EXTENDED REPORT

The ICIDH-2 as a framework for the assessment of functioning and disability in rheumatoid arthritis

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Objective: To investigate by a cross sectional study in patients with rheumatoid arthritis (RA) the relationship between measures of impairment, activity limitation, and participation of the model of functioning and disability (ICIDH-2).

Methods: Inclusion data of patients with RA (n=803) from the Swiss Clinical Quality Management Group were used. Impairments were measured by the Short Form-36 (SF-36) bodily pain scale, rheumatoid arthritis disease activity index (RADAI), disease activity score (DAS28), and radiographic scoring (x ray). Activity limitation was measured with the Health Assessment Questionnaire (HAQ) and the SF-36 physical functioning scale. Participation was measured with the SF-36 role and social functioning scales. Spearman (partial) correlations were used for analysis.

Results: Impairment and activity limitation dimensions of the ICIDH-2 model are related; correlations with the HAQ were: SF-36 bodily pain ($r_s=-0.61$), RADAI ($r_s=0.58$), DAS28 ($r_s=0.49$), and x ray ($r_s=0.35$). Similar correlations were found for SF-36 physical functioning. Activity limitation and participation restriction dimensions are also related: the HAQ correlates well with SF-36 role-physical ($r_s=-0.53$) and SF-36 social functioning ($r_s=-0.43$); SF-36 physical functioning correlates similarly. For impairment and participation restriction dimensions only SF-36 bodily pain is substantially correlated ($r_s=0.47$ and 0.48) with SF-36 role-physical, after correcting for the influence of the activity limitation dimension (HAQ and SF-36 physical functioning).

Conclusions: In this cross sectional study of patients with RA, impairments are associated with activity limitations, and activity limitations are associated with participation restrictions. Pain is the only impairment directly associated with participation restrictions. Based on the results of this study, it is strongly recommended that the ICIDH-2 framework is used in clinical trials and observational studies including the assessment of disease consequences in RA.

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Rheumatoid arthritis (RA) is a chronic disabling disease. As patients with RA may have a shorter life expectancy than the general population,^{1,2} and their increase in disability may be serious,² RA must not be looked at as a benign, non-fatal disease.¹ Features of active RA can be assessed by clinical tools and can be represented by biological markers like the C reactive protein (CRP) and by inflammatory cytokines.³ The latter are thought to have a major role in the pathogenesis of the disease,⁴ but the cause of RA is still unknown.^{4,5} Thus the clinical features seen in patients are, at best, indicators of the underlying disease process.

The RA disease process may lead to impairments in functions and structures of the body, such as pain, fatigue, joint stiffness, joint swelling, loss of range of motion, muscular weakness, and joint damage. Impairments may induce activity limitations, such as difficulties in walking, climbing stairs, dressing, doing duties, or manipulating objects. Impairments, and especially activity limitations, may restrict participation in society, which means restrictions in fulfilling family roles, roles at work, and in the wider social environment. The relations between impairments, activity limitations, and participation restrictions can in turn be influenced by the disease process itself and by other factors such as anxiety, depressiveness or depression, coping strategies, social support, life style, or job demands.

Based on earlier work by Nagi and the World Health Organisation,^{6,7} several models have been used to describe systematically the consequences of disease in general,^{8,9} of rheumatic disease in adults,¹⁰ and also in children.^{11,12} With integration of experience from the past, a new model is currently in the final phase of construction (fig 1), the

so-called "Model of functioning and disability" of the International Classification of Impairments, Disabilities, and Handicaps (ICIDH-2).¹³ This model was considered in the description of the consequences of RA disease above. According to the ICIDH-2, information is organised into three dimensions: (a) body level; (b) individual level; (c) societal level. These dimensions are named: (a) body functions and structure; (b) activities; and (c) participation. In addition, contextual factors are recognised which include both personal and environmental factors. More specifically, the model distinguishes disease from disease consequences and influencing contextual factors; the model links its dimensions with double sided arrows, symbolising room for bidirectional influences and interactions; and disease consequences can be named in positive terms, emphasising that abilities as well as disabilities are regarded as important factors. For the purpose of this article, we use the negative aspects.

So far, the conceptual model of the ICIDH-2 seems to fit well to a chronic disease such as RA. However, the "empty" ICIDH-2 model as presented in fig 1A does not contain real information. The model has to be "filled" with valid estimators

Abbreviations: CRP, C reactive protein; DAS28, disease activity index; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Questionnaire; ICIDH, International Classification of Impairments, Disabilities, and Handicaps; RA, rheumatoid arthritis; RADAI, rheumatoid arthritis disease activity index; SF-36, Short Form-36

Figure 1 (A) Modelling function and disability.¹³ Reproduced with permission of the WHO. (B) Allocation of variables to the ICIDH-2 model of functioning and disability.

of the underlying dimensions and with strengths of the relations in between (fig 1B). Ideally, the direction and the magnitude of causal relations between dimensions, and the influence of modifying factors of these relations, are known. This study is a first step in documenting the fit of the ICIDH-2 model to RA.

This cross sectional study in patients with RA aims at investigating the relationship between measures of the impairment, activity limitation, and participation dimensions of the model of functioning and disability (ICIDH-2).

PATIENTS AND METHODS

Patients

We made use of the data from a Swiss-wide cohort of patients with RA taking part in a clinical quality management project, the Swiss Clinical Quality Management in RA (SCQM).¹⁴ Participating rheumatologists and patients are from university and regional hospitals and private practices. Patients may be included if they have a diagnosis of RA according to the 1987 revised American College of Rheumatology (ACR) criteria,¹⁵ and give their written consent. The data are taken from all inclusion visits from August 1997 until October 1998.

Data collection

The inclusion visit includes clinical examination and the taking of a blood sample. Questionnaires are filled in by the patient immediately, or at home, and returned to the rheumatologist the same week. The data are collected by the rheumatologist and sent to the coordination centre, together with radiographs of the hands and feet that are not older than six

months. Data are only accepted by the coordination centre if all forms are complete.

Variables

The dimensions of the ICIDH-2 model (fig 1) were constructed based on the data already acquired for the clinical quality management programme.

Rheumatoid factor positivity,^{16–18} sex, and disease duration¹⁸ were chosen as factors that represent the disease (RA). These factors can be thought of as closely related to the underlying disease and as predictive for the disease course. However, there is no definitive agreement on which factors are predictive for disease course in RA, except that no one factor alone is powerful enough.¹⁵

The composite measures disease activity score (DAS28),¹⁹ rheumatoid arthritis disease activity index (RADAI),^{20, 21} and bodily pain of the Short Form-36 (SF-36),²² reflect disease activity on impairment level. Composite measures rather than single measures were used because they may describe the underlying disease activity better than single measures.²³ The RADAI is a questionnaire on signs and symptoms of RA with scores ranging from 0 to 10, where 0 indicates no problems and higher scores indicate a higher level of disease activity.

The DAS28 was calculated from the results of a 28 swollen joint count, a 28 tender joint count, and the erythrocyte sedimentation rate (ESR).¹⁹ The DAS28 ranges virtually from 0 to 10, with higher values indicating a higher level of disease activity.

The SF-36 on general health,²² counts eight subscales ranging from 0 to 100, with higher scores indicating a better health condition. Validated German, French, and Italian SF-36 questionnaires were used.²⁴ Damage to the joints was assessed by radiographs of the hands and feet. Joint damage was scored according to the method proposed by Rau *et al*, with a slight modification of the scoring for the wrist joint (x ray score).²⁵ The score ranges from 0, indicating no destruction, to 160, indicating complete destruction of included joints.

The disability section of the Stanford Health Assessment Questionnaire (HAQ),^{26–29} and the physical functioning scale of the SF-36 were used to describe activity limitations. Most items of the SF-36 physical functioning scale concern the legs, whereas the HAQ contains a lot of items that are related to functioning of the arms. The HAQ score ranges from 0 to 3, with higher scores indicating more severe problems.

The role-physical, role-emotional, and social functioning scales of the SF-36 were defined as dealing with societal roles and societal functioning.²²

Educational level and living together (yes/no) were chosen as environmental factors^{30, 31}; vitality and mental health of the SF-36, number of comorbidities, and age were regarded as personal factors. Comorbidities were self assessed with a standardised questionnaire.³² Educational level was self assessed on a six item scale, ranging from “no formal education” to “university”. Educational level was regarded as a proxy for societal level; however, income level or living area may in fact be better estimators.³⁰ In the case of RA, the SF-36 vitality scale may reflect aspects of fatigue as well as depressiveness.

Data processing and statistical analysis

The data were stored in an Access 7.0 relational database and were processed with SAS 6.11 statistical software package.³³ For the description of sex differences in the population, the two sample *t* test or two sample Wilcoxon test was used for continuous data; the χ^2 test was used when comparing numbers in groups. Spearman's correlation coefficient was used to study relationships between continuous variables. Effects of potentially mediating variables were excluded using Spearman's partial rank order correlations.³⁴ A partial correlation coefficient is a measure of the strength of the relationship between two variables after controlling for the effects of another variable.³⁵

Table 1 Population characteristics

	Men	Women	Total
Number	230	572	803
Age (years), mean (SD)	60 (12)	59 (13)	59 (13)
Disease duration (years), median (IQR)	5 (2–13)	8 (3–15)*	7 (2–14)
RA <2 years, No (%)	65 (31)	106 (20)*	171 (23)
RF+, No (%)	153 (74)	393 (75)	546 (75)
NSAIDs yes, No (%)	156 (71)	403 (73)	559 (72)
DMARDs yes, No (%)	202 (91)	497 (90)	699 (90)

*p<0.001 for differences between the sexes.

IQR, Interquartile range; %, column percentage based on non-missing values. One patient did not indicate sex; RF, rheumatoid factor; NSAIDs, non-steroidal anti-inflammatory drugs; DMARDs, disease modifying antirheumatic drugs.

Table 2 Correlations between measures of the activity limitation dimension and impairment and participation dimensions. Results are shown as mean (SD) or median (IQR)

	No	Possible range	Score	Activity	
				HAQ (r_s)	SF-36 PF (r_s)
Impairment					
SF-36 BP	795	0–100	45 (24)	–0.61	0.59
DAS28	776	0–10	4.2 (1.6)	0.49	–0.46
RADAI	781	0–10	3.2 (1.8–5)	0.58	–0.55
x Ray score	663	0–160	6 (0–23)	0.35	–0.30
Activity					
HAQ	788	0–3	1.0 (0.38–1.63)	1.0	–0.77
SF-36 PF	786	0–100	55 (33.3–80)	–0.77	1.0
Participation					
SF-36 SF	794	0–100	88 (63–100)	–0.43	0.49
SF-36 RE	753	0–100	100 (33–100)	–0.26	0.30
SF-36 RP	773	0–100	25 (0–100)	–0.53	0.52

No, represents the number of non-missing values. p<0.0001 for all r_s .

Correlations are calculated on samples varying from n=747 to n=795, except for correlations with x ray score, where the smallest sample size is n=653. SF-36 BP, SF-36 bodily pain; DAS28, disease activity score; RADAI, rheumatoid arthritis disease activity index; x ray score, Ratingen radiographic damage score; HAQ, Stanford Health Assessment Questionnaire; SF-36 PF, physical functioning; SF-36 SF, social functioning; SF-36 RE, role emotional; SF-36 RP, role physical.

Probability values lower than 0.05 (two sided) were regarded as significant. Where multiple comparisons were performed on a single hypothesis, a Bonferroni procedure was applied on α .

RESULTS

Sample

A total of 803 patients were included in the study (table 1), of whom 572 (71%) were women, who have a longer median disease duration than men. There were proportionally more men with early RA (time since diagnosis less than two years)

included in the sample. No other statistically significant differences between the sexes were noted.

The drug use in table 1 refers to the actual use.

Dimension scores

Table 2 gives the scores and distributions of the measures of impairment, activity limitation, and participation restriction. Of those measures, SF-36 bodily pain and DAS28 have a normal distribution, all other variables are skewed. Figure 2 depicts the measures of the activity limitation dimension, showing remarkable floor and ceiling effects.

Figure 2 Distributions of HAQ and SF-36 physical functioning (SF-36 PF). On the left a histogram of HAQ scores is shown (n=788), on the right, a histogram of the scores on the SF-36 PF scale (n=786).

Table 3 Correlations between measures of the impairment and participation dimensions after correction for the influence of the HAQ and SF-36 PF

After correction for:	Participation					
	SF-36 SF		SF-36 RE		SF-36 RP	
	HAQ	PF	HAQ	PF	HAQ	PF
Impairment						
SF-36 BP	0.31	0.29	0.28	0.26	0.47	0.48
DAS28	-0.19	-0.19	-0.14	-0.13	-0.23	-0.26
RADAI	-0.31	-0.30	-0.31	-0.34	-0.24	-0.36
x Ray score	0.04*	0.03*	0.08*	0.08*	0.08*	0.05*

* $p > 0.01$; all other r are significant at $p < 0.0001$. Correlations are calculated on samples varying from $n = 725$ to $n = 794$, except for correlations with x ray score, where the smallest sample size is $n = 622$. For abbreviations see table 2.

Table 4 Dimension scores by disease characteristics. Values are given as mean (SD) or as median (IQR)

	Possible range	Sex		Rheumatoid factor		Disease duration	
		Male	Female	Positive	Negative	≤ 2 Years	> 2 Years
Impairment							
SF-36 BP	0–100	48 (24)	44 (24)	44 (24)	48 (24)*	44 (22)	46 (25)
DAS28	0–10	3.9 (1.7)	4.3 (1.5)***	4.3 (1.5)	3.8 (1.6)**	4.2 (1.6)	4.2 (1.6)
RADAI	0–10	2.9 (1.6–3.6)	3.3 (1.8–5.1)	3.4 (1.9–5.0)	2.9 (1.6–4.5)*	3.3 (2.0–5.1)	3.1 (1.7–4.9)
x Ray score	0–160	4 (0–21)	6 (1–24)	7 (1–26)	3 (0–14)***	0 (0–5)	9 (2–32)***
Activity limitation							
HAQ	0–3	0.8 (0.1–1.5)	1.1 (0.5–1.8)***	1.1 (0.5–1.8)	0.8 (0.1–1.5)**	0.9 (0.3–1.4)	1.1 (0.5–1.8)***
SF-36 PF	0–100	63 (40–85)	55 (30–80)**	55 (30–80)	65 (40–83)*	66 (40–85)	55 (30–80)**
Participation restriction							
SF-36 SF	0–100	88 (63–100)	75 (63–100)	75 (50–100)	88 (63–100)	75 (63–75)	88 (56–100)
SF-36 RE	0–100	100 (33–100)	100 (33–100)	100 (33–100)	100 (33–100)	100 (0–100)	100 (33–100)
SF-36 RP	0–100	50 (0–100)	25 (0–100)*	25 (0–100)	50 (0–100)	25 (0–75)	25 (0–100)

* $p < 0.05$; ** $p < 0.001$; *** $p < 0.0001$.
For abbreviations see table 2.

Correlations within dimensions

Within the impairment dimension, SF-36 bodily pain and RADAI were highly correlated: $r_s = -0.71$ ($p < 0.0001$). SF-36 bodily pain and RADAI were both moderately correlated with the DAS28: $r_s = -0.51$ and $r_s = 0.54$, respectively ($p < 0.0001$). The correlation coefficients of the x ray score with the other three measures were lower than 0.20, but significant ($p < 0.0001$). Within the activity limitation dimension, HAQ and SF-36 physical functioning were highly correlated: $r_s = -0.77$ ($p < 0.0001$). Within the participation restriction dimension, the three measures SF-36 social functioning, SF-36 role-physical, and SF-36 role-emotional were identically intercorrelated at $r_s = 0.48$ ($p < 0.0001$).

Correlations between dimensions

The correlations of both the HAQ and the SF-36 physical functioning with measures of impairment and participation dimensions were quite similar (table 2). Of the impairment dimension, the self assessment measures SF-36 bodily pain and RADAI correlated most highly with HAQ and SF-36 physical functioning. The x ray score correlated the least with HAQ and SF-36 physical functioning. Of the participation dimension, SF-36 role-physical, and to a lesser extent SF-36 social functioning, correlated best with HAQ and SF-36 physical functioning. The correlations with SF-36 role-emotional were relatively low. The relations between measures of the impairment and participation dimensions were corrected for

Table 5 Correlations between measures of the activity limitation dimension and contextual factors

	Contextual factors				
	Education	Age	Comorbidities	SF-36 VT	SF-36 MH
Impairment					
SF-36 BP	0.10*	0.00 ^{NS}	0.20**	0.60**	0.38**
DAS28	0.00 ^{NS}	0.08*	-0.10*	-0.39**	-0.25**
RADAI	-0.06 ^{NS}	-0.04 ^{NS}	-0.16**	-0.50**	-0.39**
x Ray score	0.08 ^{NS}	0.19**	-0.05 ^{NS}	-0.06 ^{NS}	0.02 ^{NS}
Activity					
HAQ	-0.14**	0.13**	-0.23**	-0.52**	-0.30**
SF-36 PF	0.13**	-0.14**	0.26**	0.54**	0.34**
Participation					
SF-36 SF	0.03 ^{NS}	0.04 ^{NS}	0.18**	0.57**	0.63**
SF-36 RE	0.11*	0.00 ^{NS}	0.19**	0.46**	0.57**
SF-36 RP	0.06 ^{NS}	-0.09*	0.20**	0.56**	0.38**

For all Spearman's r_s , * $p < 0.05$; ** $p < 0.0001$.
SF-36 VT, Vitality; SF-36 MH, mental health. For other abbreviations, see table 2.

the influence of the HAQ and the SF-36 physical functioning. Only the partial correlations of SF-36 bodily pain with SF-36 role-physical were substantial (table 3). SF-36 bodily pain and RADAI had the highest partial correlations with all three measures of the participation dimension.

Disease and dimensions

The values of the impairment, activity, and participation dimensions are listed according to sex, rheumatoid factor, and disease duration (table 4). Differences between the sexes were found for disease activity (DAS28), activity limitation (HAQ and SF-36 physical functioning), and for SF-36 role-physical. For rheumatoid factor, significant differences were found in all measures of the impairment and activity limitation dimension. Between early RA (disease duration ≤ 2 years) and late RA there were significant differences for *x* ray score, HAQ, and SF-36 physical functioning. Because in our sample, the women had longer disease duration than the men, the influence of sex corrected for disease duration was studied in addition. In early RA, no sex difference between HAQ and SF-36 physical functioning score was found. In late RA, there was a difference between the sexes for the HAQ: a median of 0.8 for men and 1.2 for women ($p=0.0002$), for SF-36 physical functioning there was a relatively small and non-significant difference of five points in favour of men ($p=0.02$). The α error level for this four group comparison was set at 0.0125.

Contextual factors and dimensions

Among the defined contextual factors, SF-36 vitality and mental health, followed by comorbidities, had the highest correlations with the measures of the impairment, activity and participation dimensions, except for the *x* ray score (table 5). There were no differences in HAQ or SF-36 physical functioning ($p>0.05$) for people living alone or together (results not shown).

DISCUSSION

The results of this cross sectional study in patients with RA show that joint damage (*x* ray score) is not related to disease activity (DAS28), but is related to activity limitation (HAQ, SF-36 physical functioning). The measures of the impairment dimension (bodily pain, RADAI, DAS28, *x* ray score) are relatively well correlated with measures representing activity limitation (HAQ, SF-36 physical functioning). The measures of the activity limitation dimension (HAQ, SF-36 physical functioning) are relatively well correlated with measures that represent participation restriction, especially SF-36 role-physical. The measures of the impairment dimension are not directly related to measures of the participation restriction dimension, except for SF-36 bodily pain, which correlates with SF-36 role-physical.

In our cross sectional study there is a low correlation between disease activity (DAS28) and joint damage (*x* ray score). This is logical as joint damage can be seen as the product of disease activity in the past. Thus the momentary level of disease activity is independent of the level of joint damage. It has been pointed out that in early RA, time integrated disease activity (CRP) may very well predict joint damage.³⁶

As a consequence, it can be stated that activity limitations, as well as pain, may be important causes of participation restrictions in patients with RA. Furthermore, our results support the use of the ICIDH-2 model of the World Health Organisation as a framework for the assessment of disease consequences in patients with RA. Firstly, it is possible to put the ICIDH-2 model into operation with validated measures for use in RA that already exist. In addition, the relation between the impairment, activity limitation, and participation restriction dimensions follow the expectations about the process of disablement in RA derived from other studies.

The effect of coping on disability was studied longitudinally in a sample of 63 male patients with RA.³⁷ It was found that disease activity was directly related to both pain and the cognitive coping process, which in turn were related to physical and psychological disability at six months. Similar results to those of our study were found in a cross sectional study of 706 patients with early RA (≤ 4 years) from four European countries.³⁸ It was found that the Ritchie articular index, sex, ESR, and disease duration were correlated with disability (HAQ), whereas rheumatoid factor, age, education level, and joint damage (*x* ray score) were not. In our study we found no difference between the sexes in the HAQ score in early RA, but this was found in later RA. In a longitudinal study with 85 patients with RA,³⁹ it was found that sex, age, joint count, disease duration, depression, self efficacy, pain, and the Keitel function scale explained 64% of the variance in the current HAQ score and 49% of the variance in HAQ at one year's follow up. An interesting consideration on longitudinal development of disability comes from a study of 337 patients with RA.⁴⁰ Multivariate regression analysis showed that in early RA (< 5 years) functional disability (M-HAQ) is mainly related to the level of inflammation. In late RA (> 5 years) functional disability depends on the disease duration, joint damage, and extra-articular manifestations.⁴⁰

The influences of disease characteristics and contextual factors on relations between the dimensions of the ICIDH-2 are best evaluated with a longitudinal study. A cross sectional study including patients with a large range of age and disease duration cannot replace a longitudinal study of within-patient changes.⁴¹

In contrast with previous studies on the modelling of disease consequences in RA, we tried to integrate participation restriction, as foreseen by the ICIDH-2.¹³ Three subscales of the SF-36 (social functioning, role-emotional, role-physical) were thought to reflect participation restriction. However, despite a wide span of disease duration and a wide range of HAQ scores, there were ceiling effects for the role-emotional and social functioning scales, indicating no participation restrictions. The question can be raised whether participation restrictions in RA can be measured by the SF-36, assuming larger participation restrictions in the RA population. Other studies that used the SF-36 with even more severely disabled patients with RA show the same pattern as in our study.^{42, 43} Work disablement, in particular, is not considered specifically in the SF-36. Another limitation of our study is that the *x* ray score showed a floor effect, indicating that a lot of patients have only a few erosions of the scored joints. The reason may well be that the sample is population based and includes a lot of patients with mild RA. The floor effect may contribute to the relatively low correlations of other measures with the *x* ray score. In our study several contextual factors potentially relevant to patients with RA have not been studied, but there are logical as well as scientific arguments for including coping style,³⁷ depression or depressiveness, and self efficacy³⁹ as variables when studying disease consequences in RA. Future studies may focus on participation restriction and factors potentially influencing participation.

We are convinced that the ICIDH-2 offers a useful framework for understanding the complex relationship of disease consequences in RA. This understanding may have practical implications for assessment in studies and for treatment as well.

For studies, the framework of the ICIDH-2 can be used to model relations between disease consequences and influencing factors in advance. This may not only help in stating study expectations and primary outcome measures but also in correcting for confounding and/or effect modification after the study has been done. However, a prerequisite is that disease consequences and contextual factors are measured reliably and validly within the context of the study. To standardise the design and reporting of (longitudinal) observational studies

in rheumatology, the OMERACT IV conference recommended a preliminary core set of seven domains, in congruence with the ICDH-2 model.⁴⁴ These domains are health status, disease process, damage, mortality, toxicity/adverse reactions, and, if appropriate, work disability and costs.

Modelling of the disease consequences of RA may have practical implications for treatment also. Awareness can be raised of the burden of the disease to the patient and of possible treatment approaches, beyond suppression of disease activity alone. Further, disease consequences can be assessed systematically to enable planning of treatment strategies and monitoring of treatment outcomes.⁴⁵ It may be an advantage for multidisciplinary patient care if modelling and systematic assessment of disease consequences are used to find a common language, define common goals, and coordinate treatments.⁴⁶

Future studies should try to study the direction and measure the magnitude of causal relations between dimensions of the ICDH-2 model, and quantify the influence of modifying factors on these relations. This can be done using multivariate modelling in longitudinal studies.

CONCLUSION

In this cross sectional study of patients with RA, impairments are associated with activity limitations, and activity limitations are associated with participation restrictions. Pain is the only impairment directly associated with participation restrictions. Based on the results of this study, we strongly recommend the use of the ICDH-2 framework in clinical trials and observational studies, including the assessment of disease consequences in RA.

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