

Construction of an ICF core set and ICF-based questionnaire assessing activities and participation in patients with systemic sclerosis

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Abstract

Objectives. To develop an International Classification of Functioning, Disability and Health (ICF) core set for SSc and to conceive a patient-centred ICF-based questionnaire assessing activities and participation in patients with SSc.

Methods. The construction of the ICF core set followed two steps. In the first step, meaningful concepts related to SSc were collected using data source triangulation from patients ($n = 18$), experts ($n = 10$) and literature ($n = 174$ articles). In the second step, concepts were linked to the best-matching ICF categories by one reviewer according to prespecified linking rules. Finally, patient-reported activities and participation categories of the ICF core set were translated into understandable questions.

Results. After linking concepts to ICF categories, 150 ICF categories were collected from focus groups, 22 from experts and 82 from literature. After fusion of the sources and removal of duplicates, the ICF core set included 164 categories: one at the first level, 157 at the second level and six at the third level, with 50 categories on body functions, 15 on body structures, 52 on activities and participation, and 47 on environmental factors. Patient-reported ICF categories on activities and participation were translated into a patient-centred ICF-based 65-item questionnaire.

Conclusion. The present study proposes an ICF core set that offers a conceptual framework for SSc patients' care and health policy. Using a patient-centred approach, a patient-centred ICF-based questionnaire, the Cochin Scleroderma ICF-65 questionnaire, assessing activities and participation in patients with SSc, was conceived.

Trial registration. ClinicalTrials.gov, <http://clinicaltrials.gov>, NCT01848418.

Key words: International Classification of Functioning, Disability and Health (ICF), ICF core set, SSc

Rheumatology key messages

- Our ICF core set comprehensively describes the functioning of people with SSc.
- Our patient-centred ICF-derived self-administered questionnaire assesses activities and participation important to people with SSc.
- It offers a relevant conceptual framework for health care and policy in SSc.

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Introduction

SSc is a rare autoimmune disease involving skin, vessels, joints and internal organs [1, 2]. It significantly impairs patients' functioning and health-related quality of life [3, 4]. The International Classification of Functioning, Disability and Health (ICF) was proposed by the World Health Organization (WHO) in 2001 in order to set a unified language and common conceptual framework to cover all aspects of human functioning. These aspects include body structures and functions, and activities and participation, and interact with environmental and personal factors. In the case of SSc, all the spectrum of functioning can be affected leading to disability, as defined by the WHO as 'an umbrella term, covering impairments, activity limitations, and participation restrictions. Impairment is a problem in body function or structure; activity limitation is a difficulty encountered by an individual in executing a task or action; and participation restriction is a problem experienced by an individual in involvement in life situations'.

Guidelines regarding assessment of SSc have progressively shifted from recommendations for quantifying organ damage [5] to recommendations for measuring functioning [6]. However, these recommendations refer to physical functioning and health-related quality of life, [7] rather than to functioning as defined by the WHO. In the past decade, efforts have been made to increasingly implement patient-reported outcomes such as the Scleroderma Health Assessment Questionnaire [4, 8], the Cochin Hand Function Scale [8, 9], the Mouth Handicap in SSc Scale [9, 10] and the McMaster Toronto Arthritis Patient Preference Disability Questionnaire [11, 12], to specifically assess SSc-specific activity limitation in trials [13] and daily practice. The clinical interpretation of these scores is challenging [14] and most of these instruments have been developed to assess disease consequences, rather than individuals' functioning. Further, they have been derived from literature and experts' view rather than patients'. Therefore, they cover selected aspects of the whole patient experience of SSc and disregard others such as participation. In an initiative designed to overcome these limitations and to clarify processes leading to development of ICF core sets in SSc, the European Scleroderma Trials and Research group suggested combining complementary strategies and to triangulate data sources in order to obtain the broadest collection of SSc descriptors [15].

In the present study, we constructed an ICF core set for patients with SSc and translated patient-reported activities and participation categories of the ICF core set into an original patient-centred ICF-based questionnaire assessing activities and participation.

Methods

Study design overview

The construction of the ICF core set for SSc followed current guidelines [16]. In the first step, concepts relevant to patients with SSc were collected using data source

triangulation from patients using a qualitative approach, from professionals using an expert survey and from literature using a systematic review. In the second step, the concepts collected using these three sources were linked to the best-matching ICF categories by one reviewer (A.P.) using standardized linking rules [17]. Finally, patient-reported activities and participation categories of the ICF core set were translated into understandable questions by a sociologist of the French ICF Research Branch (S.A.) and double-checked with the reviewer who linked collected concepts to ICF categories (A.P.) such that ICF categories and derived questions were consistent. The SCISCIF (Conception of an ICF Core Set for Systemic Sclerosis) study complied with the Declaration of Helsinki. The locally appointed ethics committee (Comité de Protection des Personnes Île-de-France I) approved the research protocol. Informed consent was obtained from all the participating subjects.

Collection of concepts from patients

To identify which functioning, personal and environmental factors were meaningful to patients with SSc, we used a qualitative approach with focus group interviews [16]. A convenience sample of 18 patients followed up in a tertiary care centre [Centre de Référence pour les Maladies Systémiques Auto-Immunes Rares d'Île-de-France (Cochin Hospital, Paris, France)] was invited to participate in focus groups. Recruitment started in October 2012 and was completed in June 2013. The number of patients was determined by convenience based on the number of eligible patients on the specified period of time. This convenience sample allowed reaching data saturation defined as the point at which no new information or themes were observed for the data [18]. Inclusion criteria, stated in 2010, were: 18 years and older, diagnosis of SSc according to 1980 ACR [19] and/or Leroy and Medsger criteria [20]. Eventually, all patients fulfilled the 2013 ACR/EULAR criteria [21]. Exclusion criteria were: severe chronic disease (stroke, multiple sclerosis, Parkinson's disease, etc.), cognitive or behavioural disorders making assessment impossible, and inability to speak French. No patients refused to participate or dropped out. Concepts were collected using semi-structured interviews conducted during four focus groups, with a maximum of six participants per group, in a consultation room at Cochin Hospital, on 27 October 2012, 15 December 2012, 19 January 2013 and 21 June 2013. Focus groups were non-mixed-gender to encourage free talk between participants especially regarding possible genital and sexual issues. All 3-h focus group sessions were chaired by the same experienced sociologist (S.A.) trained to conduct qualitative studies and specialized in health research. No relationship was established prior to study commencement between her and the participants and no one else was present besides participants and researcher. A short introduction to the purpose of the study was given in lay terms to all patients at the beginning of each focus group. Interviews were designed to encourage discourse and

comments on each participant's experiences and views and the moderator held back every time she felt it necessary to encourage free talk between participants. The moderator focused on patients' views on SSc, namely disease consequences and subsequent adjustments and expectations for improving health care [22]. The moderator structured the interview using three lists based on the ICF: a list of body functions and structure, a list of activities and participation, and a list of environmental factors. Focus group sessions were audio-recorded, anonymized and fully transcribed by the interviewer with the interviewees' agreement in order to complete the notes taken. The content of the observation notes and written transcripts were analysed by one researcher, a senior specialist in physical and rehabilitation medicine, who had experience in ICF linking (A.P.). The transcripts were decomposed into key themes, themselves divided into meaningful concepts. Participants were not asked to provide any feedback on the findings. No software was used to manage the data.

Collection of concepts from experts

Ten international French-speaking experts [seven physicians (three senior specialists in internal medicine, two in dermatology, one in physical and rehabilitation medicine and one in rheumatology), one physiotherapist, one occupational therapist and one patient from the French patients' association (Association des Sclérodermiques de France) (see Acknowledgements) not involved in the design or in the conduct of the study and with focal expertise in SSc manifestations were surveyed [15]. A standardized checklist of all ICF body functions and structures was submitted by mail or email from 16 July 2014 to 4 August 2014. Experts were asked to select, in the checklist, all the second level items that seemed significantly modified by SSc. An item of the checklist was included in the final core set when it was cited by at least eight experts. Experts were not surveyed about activities and participation and environmental factors, because their views regarding these components are inconsistent with those from patients [23].

Collection of concepts from literature

The PubMed database was searched on 7 June 2016, using the following keywords ('systemic sclerosis' AND 'outcome measures'). The search was limited to articles in English or French, involving humans and published in the previous 10 years. Titles and abstracts were qualitatively assessed by two independent reviewers (F.S. and A.P.). After consensus on eligible titles and abstracts, full-texts were retrieved and independently examined. After removal of duplicates and consensus on eligible full-texts, articles were further reviewed if they reported at least one outcome measure from a randomized controlled trial, a cross-sectional study or a prospective cohort study. Articles were excluded if they did not report an outcome measure or if they were reviews, meta-analyses, case reports, letters, retrospective

studies or secondary studies. In order to avoid selection of concepts that would reflect limited views of specific categories of health care providers, outcome measure instruments were fully reviewed if they were reported at least twice by at least two independent groups. For each article, outcome measures were analysed as long as they were considered to reflect the health status or functioning of patients with SSc, resulting from an intervention or just a survey. Each item of each instrument was deconstructed into its most basic meaningful concepts.

Linking of concepts to ICF categories

ICF codes related to ICF categories are built in the same way with a letter referring to one of the four ICF components [namely body function (b), body structure (s), activities and participation (d) or environmental factors (e)] and a series of one to five numbers referring to the levels (the first digit refers to a chapter of an ICF category and constitutes an item at the first level, the two following digits refer to a subheading of the related chapter and constitute an item at the second level, digits four and five refers to the third and fourth levels and are, respectively, subparts of the previous subparts). For the purpose of our study, the list of most basic concepts generated by patients, experts and literature was linked to the best-matching ICF categories by one reviewer (A.P.), with experience in ICF linking, according to prespecified standardized linking rules [24] and their updates [17, 25]. Briefly, all meaningful concepts within each item of a health status measurement were identified. Each concept was then linked as specifically as possible. Every item 'unspecified' or 'other specified' was avoided and the upper level item was chosen. Clinical outcome measures were linked regarding the aim with which the clinical measure was used, and could vary from one investigation to another. Meaningful concepts referring to health in general were assigned 'nd-gh', those referring to a health condition were assigned 'nd-hc'. Finally, some concepts could not be assigned to any ICF item and were assigned 'nd-nc'. At the end of each linking, if several items of third or fourth levels belonged to the same item of second level, they were replaced by this item of second level. The final ICF core set resulted from the pooled collection of ICF categories generated by the three sources of concepts, namely patients, experts and literature. We did not perform further selection of the generated ICF categories by health professionals using group consensus exercises or Delphi consensus process as usually recommended, and did not to seek for face and content validity from specific groups [26, 27], because we thought that these additional steps would have altered the comprehensiveness of the ICF core set. Indeed, important discrepancies have been reported between health professionals' views and patients' [22]. Quantitative variables were described with means (standard deviation) and qualitative variables with absolute numbers (%).

Results

Patients

Overall, 18 French-speaking patients with SSc participated in four focus groups: the first group included six women, the second four women, the third two men and the fourth six men. Mean (s.d.) age was 56.5 (16.2) years, 8/18 (44.4%) participants had a diffuse cutaneous SSc and 8/18 (44.4%) a limited cutaneous SSc. For 2/18 (11.1%) participants, the disease subset was not recorded. Mean disease duration was 10.8 (9.9) years (Supplementary Table S1, available at *Rheumatology* online).

ICF categories generated by patients

Concepts collected from focus groups were linked to 150 ICF categories in total and included 41 categories on body functions, 14 on body structures, 50 on activities and participation, and 45 on environmental factors (Table 1). Overall, 77 categories of the ICF core set were generated by patients only, including 14 categories on body functions, eight categories on body structures, with two items of chapter 2: The Eye, Ear and Related Structures only related to the eye structure (s220 and s230) and 22 categories on activities and participations, with five of six items of chapter 8: Major Life Areas. All the 15 environmental factor items belonging to chapter 5: Services, Systems and Policies were generated only from patients' perspectives.

ICF categories generated by experts

Concepts collected from experts were linked to 22 ICF categories in total and included 15 categories on body functions and seven on body structures, with one of each generated only from experts survey. Most of the items reported by the experts were related to chapters 4 and 8, Function and Structures of the Cardiovascular, Haematological, Immunological and Respiratory Systems and Skin and Related Structures, respectively (Table 1). The 11 items from chapter 1 of Body Functions: Mental Functions were generated by patients and literature only (with six of them generated by both), but none by a sufficient number of experts to be sustained into the final ICF core set.

ICF categories generated by literature

PubMed search yielded a total of 743 references. A total of 174 articles were included in the analysis and served to collect concepts (Fig. 1), including 19 scales and 117 clinical outcome measures. All the scales included in the final analysis are presented in Supplementary Table S2, available at *Rheumatology* online. Concepts collected from literature were linked to 82 ICF categories in total and included 33 categories for body functions, five for body structures, 30 for activities and participation, and 14 for environmental factors. Seven categories, belonging to the body function section, two categories belonging to activities and participations and two categories belonging to

environmental factors were generated from the literature only (Table 1).

ICF core set

After fusion of the three sources of concepts, the ICF core set included a total of 164 ICF categories: one at the first level, 157 at the second level, and six at the third level, with 50 categories on body functions, 15 on body structures, 52 on activities and participation, and 47 on environmental factors (Table 2). Overall, 91 items were generated from only one source: 77 from patients, two from experts and eleven from literature. Based on the generated categories, all chapters of the ICF were represented in the final ICF core set, except chapter 1 of the body structures section: Structure of the Nervous System. Most of the body function categories belonged to chapter 1: Mental Functions (11 items), chapter 4: Function of the Cardiovascular, Haematological, Immunological and Respiratory Systems (eight items) and chapter 5: Functions of the Digestive, Metabolic, and Endocrine Systems (seven items). Most of the body structures categories belonged to chapter 4: Structure of the Cardiovascular, Immunological and Respiratory Systems (three items), chapter 7: Structure Related to Movement (three items) and chapter 8: Skin and Related Structures (three items). Most of the activities and participation categories belonged to chapter 4: Mobility (11 items), chapter 5: Self Care (seven items) and chapter 7: Interpersonal Interactions and Relationships (seven items). Finally, most the environmental factors categories belonged to chapter 5: Services, Systems and Policies (15 items), chapter 1: Products and Technology (10 items) and chapter 3: Support and Relationships (10 items).

Patient-centred ICF-based questionnaire for activities and participation

The 51 activities and participation ICF categories generated by patients were translated into understandable questions by the sociologist who interviewed them (S.A.). This allowed building a patient-centred ICF-based 65-item questionnaire on activities and participation, the Cochin Scleroderma ICF-65 questionnaire (Table 3). Four categories (d159, d535, d845 and d860) out of 51 were grouped together with other categories (d155, d530, d840 and d6200) to generate common questions because they referred to the same category of data in the focus groups. One code (d7401) was abandoned: participants of the focus groups quoted 'subordinate relationship' without any further details enabling a precise interpretation of this piece of data. In 12 cases, the sociologist decided to keep the fourth level ICF code and generated more than one question because the diversity of the situations described by the patients could not be translated into a unique question. This is, for instance, the case for d410 ('changing basic body position'), which gathered several situations such as d4101, 4102 and 4103 that were included in 'to get down on my knees, to squat alone', 4104 'to stand up alone' and 4105 'to bend forward'.

TABLE 1 Number of categories collected by source

	Patients	Experts	Literature	All sources ^a
Body functions	41	15	33	50
Body structures	14	7	5	15
Activities and participation	50	NA	30	52
Environmental factors	45	NA	14	47
Total number of categories	150	22	82	164

^aAfter removal of duplicates. NA: not assessed.

Discussion

The present ICF core set for patients with SSc was constructed based on a comprehensive data source triangulation as recommended [15] and included 164 ICF categories. The large number of ICF categories reflects the comprehensiveness of our sources and the great clinical heterogeneity of SSc and provides a relevant mapping of functioning of patients with SSc.

Patient-reported activities and participation of the ICF core set were translated into a patient-centred ICF-based 65-item questionnaire, the Cochin Scleroderma ICF-65 questionnaire. Because one of our objectives was to derive from the ICF core set a patient-reported outcome measure, we prioritized on patients' perspectives, as recommended by the US Food and Drug Administration guidance for patient-reported outcomes [28, 29]. The qualitative patient-centred approach identified 151/165 (91.5%) categories of the final ICF core set and 78/165 (47.3%) categories were generated by patients only. In terms of number of concepts and ICF categories generated by our patients, our results were consistent with previous findings by Stamm *et al.* [30] Using a similar patient-centred approach in 63 patients with SSc from four European countries, patients included in their study generated 181 categories in Austria, 99 in Romania, 159 in Sweden and 114 in Switzerland, and 86 higher-level ICF categories. Interestingly, only 19/86 (22.1%) categories were generated by patients from all countries (b130+b4552, b134, b152, b280, b415, b440, b510, b710+b715+b8, b898), and 23/86 (26.7%) categories emerged in one country only. This result suggests a great heterogeneity of SSc conceptual framework across countries [30]. Our population shared all the categories generated by patients from all the countries included in the study by Stamm *et al.*, except item b898. Item b898 was not included in our core set because we avoided any item 'unspecified' or 'other specified' and linked the concept to the upper level item. Our results, along with the findings of Stamm *et al.*, support the above categories as possibly universal items of the core set for SSc. However, a validation of other categories for different cultural backgrounds remains necessary. The possibility of constructing a cross-cultural measurement of functioning for patients with SSc on the basis of the

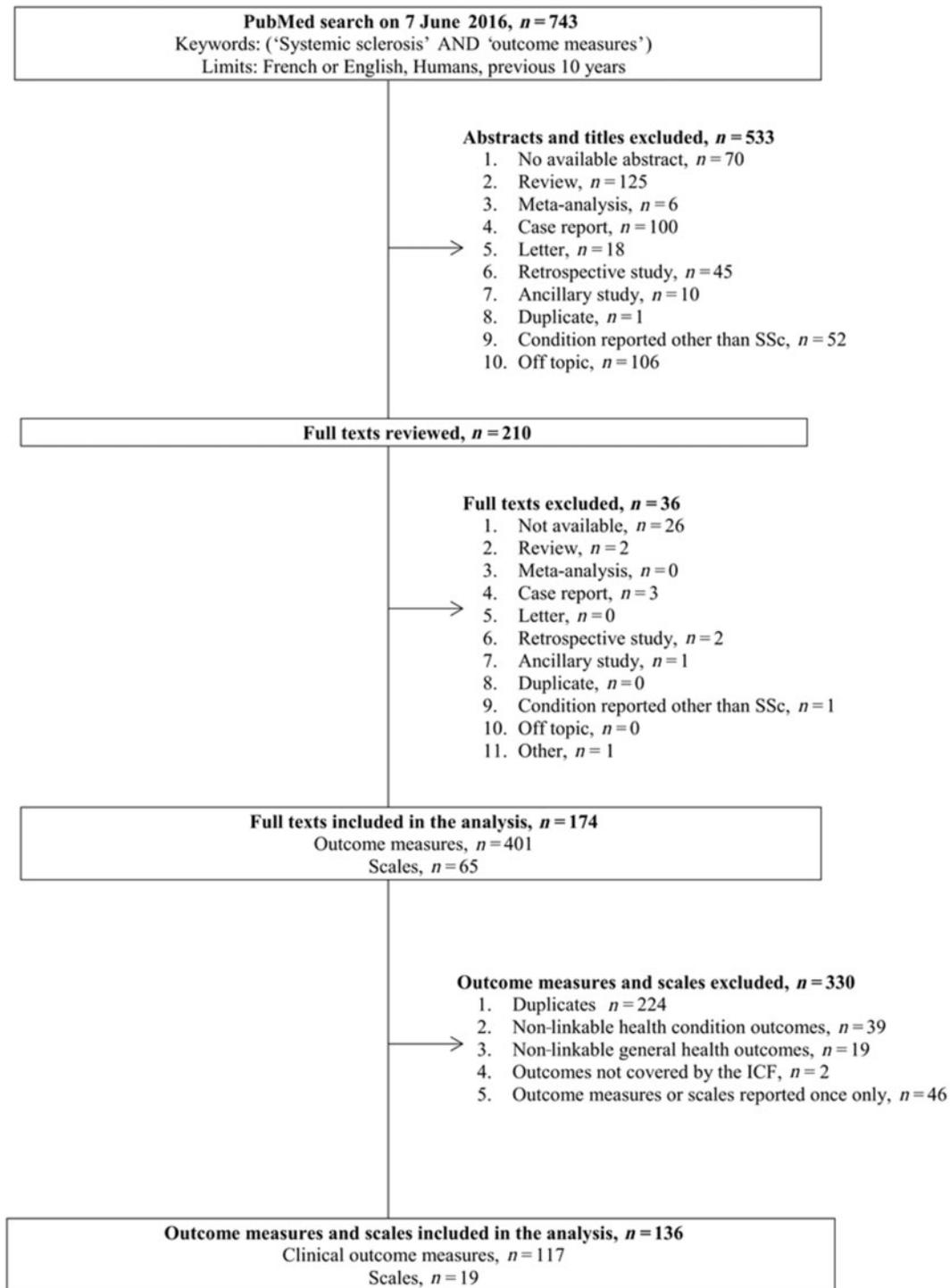
present ICF core set could be further explored in a multi-centre study with experts and patients from different countries using a Rash analysis, which may allow calculation of country-specific scores.

Regarding each source of concepts, one can notice that patients' perspectives covered all the 29 chapters included in the final ICF core set. Experts generated only two additional categories. Several hypotheses could explain our finding: experts mainly generate the same categories as patients, experts were too few or the cut-off for agreement at 80% was too high. Literature generated only 11 additional categories, mainly regarding body functions. Interestingly, categories related to environmental factors were massively generated from patients' perspectives, which contrasts with the lack of available instruments to assess these factors to date.

Involving a target population in the development of a patient-reported outcome measure is recommended [23, 28] and compulsory to satisfy regulatory bodies of the validity of labelling claims in medical product development [28]. However, most sets of response measures for clinical trials of SSc are disease-centred and disregard patients' views and needs [7]. As recently reviewed by Pauling *et al.* [23], only 7/13 (53.8%) patient-reported outcomes aiming at assessing patients with SSc did actually involve the target population in the items and domains' generation stage, namely the UK Scleroderma Functional Score [31], the Symptom Burden Index [32, 33], the SSc Questionnaire [34], the Scleroderma Assessment Questionnaire [35], the UCLA Scleroderma Clinical Trials Consortium Gastrointestinal Tract 1.0 and 2.0 questionnaires [36, 37] and the Mouth Handicap in Systemic sclerosis Scale [10]. Only 1/13 (7.7%) patient-reported outcomes involved a target population in the conceptual framework generation, namely the Mouth Handicap in SSc score [10]. Few generic ICF-based patient-reported outcomes have been developed. They include the Health and Functioning ICF-60 [38] and the WHO Disability Assessment Schedule 2.0 [39], for example. However, they do not target patients with SSc and have the same limitations as previous instruments.

In the present study, we built our patient-centred ICF-based questionnaire by deriving questions only from the patient-reported activities and participation section of

Fig. 1 Selection of outcome measures and scales from the literature used for the collection of concepts



ICF: International Classification of Functioning, Disability and Health.

the ICF core set. Our questionnaire was designed to have a strong content and face validities for activities and participation. Therefore, its construction included patient representation at every stage [28, 29]. In addition,

structuring patients' interviews using the ICF domains allowed us to map some aspects of functioning that may not have been spontaneously reported by patients.

TABLE 2 Comprehensive 164-item ICF core set for patients with SSc

ICF code	ICF category	Source
50 body functions		
b117	Intellectual functions	(1)
b126	Temperament and personality functions	(1), (3)
b130	Energy and drive functions	(1), (3)
b134	Sleep functions	(1), (3)
b1400	Sustaining attention	(3)
b144	Memory functions	(1), (3)
b147	Psychomotor functions	(1)
b152	Emotional functions	(1), (3)
b1600	Pace of thought	(1)
b164	Higher-level cognitive functions	(1), (3)
b180	Experience of self and time functions	(1)
b210	Seeing functions	(1)
b240	Sensations associated with hearing and vestibular function	(1)
b250	Taste function	(1)
b265	Touch function	(1)
b270	Sensory functions related to temperature and other stimuli	(1), (3)
b280	Sensation of pain	(1), (3)
b320	Articulations functions	(1)
b410	Heart functions	(1), (2), (3)
b415	Blood vessel functions	(1), (2), (3)
b420	Blood pressure functions	(3)
b430	Haematological system functions	(3)
b435	Immunological system functions	(1), (3)
b440	Respiration functions	(1), (2), (3)
b445	Respiratory muscle functions	(1), (2), (3)
b455	Exercise tolerance functions	(1), (2), (3)
b510	Ingestion functions	(1), (2), (3)
b515	Digestive functions	(1), (2), (3)
b520	Assimilation functions	(2), (3)
b525	Defecation functions	(1), (3)
b530	Weight maintenance functions	(1), (3)
b535	Sensations associated with the digestive system	(1), (3)
b550	Thermoregulatory functions	(1), (3)
b610	Urinary excretory functions	(3)
b620	Urination functions	(1)
b630	Sensations associated with urinary functions	(1)
b640	Sexual functions	(1), (3)
b660	Procreation functions	(1)
b670	Sensations associated with genital and reproductive functions	(1)
b710	Mobility of joint functions	(1), (2), (3)
b7202	Mobility of carpal bones	(3)
b730	Muscle power functions	(1), (2), (3)
b740	Muscle endurance functions	(1), (2), (3)
b770	Gait pattern functions	(1)
b7800	Sensation of muscle stiffness	(3)
b810	Protective functions of the skin	(1), (2)
b820	Repair functions of the skin	(1), (2), (3)
b830	Other functions of the skin	(3)
b840	Sensation related to the skin	(1), (2)
b860	Functions of nails	(2)
15 body structures		
s220	Structure of eyeball	(1)
s230	Structures around eye	(1)
s320	Structure of mouth	(1), (2), (3)
s410	Structure of cardiovascular system	(1), (2), (3)
s420	Structure of immune system	(2)
s430	Structures of respiratory system	(1), (2), (3)
s520	Structure of oesophagus	(1), (2), (3)

(continued)

TABLE 2 Continued

ICF code	ICF category	Source
s540	Structure of intestine	(1)
s610	Structure of urinary system	(1)
s730	Structure of upper extremity	(1)
s750	Structure of lower extremity	(1)
s770	Additional musculoskeletal structures related to movement	(1)
s810	Structure of areas of skin	(1), (2), (3)
s830	Structure of nails	(1), (2)
s840	Structure of hair	(1)
52 activities and participation		
d155	Acquiring skills	(1)
d160	Focusing attention	(1)
d166	Reading	(1)
d170	Writing	(1), (3)
d175	Solving problems	(1), (3)
d177	Making decisions	(1)
d2101	Undertaking a complex task	(1)
d220	Undertaking multiple tasks	(1)
d230	Carrying out daily routine	(1), (3)
d240	Handling stress and other psychological demands	(1)
d330	Speaking	(1), (3)
d350	Conversation	(1)
d360	Using communication devices and techniques	(1)
d410	Changing basic body position	(1), (3)
d415	Maintaining a body position	(1), (3)
d430	Lifting and carrying objects	(1), (3)
d435	Moving objects with lower extremities	(3)
d440	Fine hand use	(1), (3)
d445	Hand and arm use	(1), (3)
d450	Walking	(1), (3)
d455	Moving around	(1), (3)
d460	Moving around in different locations	(1), (3)
d470	Using transportation	(1)
d475	Driving	(1), (3)
d510	Washing oneself	(1), (3)
d520	Caring for body parts	(1), (3)
d530	Toileting	(1), (3)
d540	Dressing	(1), (3)
d550	Eating	(1), (3)
d560	Drinking	(3)
d570	Looking after one's health	(1), (3)
d6200	Shopping	(1), (3)
d630	Preparing meals	(1), (3)
d640	Doing housework	(1), (3)
d650	Caring for household objects	(1), (3)
d660	Assisting others	(1)
d710	Basic interpersonal interactions	(1)
d720	Complex interpersonal interactions	(1)
d730	Relating with strangers	(1)
d7401	Relating with subordinates	(1)
d750	Informal social relationships	(1), (3)
d760	Family relationships	(1)
d770	Intimate relationships	(1), (3)
d825	Vocational training	(1)
d830	Higher education	(1)
d840	Apprenticeship (work preparation)	(1)
d845	Acquiring, keeping and terminating a job	(1)
d850	Remunerative employment	(1), (3)
d860	Basic economic transactions	(1)
d920	Recreation and leisure	(1), (3)
d930	Religion and spirituality	(1), (3)
d950	Political life and citizenship	(1)

(continued)

TABLE 2 Continued

ICF code	ICF category	Source
45 environmental factors		
e110	Products or substances for personal consumption	(1), (3)
e115	Products and technology for personal use in daily living	(1), (3)
e120	Products and technology for personal indoor and outdoor mobility and transportation	(1), (3)
e125	Products and technology for communication	(1)
e135	Products and technology for employment	(1), (3)
e140	Products and technology for culture, recreation and sport	(1)
e150	Design, construction and building products and technology of buildings for public use	(1)
e155	Design, construction and building products and technology of buildings for private use	(1), (3)
e160	Products and technology of land development	(1)
e165	Assets	(1)
e2100	Land forms	(1)
e215	Population	(1)
e225	Climate	(1), (3)
e260	Air quality	(1), (3)
e3	Support and relationships	(3)
e310	Immediate family	(1), (3)
e315	Extended family	(1)
e320	Friends	(1), (3)
e325	Acquaintances, peers colleagues, neighbours and community members	(1)
e330	People in position of authority	(1)
e340	Personal care providers and personal assistants	(1)
e345	Strangers	(1)
e350	Domesticated animals	(1)
e355	Health professionals	(1)
e410	Individual attitudes of immediate family members	(1)
e415	Individual attitudes of extended family members	(1), (3)
e420	Individual attitudes of friends	(3)
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members	(1), (3)
e435	Individual attitudes of people in subordinate positions	(1)
e445	Individual attitudes of strangers	(1)
e450	Individual attitudes of health professionals	(1)
e460	Societal attitudes	(1), (3)
e510	Services, systems and policies for the production of consumer goods	(1)
e515	Architecture and construction services, systems and policies	(1)
e520	Open space planning services, systems and policies	(1)
e525	Housing services, systems and policies	(1)
e540	Transportation services, systems and policies	(1)
e545	Civil protection services, systems and policies	(1)
e550	Legal services, systems and policies	(1)
e555	Associations and organizational services, systems and policies	(1)
e560	Media services, systems and policies	(1)
e570	Social security services, systems and policies	(1)
e575	General social support services, systems and policies	(1)
e580	Health services, systems and policies	(1)
e585	Education and training services, systems and policies	(1)
e590	Labour and employment services, systems and policies	(1)
e595	Political services, systems and policies	(1)

Sources: (1): patients; (2): experts; (3): literature. ICF: International Classification of Functioning, Disability and Health.

Limitations

Because we did not construct a brief version of the ICF core set, a limitation is its length, which may reduce its applicability. We did not perform a Delphi consensus of health professionals after the construction of the ICF core set. These methodological choices were prespecified, to ensure that all the categories generated by patients remained in the final ICF core set. Patients were recruited in France from a single tertiary care centre. This recruitment

did not allow assessing differences in conceptual framework across countries, and patients included may not have been fully representative of all the French population with SSc. Experts were mainly French and exclusively French-speaking and may not have been fully representative of SSc experts. Further, the non-physician experts could not include any concept that was not supported by also 2/3 of the physicians, because we prespecified an 80% agreement, without a consensus method like Delphi,

TABLE 3 Cochin Scleroderma ICF-65 questionnaire for activities and participation in patients with SSc

ICF code	Derived question
d1	Learning and applying knowledge <i>Because of my SSc, I feel limited in the following daily activities:</i>
d155 (d159)	Q1. Learning new things?
d160	Q2. Focusing my attention?
d166	Q3. Reading?
d170	Q4. Writing with a pen or a pencil?
d175	Q5. Solving problems of daily life?
d177	Q6. Making decisions?
d2	General tasks and demands <i>Because of my SSc, I feel limited in the following daily activities:</i>
d2101	Q7. Undertaking a complex task requiring several steps?
d220	Q8. Undertaking multiple simultaneous or successive tasks?
d230	Q9. Carrying out daily routine (planning, carrying out, undertaking tasks and demands of daily life)?
d2303	Q10. Managing my own activity level?
d240	Q11. Handling stress and other psychological demands?
d2400	Q12. Handling responsibilities in my personal and professional life?
d3	Communication <i>Because of my SSc, I feel limited in the following daily activities:</i>
d330	Q13. Expressing myself and making myself understood in oral language?
d350 (d3500)	Q14. Starting a conversation or conversing with one person or many people?
d360	Q15. Using a landline or a mobile phone?
d3601	Q16. Using a computer (reading the computer screen and/or writing using a keyboard)?
d4	Mobility <i>Because of my SSc, I feel limited in the following daily activities:</i>
d410	Q17. Changing my body position?
(d4101, d4102, d4103)	Q18. Kneeling down, squatting alone?
d4104	Q19. Standing up alone?
d4105	Q20. To bend forward?
d4150	Q21. Maintaining a lying position?
d4154	Q22. Maintaining a standing position?
d430 (d4300, d4301)	Q23. Lifting and carrying objects in my hands even when moving?
d440 (d4400, d4401)	Q24. Manipulating small objects using my fingers and hands?
d445	Q25. Moving arms (raise, flex, extend)?
(d4450, d4451)	Q26. Pulling or pushing an object?
d450	Q27. Walking?
d455	Q28. Moving downwards (a step, a slope, a ladder)?
d4551	Q29. Moving upwards or downwards (a step, a stool, a slope, a ladder)?
d4552	Q30. Running?
d460	Q31. Going somewhere (inside and outside the home)?
d470	Q32. Taking a plane or a train?
d4702	Q33. Using public transportation (bus, metro, tramway)?
d475	Q34. Driving (a car, a motorcycle, a bicycle)?
d5	Self-care <i>Because of my SSc, I feel limited in the following daily activities:</i>
d510	Q35. Washing myself?
d520 (d5202, d5203, d5204)	Q36. Caring for my physical appearance (combing, shaving, removing hair, brushing teeth, caring for skin, hands, feet, making up, choosing my clothes)?
d530 (d5301, d5308)	Q37. Toileting?
d540 (d5400, d5401, d5402, d5403)	Q38. Putting on clothes, taking off clothes, putting on footwear, taking off footwear?
d550	Q39. Eating?
d570	Q40. Looking after my health?
d6	Domestic life <i>Because of my SSc, I feel limited in the following daily activities:</i>
d6200 (d860)	Q41. Shopping?
d630	Q42. Preparing meals?
d640 (d6400, d6403)	Q43. Doing housework (washing dishes, washing clothes, housekeeping, ironing, cleaning)?
d650 (d6505, d6506)	Q44. Tinkering, gardening, feeding and taking care of my domestic animals?

(continued)

TABLE 3 Continued

ICF code	Derived question
d660 (d6600, d6604)	Q45. <i>Assisting others (family members, neighbours, relatives) according to their needs?</i>
d7	Interpersonal interactions and relationships <i>Because of my SSc, I feel limited in the following daily activities:</i>
d710 (d7100, d7101, d7102)	Q46. <i>Interacting with someone in a contextually and socially appropriate manner?</i>
d7105	Q47. <i>Accepting bodily contact (allowing physical contact, hugging)?</i>
d720	Q48. <i>Forming and terminating relationships?</i>
d7202	Q49. <i>Regulating emotions, verbal aggression and physical aggression in interactions with others?</i>
d730	Q50. <i>Engaging in contacts with strangers for specific purposes (asking for directions, making a purchase, reporting a problem)?</i>
d750	Q51. <i>Having and maintaining relationships with friends?</i>
d760 (d7601, d7603)	Q52. <i>Having and maintaining relationships with the members of my family?</i>
d770 (d7700)	Q53. <i>Creating and maintaining close or romantic relationships with someone?</i>
d7702	Q54. <i>Having a satisfying sexual life?</i>
d8	Major life areas <i>Because of my SSc, I feel restricted in participating in the following daily activities:</i>
d825	Q55. <i>Taking an exam?</i>
d830	Q56. <i>Engaging in an educational programme (being present, being diligent)?</i>
d840 (d845, d8450, d8451, d852)	Q57. <i>To seek, to change, to find or to keep a job?</i>
d850	Q58. <i>Doing all the required tasks and activities of my job?</i>
d8502	Q59. <i>Working full-time?</i>
d9	Community, social and civic life <i>Because of my SSc, I feel restricted in participating in the following daily activities:</i>
d920	Q60. <i>Travelling in France or overseas?</i>
d9201	Q61. <i>To do sport?</i>
d9202	Q62. <i>Going to cultural events (shows, museums, exhibitions)?</i>
d9203	Q63. <i>Doing handicrafts (sewing, collections, craftwork)?</i>
d930	Q64. <i>Having and developing my spiritual life?</i>
d950	Q65. <i>Participating in local and political life as a citizen (vote, local debate, unionism)?</i>

ICF: International Classification of Functioning, Disability and Health.

to include an expert concept. Finally, existing guidelines for using the ICF in clinical practice are designed for clinicians, but not for patients and do not address the construction of patients' self-administered questionnaires.

Conclusion

In summary, using data source triangulation, with priorities given to patients' views, we developed an ICF core set that offers a conceptual framework for SSc patients' care and health policy. Using a patient-centred approach, we also conceived a patient-centred ICF-based 65-item questionnaire, the Cochin Scleroderma ICF-65 questionnaire, assessing activities and participation in patients with SSc. ICF-based patient-reported outcomes may be more sensitive and comprehensive than currently available ones in providing a mapping of functioning in patients with SSc.

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Supplementary data

Supplementary data are available at *Rheumatology* online.

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