joint pain
__Loss of appetite	__Heartburn or stomach gas	__Back pain
__Skin rash or hives	__Stomach pain or cramps	__Neck pain
__Unusual bruising or bleeding	__Nausea	__Use of drugs not sold in stores
__Other skin problems	__Vomiting	__Smoking cigarettes
__Loss of hair	__Constipation	__More than 2 alcoholic drinks per day
__Dry eyes	__Diarrhea	__Depression - feeling blue
__Other eye problems	__Dark or bloody stools	__Anxiety - feeling nervous
__Problems with hearing	__Problems with urination	__Problems with thinking
__Ringing in the ears	__Gynecological (female) problems	__Problems with memory
__Stuffy nose	__Dizziness	__Problems with sleeping
__Sores in the mouth	__Losing your balance	__Sexual problems
__Dry mouth	__Muscle pain, aches, or cramps	__Burning in sex organs
__Problems with smell or taste	__Muscle weakness	__Problems with social activities

Please check (√) here if you have had none of the above over the last month: _____.

6. When you awakened in the morning OVER THE LAST WEEK, did you feel stiff? ☐ No ☐ Yes
If "No," please go to Item 7. If "Yes," please indicate the number of minutes_____, or hours _____ until you are as limber as you will be for the day.

7. How do you feel TODAY compared to ONE WEEK AGO? Please check (✓) only one.
☐ Much Better (1), ☐ Better (2), ☐ the Same (3), ☐ Worse (4), ☐ Much Worse (5) than one week ago

8. How often do you exercise aerobically (sweating, increased heart rate, shortness of breath) for at least one-half hour (30 minutes)? Please check (✓) only one.
☐ 3 or more times a week (3), ☐ 1-2 times per week (2), ☐ 1-2 times per month (1),
☐ Do not exercise regularly (0), ☐ Cannot exercise due to disability/handicap (9)

9. How much of a problem has UNUSUAL fatigue or tiredness been for you OVER THE PAST WEEK?
FATIGUE IS NO PROBLEM 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 FATIGUE IS A MAJOR PROBLEM

10. Over the last 6 months have you had: [Please check (√)]

☐No ☐Yes An operation or new illness	☐No ☐Yes Medical emergency or stay overnight in hospital	☐No ☐Yes A fall, broken bone, or other accident or trauma	☐No ☐Yes An important new symptom or medical problem
☐No ☐Yes Side effect(s) of any medication or drug	☐No ☐Yes Smoke cigarettes regularly	☐No ☐Yes Change(s) of arthritis or other medication	☐No ☐Yes Change(s) of address
☐No ☐Yes Change(s) of marital status	☐No ☐Yes Change job or work duties, quit work, retired	☐No ☐Yes Change of medical insurance, Medicare, etc.	☐No ☐Yes Change of primary care or other doctor

Please explain any "Yes" answer below, or indicate any other health matter that affects you:

SEX: ☐ Female, ☐ Male ETHNIC GROUP: ☐ Asian, ☐ Black, ☐ Hispanic, ☐ White, ☐ Other_____
MARITAL STATUS: ☐ Single, ☐ Married, ☐ Divorced, ☐ Widowed, ☐ Separated
Your Occupation _____ Please circle the number of years of school you have completed:
Work Status: ☐ Full-time, ☐ Part-time, ☐ Disabled 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
☐ Homemaker, ☐ Self-Employed, ☐Retired,
☐ Seeking work, ☐ Other_____ Please write your weight: _____ pounds or kg height: _____ inches or cm
Your Name_____ Date of Birth _____ Today's Date _____

Page 2 of 2 Thank you for completing this questionnaire to help keep track of your medical care. M801.04NP2

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Date: _____ Signature_____

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Fig. 3. Multi Dimensional Health Assessment Questionnaire.
Sources: ref. (21) Toward a multidimensional Health Assessment Questionnaire (MDHAQ): assessment of advanced activities of daily living and psychological status in the patient-friendly health assessment questionnaire format.
(22) Further development of a physical function scale on a MDHAQ for standard care of patients with rheumatic diseases.

patient global assessment (15). Physical function, pain, and patient global assessment are the 3 patient self-report measures among the 7 RA core data set measures (32, 33). The HAQ-DI has proven useful in routine clinical care, and also has been translated into many languages.

c. A multidimensional HAQ (MDHAQ)

The MDHAQ (Fig. 3, Table I) is described in greater detail, both because it is less known than WOMAC and HAQ, and because it is the instrument used in the 2 most recent studies documenting a similar disease burden in OA and RA (11-13). The MDHAQ was developed initially after introducing the HAQ into routine clinical care in 1980, a few weeks after publication of the HAQ, as a possible advance for clinical care, much as a new laboratory test.

The clinic receptionist was instructed to ask each patient with RA to complete the HAQ in the waiting area before seeing the rheumatologist. It quickly became apparent that the goal to have each RA patient complete the HAQ was feasible only if the receptionist requested all patients (with any diagnosis), rather than selected RA patients, to complete the questionnaire. Although initially an unexpected finding, the questionnaire was found to be informative in patients with all rheumatic diseases, which was subsequently documented in later reports (23, 28, 34-36).

A number of changes were initiated on the HAQ, based on the developer's experience in developing a radio immunoassay for DNA antibodies (37-39), and managing a clinical immunology laboratory, in which minor changes of the ionic strength or pH of a buffer were made to improve the sensitivity and specificity of an assay without documenting these changes. The evolution of the HAQ into the MDHAQ over 25 years from 1980–2005 differed from most patient questionnaires such as the WOMAC and HAQ, which resulted from research efforts with psychometric testing prior to use (40).

Development was based on principles of continuous quality improvement (CQI) (40), incorporating features that appeared useful in clinical care and feedback from patients, rather than as a research activity, although psychometric criteria for validity and reliability were met (21, 22), and advances in clinical research results emerged (11-13, 28, 29, 41-45). After recognition of physical function as far more significant than laboratory tests or imaging data in the prognosis of work disability and premature mortality in RA (46-50), it was felt appropriate to include a patient questionnaire as a requirement for each visit, analogous to a laboratory test used in clinical care (51). Since the MDHAQ was developed in the clinic, feasibility and provision of clinically-relevant information were emphasised.

Details of development of the MDHAQ has been presented in several reports (21, 22, 51-53); and features on the MDHAQ not found on the HAQ are summarised in Table I and below:

The physical function scale includes 10 items, 8 from the original HAQ, one from each HAQ category, and 2 complex activities, "walk 2 miles or 3 kilometers," and "participate in recreation and sports as you would like" (21, 22); the 10 activities are scored 0–3, with a 0–30 total function score, converted to 0–10 (21, 22). This change was made during the 1990s, as clinical status of rheumatology patients had improved since the 1970s when the HAQ was developed (21), and scores of "zero" (floor effects) reported by 23% of patients on the MHAQ and 16% of patients on the HAQ, while function was not entirely normal in most patients, and a score of zero was reduced to <5% on the MDHAQ (21).

Three mental health queries were added in the user-friendly HAQ format, concerning sleep quality, anxiety and depression, scored 0–3.3, rather than 0–3, to provide a 0–9.9 "psychological HAQ" (21, 22). These items and other features of the MDHAQ are similar to the content of some more generic questionnaires such as the Short Form 36 (SF-36) (54) and Patient-Reported Outcomes Measurement Information System (PROMIS29) (55, 56), which include more extensive items concerning psychological distress.

The VAS for pain and patient global assessment were converted to visual numerical scales (VNS) of 21 circles, each numbered at 0.5 intervals, for ease of scoring and photocopying (which often changes slightly the length of a 10 cm line) by a health professional (52, 57).

RAPID3 (routine assessment of patient index data), a 0–30 composite index of three 0–10 scales for physical function, pain, and patient global estimate (58, 59), was developed; RAPID3 is scored in about 5 seconds [compared to 42 seconds for the HAQ-DI (60)], and is correlated significantly in RA with the disease activity score (DAS28) and clinical disease activity index (CDAI) (59, 61).

A 0–10 fatigue VNS was added (62) because fatigue is a common problem in rheumatology care (62, 63).

A painful joint count according to the rheumatoid arthritis disease activity index (RADAI) (64) was incorporated and modified to include neck and back on a 0–3 scale for a total of 0–54 (8, 65); the RADAI is useful to monitor inflammatory joint disease even beyond RA (65), but, ironically, very high scores suggesting involvement of almost all joints provide a clue to fibromyalgia (30, 66).

A 60-symptom checklist can serve as a review of systems, but high numbers of symptoms also provide clues to fibromyalgia (8, 30, 66, 67).

Medical history information concerns morning stiffness, change in status, exercise status, recent illness, falls, hospitalisation, change in medication, adverse events of medication, and new symptoms (8).

Demographic information, including age, marital status, occupation, work status, and formal education level are included (Fig. 3, Table I).

A 4-page version, which serves as a standard medical "intake" questionnaire, concerning past illnesses, surgery, family history, allergies, medications and demographic data (41).

MDHAQ information can improve documentation, and facilitate a focus on issues of concern to the patient and physician for higher quality visits with better communication, saving time for both (68). Furthermore, the MDHAQ has been used in OA clinical trials with results comparable to a WOMAC, and databases of MDHAQ data from routine clinical care have been used to document similarity of disease burden in OA and RA, clues to the presence of fibromyalgia, recognition of ineffectiveness of opioids in OA, and similar levels of depression and psychological distress in OA and RA, as presented below.

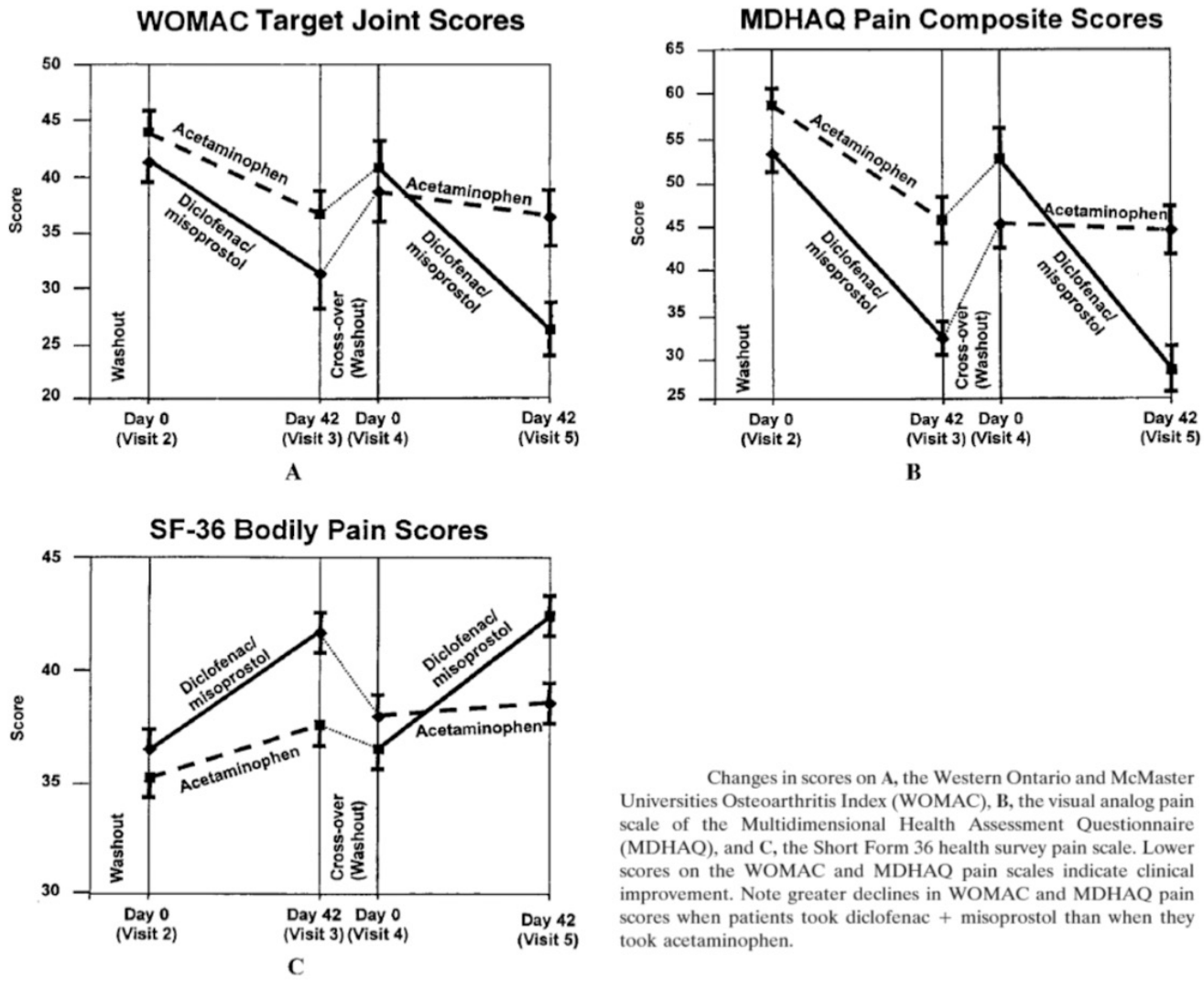
Table I. Comparison of the Western Ontario McMaster (WOMAC), health assessment questionnaire (HAQ), multidimensional health assessment questionnaire (MDHAQ).

Contents	Features	WOMAC	HAQ	MDHAQ
	First report	1988	1980	1999
	Patient completion	5-10 mins	5-10 mins	5-10 mins
Basic items	# Activities of daily living	17 items	20 items	10 items
	Pain	5 items	10 cm VAS	21 circle VNS
	Patient global VAS	No	10 cm VAS	21 circle VNS
	Stiffness	2 items	No	Mins AM stiffness
Further items of patient status	Change in global status	No	No	1 week
	Fatigue	No	No	21 circles
Psychological items	Anxiety,	No	No	1 item
	Depression	No	No	2 items
	Sleep quality	No	No	1 item
Role items	Social role	No	No	No
	Work capacity	No	No	1 item
"Medical" items	Self-report painful joint count	No	No	0-54 scale
	Symptom checklist	No	No	60 symptoms
	Medical history	No	No	Yes
	Demographic data	No	No	Yes
	Social history	No	No	Yes
Indices	Index for clinical status	No	No	RAPID3
	Index for fibromyalgia	No	No	FAST3
	Index for adverse events	No	No	Yes
Additional features	Scoring templates	No	No	Yes
	MD scan ("eyeball")	10-15 secs	30 seconds	10-15 secs
	Time to score	?	41.8 seconds	5 seconds

II. Use of the MDHAQ in OA clinical trials based on observations in routine clinical care

a. Documentation that self-report data in OA are more sensitive to change in clinical status than observer-assessed data

In the mid-1980s, a clinical trial was conducted to compare the results of 2



Changes in scores on A, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), B, the visual analog pain scale of the Multidimensional Health Assessment Questionnaire (MDHAQ), and C, the Short Form 36 health survey pain scale. Lower scores on the WOMAC and MDHAQ pain scales indicate clinical improvement. Note greater declines in WOMAC and MDHAQ pain scores when patients took diclofenac + misoprostol than when they took acetaminophen.

Fig. 4. Change in clinical status in an osteoarthritis crossover clinical trial to compare diclofenac/misoprostol to acetaminophen over 6 weeks each according to 3 self-report questionnaires. Source: ref. (24).

forms of aspirin in the management of OA (26). At that time, the traditional measures chosen by the pharmaceutical company sponsor to assess possible efficacy included pain on active motion, pain on passive motion, joint tenderness, joint swelling, joint crepitus, and walking time (26) (Table II).

An investigator (TP) suggested the inclusion of a modified version of the HAQ (15) termed the MHAQ (69), which was being used in routine care and appeared informative in patients with all rheumatic diseases (35, 40). Although there was some initial resistance, based on the HAQ being regarded as a "disease-specific" instrument for RA, the sponsor agreed to add this measure to the clinical trial protocol. The results indicated median "improved status" according to the 7 traditional observer-reported measures of 23% (range 3–43%) *versus* 43% (range 12–59%) for the patient-reported measures, and median "unchanged status" for the traditional observer-reported measures of 73% (range 47–90%) *versus* 25% according to the MDHAQ patient-reported measures (26). Significant correlations were seen between the observer-reported physical measures and self-report questionnaire measures, indicating that both types of measures detect similar information (26) (Table II).

These observations may be regarded as a "proof of concept" study that patient self-report questionnaires appear valid, sensitive, and more informative than traditional observer-reported measures in OA. A brief report was published in 1988 (26), ironically the same year as the publication of the WOMAC (16). It was appropriate that the WOMAC became the "gold standard" instrument of choice for OA, based on extensive psychometric analyses of validity and reliability in the original and subsequent reports (70-72), while further development of the MHAQ was pursued in routine clinical care (36, 51).

At this time, it would be unthinkable to perform a clinical trial or any clinical research in OA without a WOMAC, but inclusion of a patient questionnaire did not begin until the mid-1980s. The findings further indicate that the HAQ and its derivative MHAQ and MDHAQ appear quite informative to describe clinical status and changes in

OA. Ultimately, the MDHAQ has been used in recent years to document prospectively the similar disease burden in OA compared to RA (11-13).

b. Two osteoarthritis clinical trials in which the results appear quite similar according to MDHAQ pain scores, WOMAC, and SF 36 questionnaires

In the late 1990s, a multicentre, crossover clinical trial was conducted to compare the efficacy of diclofenac/misoprostol (Arthrotec) to acetaminophen in ambulatory patients with OA of the hip or knee (24), who had Kellgren/Lawrence radiographic grade 2–4 (73) and a score of >30 mm on a 100-mm visual analogue pain scale (74, 75). Patients were randomised to one of two groups in a crossover design to receive either medication for 6 weeks each. The primary outcome was the WOMAC target joint, the validity of which had been established in OA clinical trials.

In addition, patients were assessed according to the MDHAQ pain VAS and the SF 36 bodily pain score. The SF-36 is a 36-item "generic" patient self-report questionnaire (54), with 8 scales grouped as 4 physical component summary (PCS) scores – vitality, physical function, bodily pain, general health, and 4 mental component summary (MCS) scores – physical role function, emotional role function, social role function, and mental health. In contrast to most other scales such as the WOMAC, HAQ and MDHAQ, higher scores indicate better status, *e.g.* a score of 100 is equivalent to no disability and zero to maximum disability. Based on lessons learned in the earlier OA clinical trial, no investigator-reported measures were included in the study (24).

In 227 patients, significantly higher levels of improvement were seen for patients treated with diclofenac/misoprostol compared to those treated with acetaminophen (Fig. 4). Results were virtually identical according to the WOMAC, MDHAQ pain VAS, or SF-36 bodily pain scores (higher scores on the SF 36 indicate better status, unlike WOMAC and MDHAQ) (Fig. 4). The data suggest that any of the 3 questionnaires could be used to assess patients with OA, to document in detail that diclofenac/misoprostol was rated as "better" or "much better" by 57% of the 174 patients who provided such ratings for both treatment periods, while acetaminophen was rated as "better" or "much better" by 20% of these patients, and 22% reported no difference ($p<0.001$) (24).

A subsequent clinical trial with a similar design was conducted to compare 6 weeks treatment of celecoxib *versus* acetaminophen *versus* a placebo arm according to either the targeted joint WOMAC or an MDHAQ pain VAS (SF-36 was not included) (25). Results indicated superior efficacy for celecoxib compared to acetaminophen compared to a placebo according to both WOMAC target joint and MDHAQ pain VAS. Again, results were similar according to either measure, although changes according to the MDHAQ pain VAS generally were greater than according to the WOMAC target joint (25).

In routine clinical care, it is not feasible to attempt to use different questionnaires in different patients with different diagnoses. Furthermore, scores for patient functional status, pain, fatigue, morning stiffness and other measures can be most informative as a baseline measure at an initial visit of a "new" patient, when the patient often does not have a diagnosis, particularly before seeing the rheumatologist. Availability of baseline initial visit scores is desirable, particularly as maximum improvement in patient status often is seen within the first 3 months of rheumatologic care. This goal can be accomplished most feasibly by using the same questionnaire in all new (and return) patients.

Table II. Changes over 4 weeks of 19 patients with osteoarthritis of the knee according to observer- reported physical measures and patient self-report questionnaire measures.

	% Poorer status	% Unchanged status	% Improved status
Observer-reported Physical Measures			
Pain on active motion	3	73	23
Pain on passive motion	13	63	23
Joint tenderness	7	73	20
Joint swelling	13	73	13
Joint crepitus	7	90	3
Walking time	17	48	34
Observer global assessment	10	47	43
Patient Self-report Questionnaire Measures			
ADL Difficulty Scale	28	25	47
ADL Dissatisfaction Scale	40	17	43
ADL Pain Scale	28	13	59
Visual analogue pain scale	39	32	29
Patient global self-assessment	16	72	12

Source: ref. (28) Brooks *et al*. 1988 Use of self-report activities of daily living questionnaires in osteoarthritis.

Unexpected observations from MDHAQ used in routine care, stored in databases, and analysed retrospectively to provide new insights into OA

OA is as severe as RA

Five studies reported between 1989 and 2019 are among 8 reports reviewed elsewhere in this supplement (13), which document that disease burden according to the MDHAQ is substantial in OA and comparable to RA (11, 12, 17, 27, 35, 36). Four of these studies were based on data collected in routine care and analysed retrospectively (11, 12, 35, 36); one involved prospective analyses of the initial visits of new patients with OA or RA (or other rheumatic diseases), and follow-up visits 2 months later (29). The primary focus to analyse properties of the MDHAQ at sites at which all patients are asked to complete an MDHAQ at all visits to inform clinical decisions.

A pain VAS was higher in OA compared to RA in 10/11 patient groups in these reports, while MDHAQ physical function and RAPID3 were slightly higher in RA in studies before 2009 and higher in OA in later reports [see (13)]. Therefore, disease burden of pain and functional disability appear generally similar in OA to RA. In addition, the findings

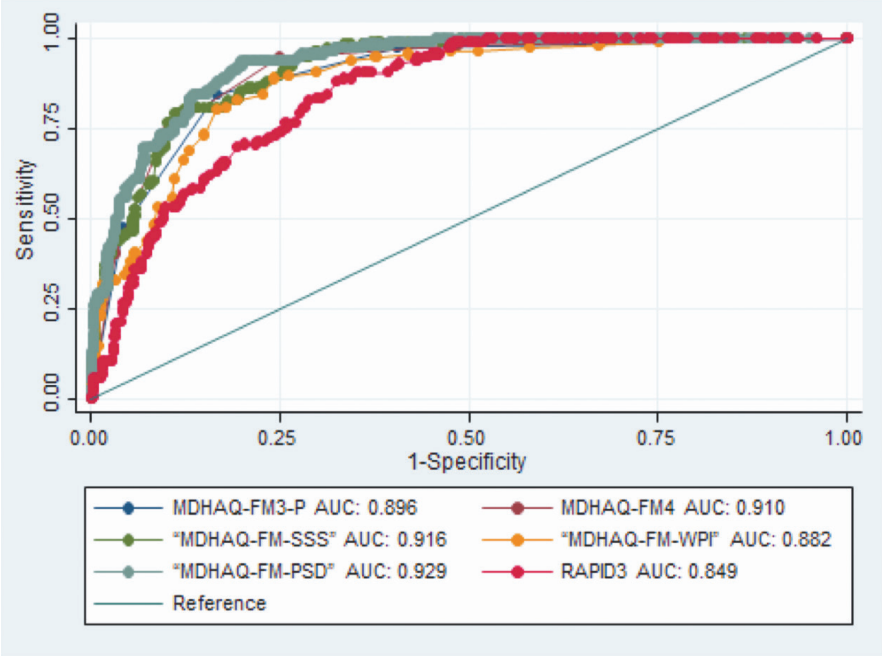


Fig. 5. Receiver operating characteristic (ROC) curves to compare the capacity of all MDHAQ based composite indices to discriminate between patients with or without FM according to the 2011 revised criteria as reference standard.
AUC: Area under the ROC curve; RADAI: Rheumatoid arthritis disease activity index self-report painful joint count, "MDHAQ-SSS": sum of fatigue, problems with thinking/memory, good night sleep, headaches, stomach pain/cramps and depression; "MDHAQ-WPI": self-report painful joint count including back and neck (0-54), divided by 3; "MDHAQ-PSD": the sum of "MDHAQ-SSS" and "MDHAQ-WPI"; MDHAQ-FM3P: FAST3P cumulative index including pain, self-report painful joint count and symptom checklist; MDHAQ-FM3F: FAST3F cumulative index including fatigue, self-report painful joint count and symptom checklist; MDHAQ-FM4: FAST4 cumulative index including pain, fatigue, self-report painful joint count and symptom checklist. Source: ref. (30).

reflect the potential value of using identical patient questionnaire measures in all patients at all visits in routine care settings, analogous to using the same laboratory tests such as erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) in all rheumatic diseases, and maintaining a database of the results for later analyses.

Recognition of fibromyalgia in OA and other rheumatic diseases

Early observations in routine clinical care indicated that patients with high, often the highest, scores on certain MDHAQ scales were seen in patients with fibromyalgia (76). Some observers suggested that these phenomena indicated that patient questionnaires were highly limited (or entirely useless) in clinical rheumatology. Several fibromyalgia-specific questionnaires were developed (77-79), and the 2011 and 2016 updated criteria for fibromyalgia are based exclusively on patient questionnaire scores for widespread pain and somatic symptoms (80-82).

Of course, as noted, "disease-specific" questionnaires may add important insights in research settings concerning mechanisms, which are not available from more generic questionnaires, but it is not feasible in routine care to ask the clinic staff to give different questionnaires to patients with different diagnoses, as noted above. Therefore, another approach might be to use information on the MDHAQ that might provide clues to the presence of fibromyalgia.

In 1990, it was reported that high scores for pain and low scores for physical function provided a clue to fibromyalgia (76). In 75 patients with fibromyalgia and 75 control patients with RA (matched for age and sex), a ratio of 0–10 pain VAS (PVAS) to 1–4 scores for difficulty in activities of daily living (DADL) <3 were seen in 67% of RA patients *versus* 28% of patients with non-inflammatory diffuse musculoskeletal pain, while ratios >5 were seen in 27% of patients with non-inflammatory diffuse musculoskeletal pain, but no patients with RA (76).

In 2004, it was recognised that scores on a 0–10 fatigue VAS and 0–60 symptom checklist were significantly higher in 78 patients with fibromyalgia than in 149 patients with RA (66). Patients with fibromyalgia also had a lower ESR than patients with RA, but patients with fibromyalgia were distinguished from patients with RA by patient questionnaire data as effectively as by the ESR (66).

The relative acceptance of RAPID3 by the rheumatology community suggested the possibility of a further MDHAQ index that might be useful in fibromyalgia. Such an index has been reported recently as a FAST (fibromyalgia assessment screening tool) index (30, 83). Over a 6-month period, the one-page questionnaire used to score the revised 2011 fibromyalgia criteria (80) termed a polysymptomatic distress scale (PSD) [composed of a symptom severity scale (SSS) and widespread pain index (WPI)], was added to the MDHAQ in 566 patients seen in routine care for comparison with the MDHAQ scales. The MDHAQ items showing the highest agreement with the 2011 fibromyalgia criteria according to the "area under the curve" (AUC) on receiver operator characteristic (ROC) curves were compiled into FAST indices (30, 83).

The highest AUC were seen, in order, for 60 symptom checklist, RADAI self-report painful joint count, pain VAS, and fatigue VAS (30, 83). All FAST indices include the 60 symptom checklist and RADAI self-report painful joint count; FAST3-P adds a pain VAS score, FAST3-F a fatigue VAS score, and FAST4 both pain and fatigue VAS scores (30, 83). Results of ROC curves indicate an AUC greater than 0.9, as high agreement as seen in clinical medical measures (Fig. 5). Cut points of symptom checklist ≥16, painful joint count ≥16, pain VAS ≥6 and fatigue VAS ≥6 were identified as providing optimal sensitivity and specificity. Scores are 1 point each for compiling into 0–3 FAST3 indices or a 0–4 FAST4 index; scores of ≥2 for FAST3 and ≥3 for FAST4 (45, 83) are in agreement with the 2011 fibromyalgia criteria at levels greater than 80% (30, 83).

Table III. Responses to 202 patients with osteoarthritis to the query: "Which drug was most helpful for your arthritis?"

Drug	no. of patients who took this drug	no. of patients who named this drug "most helpful"	Percentage of patients who named a drug "most helpful" who named this drug	Percentage of all patients who named this drug "most helpful"
Non-steroidal anti-inflammatory drugs (NSAIDs)				
Ibuprofen (Motrin, Advil, Nuprin)	223	40	20%	13%
Naproxen (Naprosyn, Naprolyn, Aleve)	177	28	14%	9%
Nabumetone (Relafen)	80	18	9%	6%
Diclofenac (Voltaren)	63	15	7%	5%
Piroxicam (Feldene)	54	11	5%	4%
Etodolac (Lodine)	NA	10	5%	3%
Arthrotec	NA	8	4%	3%
Oxaprozin (Daypro)	54	8	4%	3%
Aspirin	113	5	2%	2%
Indomethacin	28	4	2%	1%
Flurbiprofen	20	4	2%	1%
Salsalate (Disalcid)	7	4	2%	1%
Sulindac (Clinoril)	33	2	1%	1%
Tolmetin	7	2	1%	1%
Ketoprofen (Orudis)	25	2	1%	1%
Diclofenac (Cataflam)	NA	1	<1%	<1%
Fenoprofen (Nalfon)	NA	1	<1%	<1%
Total, NSAID		161	80%	54%
Analgesic drugs				
Acetaminophen	210	31	16%	10%
Other analgesics	NA	3	1.5%	1.5%
Tylenol with codeine (#3)	NA	3	1.5%	1.5%
Hydrocodone	NA	2	1%	1%
Darvocet	NA	2	1%	1%
Total, analgesic drugs		41	20%	14%
Grand total		202	100%	67%

Source: ref. (30) Preference for non-steroidal anti-inflammatory drugs *versus* acetaminophen and concomitant use of both types of drugs in patients with osteoarthritis.

Table IV. Mean scores of 162 patients with rheumatoid arthritis and 63 patients with osteoarthritis on MDHAQ 3 psychological items.

Patients with …	n	Sleep	Anxiety	Depression	Total
Rheumatoid arthritis	162	2.13	1.69	1.66	1.82
Osteoarthritis	63	1.97	1.67	1.66	1.77

Source: ref. (21) Toward a multidimensional Health Assessment Questionnaire (MDHAQ): assessment of advanced activities of daily living and psychological status in the patient-friendly health assessment questionnaire format. Data are mean scores on a 0–3 scale.

Further studies appear needed to determine an optimal FAST index – or the possibility that different scores may be optimal in different situations. The proportion of patients with fibromyalgia on both the PSD 2011 fibromyalgia criteria questionnaire and FAST indices on the MDHAQ was higher in OA than in RA or systemic lupus erythematosus patients, emphasising again the significant disease burden of patients in with OA (Schmukler, manuscript in preparation). The MDHAQ again appeared to provide unexpected value to better characterise patients with OA.

Poor results in use of opioids compared to NSAIDs in the management of OA

Introduction of selective cyclooxygenase2 (Cox2) inhibitor non-steroidal anti-inflammatory drugs (NSAIDs) in 1999 initially was regarded as a major advance in OA therapeutics, with efficacy comparable to traditional NSAIDs and lesser likelihood of adverse gastrointestinal events. However, by the early 2000s, a significantly higher rate of cardiovascular events was recognised as associated with these drugs compared to traditional NSAIDs (84). This phenomenon led to withdrawal of several Cox 2 selective drugs from the market, and recommendations to avoid those that remained in favour of alternatives, including opioids.

Over the decade from 2001–2011, OA patients were treated with a substantially lower likelihood of any type of NSAID (Cox-2 selective or not) accompanied by a concomitant substantial increase in opioids (85). Several studies documented that falls and fractures were 3–4 times more likely in OA patients who took opioids compared to those who took NSAIDs (85-87). Furthermore, evidence was presented that opioids did not appear efficacious for many patients, including a Cochran systematic review of randomised trials showing a 0.7 cm improvement on a pain VAS, below the minimal clinically important difference of 0.9 cm (88).

Further details concerning the use of opioids in OA and general issues with contemporary opioid crisis at this time are beyond the scope of this article. We do point out that a survey of OA patients reported in 2000 indicated that 80% of 202 OA patients responded to a query concerning which drug that was "most helpful for your arthritis" by naming an NSAID (including 20% ibuprofen and 14% naproxen), while only 20% named an analgesic drug (including 16% acetaminophen and fewer than 4% an opioid (Table II) (31). These data were assembled using a simple questionnaire amended to an MDHAQ, similar to the fibromyalgia criteria PSD to the MDHAQ in recent studies (30, 83).

Of course, an extensive Cochran review provides considerably stronger evidence than a simple survey of 202 patients. Nonetheless, the conclusion that opioids are unlikely to be effective for most OA patients, with both limited efficacy and frequent adverse events, appears quite similar. The results of the patient survey appear never to have been cited in discussions of the limited

value of NSAIDs and adverse events of Cox-2 selective inhibitors, with possible alternative therapies for OA. Perhaps the substantial increase in the use of opioids for OA might have been lesser if this information had been more widely known.

It is possible that greater respect for data from patients exists at this time than 2 decades ago. In any event, the findings provide another example that one can gain informative clinical data from patients using simple questionnaires.

Recognition of similar levels of depression and psychological distress in patients with osteoarthritis as in patients with rheumatoid arthritis

As noted above, the MDHAQ introduced 3 psychological items in the user-friendly HAQ format, in large part to reduce "floor effects", *i.e*. scores of 0 in 23% of patients on the MHAQ and 16% on the HAQ, to less than 5% (21, 22). Mean 0-3 scores in the initial 1999 MDHAQ report for 3 specific queries concerning sleep quality were 2.13 in patients with RA and 1.97 in patients with OA; scores for anxiety were 1.69 in RA and 1.67 in OA; and scores for depression were 1.66 in both RA and OA (Table IV) (21). Mean overall psychological distress scale scores were 1.8 in RA and 1.77 in OA (Table IV) (21).

These observations again reinforce the similarity of OA to RA (21). Mean scores for depression in patients with OA and overall psychological distress scores were higher than seen in patients with vasculitis or scleroderma, which are regarded as severe rheumatic diseases (21). The data emphasise again that OA is a severe rheumatic disease, and a need for change in perception by the medical community and general public concerning OA.

In conclusion, scores on an MDHAQ have documented the severity of OA, comparable to RA in consequences of functional disability and pain, clues to recognition of fibromyalgia, poor results compared to NSAIDs in treatment of OA, and psychological distress in OA *versus* RA. Advantages of MDHAQ in routine care include the feasibility of using the same patient questionnaire for all patients with all diagnoses, and the MDHAQ has proven informative in all rheumatic diseases in which it has been studied (7, 23). The primary use of the MDHAQ is to inform clinical decisions in patient care, but additional creation of a long-term database can provide quantitative data which are not available from a non-quantitative, non-structured medical history, laboratory tests, imaging data, or other information in the medical record.

References

1. CASTREJON I, McCOLLUM L, TANRIOVER MD, PINCUS T: Importance of patient history and physical examination in rheumatoid arthritis compared to other chronic diseases: Results of a physician survey. *Arthritis Care Res* 2012; 64: 1250-5.
2. HANNAN MT, FELSON DT, PINCUS T: Analysis of the discordance between radiographic changes and knee pain in osteoarthritis of the knee. *J Rheumatol* 2000; 27: 1513-7.
3. BLOCK JA: Clinical features of osteoarhthritis. *In*: HOCHBERG MC, GRAVEALLESE EM, SILMAN AJ, SMOLEN JS, WEINBLATT ME, WEISMAN MH (Eds.) *Rheumatology*. 7th ed. Philadelphia: Elsevier; 2019. p. 1522-8.
4. PINCUS T: A pragmatic approach to cost-effective use of laboratory tests and imaging procedures in patients with musculoskeletal symptoms. *Prim Care* 1993; 20: 795-814.
5. PINCUS T, SOKKA T: Laboratory tests to assess patients with rheumatoid arthritis: advantages and limitations. *Rheum Dis Clin North Am* 2009; 35: 731-4, vi-vii.
6. WEED LL: Medical records that guide and teach. *N Engl J Med* 1968; 278: 652-7
7. PINCUS T, CASTREJON I: Are patient self-report questionnaires as "scientific" as biomarkers in "treat-to-target" and prognosis in rheumatoid arthritis? *Curr Pharm Des* 2015; 21: 241-56.
8. PINCUS T, CASTREJON I: MDHAQ/RAPID3 Scores: quantitative patient history data in a standardized "scientific" format for optimal assessment of patient status and quality of care in rheumatic diseases. *Bull NYU Hosp Jt Dis* 2011; 69: 201-14.
9. HAWKER GA, CROXFORD R, BIERMAN AS *et al*.: All-cause mortality and serious cardiovascular events in people with hip and knee osteoarthritis: a population based cohort study. *PLoS One* 2014; 9: e91286.
10. SOKKA T, ABELSON B, PINCUS T: Mortality in rheumatoid arthritis: 2008 update. *Clin Exp Rheumatol* 2008; 26 (Suppl. 51): S35-61.
11. CHUA JR, JAMAL S, RIAD M *et al*.: Disease burden in osteoarthritis is similar to that of rheumatoid arthritis at initial rheumatology visit and significantly greater six months later. *Arthritis Rheumatol* 2019; 71: 1276-84
12. EL-HADDAD C, CASTREJON I, GIBSON KA, YAZICI Y, BERGMAN M, PINCUS T: MDHAQ/RAPID3 scores in patients with osteoarthritis are similar to or higher than in patients with rheumatoid arthritis: a cross-sectional study from current routine rheumatology care at 4 sites. *RMD Open* 2017; 3: e000391..
13. PINCUS T, CASTREJON I, BERGMAN M, YAZICI Y, GIBSON KA: Osteoarthritis is as severe as rheumatoid arthritis: evidence over 30 years. *Clin Exp Rheumatol* 2019; 37 (Suppl. 120): S7-17.
14. SOKKA T, PINCUS T: Poor physical function, pain and limited exercise: risk factors for premature mortality in the range of smoking or hypertension, identified on a simple patient self-report questionnaire for usual care. *BMJ Open* 2011; 1: e000070.
15. FRIES JF, SPITZ P, KRAINES RG, HOLMAN HR: Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980; 23: 137-45.
16. BELLAMY N, BUCHANAN WW, GOLDSMITH CH, CAMPBELL J, STITT LW: Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988; 15: 1833-40.
17. WOLFE F, KONG SX: Rasch analysis of the Western Ontario MacMaster questionnaire (WOMAC) in 2205 patients with osteoarthritis, rheumatoid arthritis, and fibromyalgia. *Ann Rheum Dis* 1999; 58: 563-8.
18. PINCUS T, SWEARINGEN CJ, BERGMAN M, YAZICI Y: RAPID3 (Routine Assessment of Patient Index Data 3), a rheumatoid arthritis index without formal joint counts for routine care: proposed severity categories compared to disease activity score and clinical disease activity index categories. *J Rheumatol* 2008; 35: 2136-47.
19. FRIES JF, RAMEY DR: "Arthritis specific" global health analog scales assess "generic" health related quality-of-life in patients with rheumatoid arthritis. *J Rheumatol* 1997; 24: 1697-702.
20. WOLFE F: Why the HAQ-II can be an effective substitute for the HAQ. *Clin Exp Rheumatol* 2005; 23 (Suppl. 39): S29-30.
21. PINCUS T, SWEARINGEN C, WOLFE F: Toward a multidimensional Health Assessment Questionnaire (MDHAQ): assessment of advanced activities of daily living and psychological status in the patient-friendly health assessment questionnaire format. *Arthritis Rheum* 1999; 42: 2220-30.
22. PINCUS T, SOKKA T, KAUTIAINEN H: Further development of a physical function scale on a MDHAQ for standard care of patients with rheumatic diseases. *J Rheumatol* 2005; 32: 1432-9.
23. CASTREJON I: The use of MDHAQ/RAPID3 in different rheumatic diseases a review of the literature. *Bull Hosp Jt Dis* 2017; 75: 93-100.
24. PINCUS T, KOCH GG, SOKKA T *et al*.: A randomized, double-blind, crossover clinical trial of diclofenac plus misoprostol versus acetaminophen in patients with osteoarthritis of the hip or knee. *Arthritis Rheum* 2001; 44: 1587-98.
25. PINCUS T, KOCH G, LEI H *et al*.: Patient preference for Placebo, Acetaminophen (paracetamol) or Celecoxib Efficacy Studies (PACES): two randomised, double blind, placebo controlled, crossover clinical trials in patients with knee or hip osteoarthritis. *Ann Rheum Dis* 2004; 63: 931-9.

26. BROOKS RH, CALLAHAN LF, PINCUS T: Use of self-report activities of daily living questionnaires in osteoarthritis. *Arthritis Rheum* 1988; 1: 23-32.
27. SLATKOWSKY-CHRISTENSEN B, MOWINCKEL P, KVIEN TK: Health status and perception of pain: a comparative study between female patients with hand osteoarthritis and rheumatoid arthritis. *Scand J Rheumatol* 2009; 38: 342-8.
28. PINCUS T, ASKANASE AD, SWEARINGEN CJ: A multi-dimensional health assessment questionnaire (MDHAQ) and routine assessment of patient index data (RAPID3) scores are informative in patients with all rheumatic diseases. *Rheum Dis Clin North Am* 2009; 35: 819-27.
29. CASTREJON I, BERGMAN MJ, PINCUS T: MDHAQ/RAPID3 to recognize improvement over 2 months in usual care of patients with osteoarthritis, systemic lupus erythematosus, spondyloarthropathy, and gout, as well as rheumatoid arthritis. *J Clin Rheumatol* 2013; 19: 169-74.
30. SCHMUKLER J, JAMAL S, CASTREJON I, BLOCK JA, PINCUS T: Fibromyalgia Assessment Screening Tools (FAST) based on Only Multidimensional Health Assessment Questionnaire (MDHAQ) scores as clues to fibromyalgia. *ACR Open Rheumatology* 2019.
31. PINCUS T, SWEARINGEN C, CUMMINS P, CALLAHAN LF: Preference for nonsteroidal antiinflammatory drugs versus acetaminophen and concomitant use of both types of drugs in patients with osteoarthritis. *J Rheumatol* 2000; 27: 1020-7.
32. BOERS M, TUGWELL P: The validity of pooled outcome measures (indices) in rheumatoid arthritis clinical trials. *J Rheumatol* 1993; 20: 568-74.
33. FELSON DT, ANDERSON JJ, BOERS M *et al.*: The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. The Committee on Outcome Measures in Rheumatoid Arthritis Clinical Trials. *Arthritis Rheum* 1993; 36: 729-40.
34. PINCUS T, SOKKA T: Quantitative clinical rheumatology: "keep it simple, stupid": MDHAQ function, pain, global, and RAPID3 quantitative scores to improve and document the quality of rheumatologic care. *J Rheumatol* 2009; 36: 1099-100.
35. CALLAHAN LF, SMITH WJ, PINCUS T: Self-report questionnaires in five rheumatic diseases: comparisons of health status constructs and associations with formal education level. *Arthritis Care Res* 1989; 2: 122-31.
36. PINCUS T, SOKKA T: Can a Multi-Dimensional Health Assessment Questionnaire (MDHAQ) and Routine Assessment of Patient Index Data (RAPID) scores be informative in patients with all rheumatic diseases? *Best Pract Res Clin Rheumatol* 2007; 21: 733-53.
37. PINCUS T, SCHUR PH, ROSE JA, DECKER JL, TALAL N: Measurement of serum DNA-binding activity in systemic lupus erythematosus. *N Engl J Med* 1969; 281: 701-5.
38. PINCUS T: Ammonium sulphate precipitation to measure antibodies to double-stranded DNA: a simple clinical test for diagnosis and management of patients with systemic lupus erythematosus. *Lupus* 2009; 18: 1243-5.
39. PINCUS T: Immunochemical conditions affecting the measurement of DNA antibodies using ammonium sulfate precipitation. *Arthritis Rheum* 1971; 14: 623-30.
40. PINCUS T, YAZICI Y, BERGMAN M, MACLEAN R, HARRINGTON T: A proposed continuous quality improvement approach to assessment and management of patients with rheumatoid arthritis without formal joint counts, based on quantitative routine assessment of patient index data (RAPID) scores on a multidimensional health assessment questionnaire (MDHAQ). *Best Pract Res Clin Rheumatol* 2007; 21: 789-804.
41. PINCUS T: Are patient questionnaire scores as "scientific" as laboratory tests for rheumatology clinical care? *Bull NYU Hosp Jt Dis* 2010; 68: 130-9.
42. PINCUS T: RAPID3, an index of only 3 patient self-report core data set measures, but not ESR, recognizes incomplete responses to methotrexate in usual care of patients with rheumatoid arthritis. *Bull Hosp Jt Dis* 2013; 71: 117-20.
43. CASTREJON I, YAZICI Y, SAMUELS J, LUTA G, PINCUS T: Discordance of global estimates by patients and their physicians in usual care of many rheumatic diseases: association with 5 scores on a Multidimensional Health Assessment Questionnaire (MDHAQ) that are not found on the Health Assessment Questionnaire (HAQ). *Arthritis Care Res* 2014; 66: 934-42.
44. PINCUS T, SOKKA T, CASTREJON I, CUTOLO M: Decline of mean initial prednisone dosage from 10.3 to 3.6 mg/day to treat rheumatoid arthritis between 1980 and 2004 in one clinical setting, with long-term effectiveness of dosages less than 5 mg/day. *Arthritis Care Res* 2013; 65: 729-36.
45. SOKKA T, PINCUS T: Ascendancy of weekly low-dose methotrexate in usual care of rheumatoid arthritis from 1980 to 2004 at two sites in Finland and the United States. *Rheumatology* (Oxford) 2008; 47: 1543-7.
46. PINCUS T, CALLAHAN LF, SALE WG, BROOKS AL, PAYNE LE, VAUGHN WK: Severe functional declines, work disability, and increased mortality in seventy-five rheumatoid arthritis patients studied over nine years. *Arthritis Rheum* 1984; 27: 864-72.
47. PINCUS T, BROOKS RH, CALLAHAN LF: Prediction of long-term mortality in patients with rheumatoid arthritis according to simple questionnaire and joint count measures. *Ann Rheum Dis* 1994; 120: 26-34.
48. BOERS M, DIJKMANS B, GABRIEL S, MARADIT-KREMERS H, O'DELL J, PINCUS T: Making an impact on mortality in rheumatoid arthritis: targeting cardiovascular comorbidity. *Arthritis Rheum* 2004; 50: 1734-9.
49. SOKKA T, ABELSON B, PINCUS T: Mortality in rheumatoid arthritis: 2008 update. *Clin Exp Rheumatol* 2008; 26 (Suppl. 51): S35-61.
50. PINCUS T, GIBSON KA, BLOCK J: Premature mortality - the neglected outcome in rheumatic diseases? *Arthritis care Res* 2015; 67: 1043-46.
51. PINCUS T, MACLEAN R, YAZICI Y, HARRINGTON JT: Quantitative measurement of patient status in the regular care of patients with rheumatic diseases over 25 years as a continuous quality improvement activity, rather than traditional research. *Clin Exp Rheumatol* 2007; 25 (Suppl. 47): S69-81.
52. PINCUS T, BERGMAN M, SOKKA T, ROTH J, SWEARINGEN C, YAZICI Y: Visual analog scales in formats other than a 10 centimeter horizontal line to assess pain and other clinical data. *J Rheumatol* 2008; 35: 1550-8.
53. PINCUS T, CASTREJON I: An evidence-based medical visit for patients with rheumatoid arthritis based on standard, quantitative scientific data from a patient MDHAQ and physician report. *Bull NYU Hosp Jt Dis* 2012; 70: 73-94.
54. WARE JE JR, SHERBOURNE CD: The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992; 30: 473-83.
55. CELLA D, YOUNT S, ROTHROCK N *et al.*: The Patient-Reported Outcomes Measurement Information System (PROMIS): Progress of an NIH Roadmap Cooperative Group During its First Two Years. *Med Care* 2007; 45 (Suppl. 1): S3-S11.
56. CELLA D, RILEY W, STONE A *et al.*: The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol* 2010; 63: 1179-94.
57. PINCUS T, SWEARINGEN CJ: The HAQ compared with the MDHAQ: "keep it simple, stupid" (KISS), with feasibility and clinical value as primary criteria for patient questionnaires in usual clinical care. *Rheum Dis Clin North Am* 2009; 35: 787-98, ix.
58. PINCUS T, BERGMAN MJ, YAZICI Y: RAPID3- an index of physical function, pain, and global status as "vital signs" to improve care for people with chronic rheumatic diseases. *Bull NYU Hosp Jt Dis* 2009; 67: 211-25.
59. PINCUS T, SWEARINGEN CJ, BERGMAN MJ *et al.*: RAPID3 (Routine Assessment of Patient Index Data) on an MDHAQ (Multidimensional Health Assessment Questionnaire): agreement with DAS28 (Disease Activity Score) and CDAI (Clinical Disease Activity Index) activity categories, scored in five versus more than ninety seconds. *Arthritis Care Res* 2010; 62: 181-9.
60. YAZICI Y, BERGMAN M, PINCUS T: Time to score quantitative rheumatoid arthritis measures: 28-Joint Count, Disease Activity Score, Health Assessment Questionnaire (HAQ), Multidimensional HAQ (MDHAQ), and Routine Assessment of Patient Index Data (RAPID) scores. *J Rheumatol* 2008; 35: 603-9.
61. PINCUS T, HINES P, BERGMAN MJ, YAZICI Y, ROSENBLATT LC, MACLEAN R: Proposed severity and response criteria for Routine Assessment of Patient Index Data (RAPID3): results for categories of disease activity and response criteria in abatacept clinical trials. *J Rheumatol* 2011; 38: 2565-71.
62. CASTREJON I, NIKIPHOROU E, JAIN R, HUANG A, BLOCK JA, PINCUS T: Assessment of fatigue in routine care on a Multidimensional Health Assessment Questionnaire (MDHAQ): a cross-sectional study of associ-ations with RAPID3 and other variables in different rheumatic diseases. *Clin Exp*

Rheumatol 2016; 34: 901-9.
63. KIRWAN JR, MINNOCK P, ADEBAJO A *et al*.: Patient perspective: fatigue as a recommended patient centered outcome measure in rheumatoid arthritis. *J Rheumatol* 2007; 34: 1174-7.
64. STUCKI G, LIANG MH, STUCKI S, BRUHLMANN P, MICHEL BA: A self-administered rheumatoid arthritis disease activity index (RADAI) for epidemiologic research. Psychometric properties and correlation with parameters of disease activity. *Arthritis Rheum* 1995; 38: 795-8.
65. CASTREJON I, YAZICI Y, PINCUS T: Patient self-report RADAI (Rheumatoid Arthritis Disease Activity Index) joint counts on an MDHAQ (Multidimensional Health Assessment Questionnaire) in usual care of consecutive patients with rheumatic diseases other than rheumatoid arthritis. *Arthritis Care Res* 2013; 65: 288-93.
66. DEWALT DA, REED GW, PINCUS T: Further clues to recognition of patients with fibromyalgia from a simple 2-page patient multidimensional health assessment questionnaire (MDHAQ). *Clin Exp Rheumatol* 2004; 22: 453-61.
67. WOLFE F, SCHMUKLER J, JAMAL S *et al*.: Diagnosis of fibromyalgia: disagreement between fibromyalgia criteria and clinician-based fibromyalgia diagnosis in a university clinic. *Arthritis Care Res* 2019; 71: 343-51.
68. PINCUS T, SKUMMER PT, GRISANTI MT, CASTREJON I, YAZICI Y: MDHAQ/RAPID3 can provide a roadmap or agenda for all rheumatology visits when the entire MDHAQ is completed at all patient visits and reviewed by the doctor before the encounter. *Bull NYU Hosp Jt Dis* 2012; 70: 177-86.
69. PINCUS T, SUMMEY JA, SORACI SA JR, WALLSTON KA, HUMMON NP: Assessment of patient satisfaction in activities of daily living using a modified Stanford Health Assessment Questionnaire. *Arthritis Rheum* 1983; 26: 1346-53.
70. BELLAMY N: Pain assessment in osteoarthritis: experience with the WOMAC osteoarthritis index. *Semin Arthritis Rheum* 1989; 18 (Suppl 2): 14-7.
71. BELLAMY N, WELLS G, CAMPBELL J: Relationship between severity and clinical importance of symptoms in osteoarthritis. *Clin Rheumatol* 1991; 10: 138-43.
72. BELLAMY N, GOLDSMITH CH, BUCHANAN WW, CAMPBELL J, DUKU E: Prior score availability: observations using the WOMAC osteoarthritis index. *Br J Rheumatol* 1991; 30: 150-1.
73. KELLGREN JH, LAWRENCE JS: Radiological assessment of osteo-arthrosis. *Ann Rheum Dis* 1957; 16: 494-502.
74. HUSKISSON EC: Measurement of pain. *Lancet* 1974; 2: 1127-31.
75. SCOTT J, HUSKISSON EC: Vertical or horizontal visual analogue scales. *Ann Rheum Dis* 1979; 38: 560.
76. CALLAHAN LF, PINCUS T: A clue from a self-report questionnaire to distinguish rheumatoid arthritis from noninflammatory diffuse musculoskeletal pain. The P-VAS:D-ADL ratio. *Arthritis Rheum* 1990; 33: 1317-22.
77. BURCKHARDT CS, CLARK SR, BENNETT RM: The fibromyalgia impact questionnaire: development and validation. *J Rheumatol* 1991; 18: 728-33.
78. WHITE KP, HARTH M, SPEECHLEY M, OSTBYE T: Testing an instrument to screen for fibromyalgia syndrome in general population studies: the London Fibromyalgia Epidemiology Study Screening Questionnaire. *J Rheumatol* 1999; 26: 880-4.
79. IVERSEN MD: Fibromyalgia: The Fibromyalgia Impact Questionnaire (FIQ). *Arthritis Care Res* 2003; 49: S210-S3.
80. WOLFE F, CLAUW DJ, FITZCHARLES MA *et al*.: Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR Preliminary Diagnostic Criteria for Fibromyalgia. *J Rheumatol* 2011;38(6):1113-22.
81. ABLIN JN, WOLFE F: A Comparative Evaluation of the 2011 and 2016 Criteria for Fibromyalgia. *J Rheumatol* 2017; 44: 1271-6.
82. WOLFE F, CLAUW DJ, FITZCHARLES MA *et al*.: 2016 Revisions to the 2010/2011 fibromyalgia diagnostic criteria. *Semin Arthritis Rheum* 2016; 46: 319-29.
83. GIBSON KA, CASTREJON I, DESCALLAR J, PINCUS T: Fibromyalgia Assessment Screening Tool (FAST): clues to fibromyalgia on a multidimensional health assessment questionnaire (MDHAQ) for routine care. *J Rheumatol* 2019 Sep 1 [Epub ahead of print].
84. MUKHERJEE D, NISSEN SE, TOPOL EJ: Risk of cardiovascular events associated with selective COX-2 inhibitors. *JAMA* 2001; 286: 954-9.
85. DEVEZA LA, HUNTER DJ, VAN SPIL WE: Too much opioid, too much harm. *Osteoarthritis Cartilage* 2018;26(3):293-5.
86. ROLITA L, SPEGMAN A, TANG X, CRONSTEIN BN: Greater number of narcotic analgesic prescriptions for osteoarthritis is associated with falls and fractures in elderly adults. *J Am Geriatr Soc* 2013; 61: 335-40.
87. SOLOMON DH, RASSEN JA, GLYNN RJ, LEE J, LEVIN R, SCHNEEWEISS S: The comparative safety of analgesics in older adults with arthritis. *Arch Intern Med* 2010; 170: 1968-76.
88. DA COSTA BR, NUESCH E, KASTELER R *et al*.: Oral or transdermal opioids for osteoarthritis of the knee or hip. *Cochrane Database Syst Rev* 2014(9): CD003115.