

## Developing an ICF Core Set for Climacteric Syndrome based on the International Classification of Functioning, Disability and Health (ICF)

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### ABSTRACT

**Background:** The International Classification of Functioning, Disability and Health (ICF) provides a globally accepted framework for the assessment of problems in functioning in relation to health conditions. ICF Core Sets are internationally accepted shortlists of the most relevant and essential ICF categories that can be used to assess and document the functioning of patients living with specific health conditions.

**Objectives:** The objective of this paper is to outline the process of developing an ICF Core Set for Climacteric Syndrome.

**Study design:** The development of an ICF Core Set follows an established, evidence-based process and will produce a comprehensive and a brief version of the ICF Core Set. The process includes four preliminary studies: 1) a systematic literature review; 2) a multi-center, cross-sectional study in a clinical setting with women 40+ years old; 3) an online expert survey with health professionals involved in caring for the health of women with climacteric syndrome; and 4) a qualitative study with focus groups of women 40+ years old. The results will be integrated at an international consensus conference, where it will be decided which ICF categories will be included in the ICF Core Set for Climacteric Syndrome.

**Conclusion:** An ICF Core Set for Climacteric Syndrome could provide a holistic assessment of limitations in peri- and post-menopausal women and integrate the psycho-social perspective into health care practice. It could further facilitate communication between health care providers, be useful for research and teaching, and support both the transparency and the comparability of information.

### 1. Background

The menopausal transition, or peri-menopause, affects the health-related quality of life because it is accompanied by a higher level of psycho-somatic symptoms, called the climacteric syndrome. Perimenopause is “a complex period of women’s lives in which hormonal factors, family and personal relationships, work status, and self-concept change” [1]. The changed hormonal status leads to higher prevalence of cardiovascular and musculoskeletal diseases, cancer, dementia, chronic respiratory disease, diabetes, metabolic syndrome, depression, and migraine [2]. Interestingly, it has been found that women in satisfactory partnerships with a stable social network suffer less menopausal symptoms, find themselves attractive, and experience the peri-menopause-related reorganization process of their life positively. Employment is another protective factor [3]. Furthermore, the physical environment, stress, anxiety, and individual characteristics such as

motivation and personality may all affect health [4]. Thus, the menopausal transition starting at around age 40 is a sensitive life stage for self-reflection and an opportunity for interventions, including lifestyle changes, to allow for healthy aging.

If these parameters have such an influence on a woman’s well-being during peri- and post-menopause, they should also be considered when assessing functioning and limitations [1]. To assess the general quality of life of peri- and post-menopausal women, many different questionnaires have been developed such as the 36-Item Short Form Survey (SF-36) and the Menopause-Specific Quality of Life Questionnaire (MENQOL) [5,6]. However, these commonly used assessments focus only on the bodily-function aspects of functioning. The psychological, and especially the social and environmental, perspectives are often not substantively covered [7]. Furthermore, despite its variability, the climacteric syndrome can so far only be classified unidimensionally using ICD-10 (N95 Menopausal and other Perimenopausal Disorders)

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[8].

Recently, the European Menopause and Andropause Society (EMAS) proposed a new Menopause Health Care Model based on the concept of Healthy Menopause (HM). HM introduces a holistic model of care which 1) includes physical, psychological, and social functioning and 2) incorporates diseases and disorders [9,10]. Crucial to this model is a relationship triangle between the patient, a specialist nurse, and a leading clinician. Together, they set up a personalized care plan for the patient. Stute et al. proposed that each health authority/region should have such a dedicated HM medical specialist team [9]. However, it remains unclear how menopausal health could be assessed comprehensively, communicated within such a relationship triangle, and communicated outside of the triangle to a supporting, interdisciplinary network of medical experts. A common framework needs to be developed that enables the standardization of measures and supports health care planning and treatment. A holistic assessment must be based on a tool covering all types of limitations of patients with climacteric syndrome. Such an assessment must be capable of assessing and documenting the individual bio-psycho-social situation of each and every woman.

The International Classification of Functioning, Disability and Health (ICF) is an internationally recognized framework for assessing and describing a person’s health status from a bio-psycho-social perspective. WHO endorsed the ICF in 2001 to classify and describe the functioning of patients within the specific social and environmental context in which they live [11]. Not only does it provide a common language for describing patient functioning, it can also facilitate communication between users of diverse disciplines and sectors [11]. As the third health indicator complementing mortality and morbidity, functioning encompasses both a person’s intrinsic health capacity and what the person actually does or is limited in doing in everyday life in light of the interaction between this health capacity and environmental factors [2, 12,13]. In addition, the ICF enables comparisons over time of data between countries and disciplines of the healthcare system and health services. The ICF is comprised of the following components: 1) Body Functions and Structures, 2) Activities and Participation, 3) Contextual Personal Factors, and 4) Environmental Factors [14]. Other than Personal Factors, the ICF contains a comprehensive range of categories for each of these components that are hierarchically structured according to chapter (first level), followed by second, third, and fourth levels (see Fig. 1). The descriptions of the categories become more detailed proceeding downward from the chapter to the fourth level [14]. With more

than 1400 categories, the ICF is extensive, resulting in limited applicability in clinical practice [15]. This requires the development of shorter, more easily applicable subsets of ICF categories for routine use such as the ICF Generic-30 Set [16]. The ICF Generic-30 Set has been proposed as a minimal set of ICF categories for assessing general health across individuals with varying health conditions and has been demonstrated to be useful in assessing the conditions of patients in outpatient care [17]. However, the ICF Generic-30 Set has been developed mainly for the rehabilitation setting, and many conditions require disease-specific assessment tools. Therefore, much effort has been put into developing ICF Core Sets, internationally accepted shortlists of the most relevant and essential ICF categories that can be used to assess and document the functioning of patients living with a given health condition [18]. Since ICF Core Sets are considerably smaller than the whole ICF, ICF Core Sets make using the ICF more practical in clinical routine. The WHO, together with the ICF Research Branch (a cooperation partner of the WHO Collaborating Centre for the Family of International Classifications in Germany) [19], created a scientific, multi-step method for developing ICF Core Sets [15]. More than thirty-five ICF Core Sets for different health conditions have already been developed based on this method, predominately for chronic diseases and rehabilitation medicine [20]. Studies have shown that the use of these ICF Core Sets and other ICF-based tools facilitate the quick and easy assessment of the patient’s functioning and enhance cooperation within an interdisciplinary team [21,22]. This paper provides a broad overview of how the ICF Core Set for Climacteric Syndrome will be developed. The detailed methodologies, the results of the preparatory studies, and the product of the consensus conference will be published in separate papers.

## 2. Methodology

The development of the ICF Core Set for Climacteric Syndrome will follow an established, scientific, multi-method, evidence-based process developed by the ICF Research Branch in Nottwil in collaboration with the WHO Collaborating Centre for the Family of International Classifications in Germany. Through this process, we will develop a comprehensive and brief version of the ICF Core Set [15]. The methods outlined in this paper to develop an ICF Core Set have been previously described and applied in multiple scientific publications [18]. In the preparatory phase, four different types of studies will be carried out, namely 1) a systematic literature review; 2) a qualitative study with focus groups; 3) an online survey of experts; and 4) a multi-center, cross-sectional study

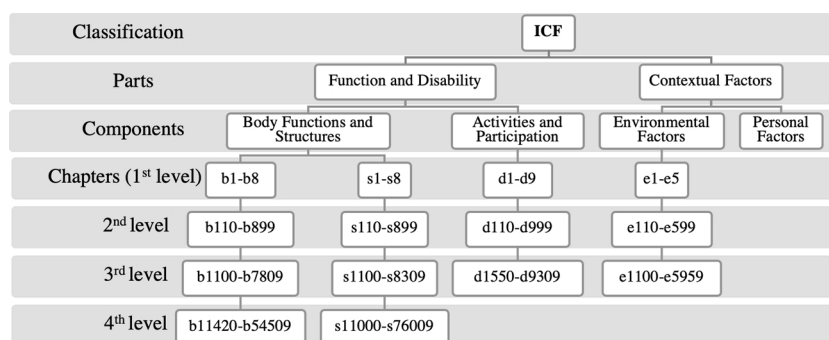


Fig. 1. Hierarchical structure of the ICF.

in a clinical setting. Phase I consists of an international consensus conference (ICC) that will be conducted to decide which ICF categories will be included in the ICF Core Set for Climacteric Syndrome. In Phase II, the newly generated Core Set will be tested and implemented (Fig. 2). This process is overseen and guided by a steering committee that includes members of the collaborating organizations. Current members are Petra Stute (University Hospital Bern), Gerold Stucki (Swiss Paraplegic Research, Nottwil), Alfred Mueck (University Clinic Tübingen, Capital Medical University, Beijing) and Luisa Eggenschwiler (University Hospital Bern). This protocol has been developed using the SPIRIT checklist (Appendix A) [23].

2.1. Preparatory Phase

This phase involves conducting four preparatory studies. To ensure the broad applicability of the ICF Core Set, each study will reflect a different perspective: 1) a systematic literature review (researcher’s perspective); 2) a multi-center, cross-sectional study (clinical perspective), 3) an expert survey (health professional’s perspective), and 4) a qualitative study (perspective of women 40+ years old in peri- and post-menopause). The results of each study will be a list of candidate categories that will be consolidated and provided to the participants of the ICC to decide on the final set of categories to be included in the ICF Core Set.

2.1.1. Literature Review (Researcher’s Perspective)

The objective of the literature review is to identify the aspects of functioning that are described, assessed, or measured in published research on women in peri- and post-menopause. It is assumed that the functioning aspects presented most often in scientific literature are considered the most relevant from the perspective of researchers. The literature search will be conducted using internet databases such as Medline, Embase, Central, CINAHL. Search terms will include “menopause,” “healthy menopause,” “peri-menopause,” “post-menopause,” “climacteric syndrome,” “functioning,” “assessment,” “quality of life.” The following inclusion criteria have been defined: 1) studies with women 40+ years old in peri- and post-menopause; 2) peer-reviewed articles in English (no older than ten years old); 3) randomized controlled trials, clinical controlled trials, cross-sectional studies, observational studies and qualitative studies; and 4) studies including heterogeneous population (e.g. menopause and breast cancer). Psychometric studies, population prevention studies, studies of phase-II clinical trials, and studies exclusively with laboratory parameters or animal experiments and letters, comments and editorials will be excluded from this literature review.

Two investigators will independently screen the abstracts resulting from the search. Based on the inclusion and exclusion criteria, the investigators will identify which abstracts to include for full text screening

and data extraction. In reviewing the full articles, the underlying concepts contained in the instruments employed in the studies outlined in the articles, as well as the concepts discussed in the article text related to the search terms, will be identified and then linked to ICF categories using established linking rules [24]. A frequency analysis of the resulting categories will be conducted. The ICF categories that are identified in at least 5% of the articles will be included in the resulting list of candidate categories.

2.1.2. Qualitative Study (Patient’s Perspective)

Focus groups with max. 7 participants will be conducted to identify which aspects of functioning, environmental, and personal factors are most important to women in peri- and post-menopause. To help ensure global applicability, attempts will be made to conduct focus groups in as many WHO world regions as possible. The local study centers will be identified through the scientific network of the project Steering Committee and main study team at the University Hospital of Bern. In addition, a request will be made to diverse national and international menopause societies to place a call for participation on their respective websites. Guidelines for appointing local study center investigators will be developed before issuing the call. The study population includes women 40+ years old who are receiving health services for menopausal symptoms. Participants are recruited during regular menopausal consultations. The questionnaire used in the focus groups will consist of 6 open-ended questions about the problems/barriers and facilitators encountered by women in peri- and post-menopause (see Table 1). The questions will cover all components of the ICF [11]. Data analysis will follow the method of meaning condensation [25,26]. Themes will be identified, broken down into meaningful concepts, and then linked to the ICF according to the ICF linking rules [24]. To support the patient-centered approach taken by the ICF, and to maximize patient input in the development of the ICF Core Set for climacteric syndrome, any ICF category that was mentioned at least once per focus group will be included in the list of candidate categories. Focus groups will be conducted until saturation is reached, i.e., when no new information emerges after conducting two consecutive focus group [25,26]. The estimated number of participants needed for significant results in focus groups is about 100 [27]. However, previous studies who applied the same methods had needed less participants to reach saturation [28,29]. Descriptive statistics will then be used to calculate the frequency of the reported categories across all focus groups.

This study has been approved by the local ethics commission (KEK Bern 2019-01330 Version 2, October 2019) and registered at the Inselspital, University Hospital of Bern, Switzerland (Nr. 4160).

2.1.3. Web-based Expert Survey (Health Professional’s Perspective)

To gather input from a multidisciplinary spectrum of experts on aspects of functioning and environmental factors that are relevant for

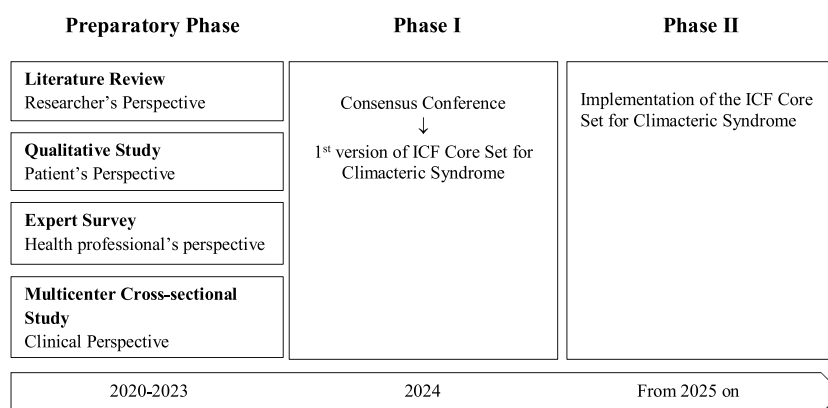


Fig. 2. Process of developing an ICF Core Set for Climacteric Syndrome.

**Table 1**  
Questions to be asked in the qualitative study and expert survey.

Qualitative study	Expert survey	ICF component covered
If you think about your body and mind, what does not work the way it is supposed to?	In your experience with women in peri- and post-menopause, what physical and mental problems do they encounter as related to their transition into menopause?	Body functions
If you think about your body, in which parts of the body do you experience the most problems?	In your experience with women in peri- and post-menopause, which parts of the body seem affected as related to menopause?	Body structures
If you think about your daily life, what problems do experience most?	In your experience with women in peri- and post-menopause, what difficulties and challenges do they face in their everyday activities and involvement in society as related to menopause?	Activities and participation
If you think about your environment and living conditions, what do you find helpful or supportive?	In your experience with women in peri- and post-menopause, what do they find helpful or supportive in terms of menopause?	Environmental factors - facilitator
If you think about your environment and living conditions, what barriers do you experience?	In your experience with women in peri- and post-menopause, what do they find hindering in terms of menopause?	Environmental factors - barrier
If you think about you as a person, what is important about you and the way you deal with menopause?	In your experience with women in peri- and post-menopause, what personal characteristics are important in the way they deal with menopause?	Personal factors

women in peri- and post-menopause, a web-based survey will be conducted. All health professionals involved in the health care of women with climacteric syndrome from all six WHO regions will participate. It is expected that the majority of participants will be gynecologists, primary care and internal medicine physicians, gynecological nurse practitioners, midwives, and psychologists/psychiatrists, as they are reflective of the menopause-treating disciplines [9,30,31]. The expert survey will be conducted online using a secure survey portal. The questions will be worded similarly to the focus group questions (see Table 1). The experts' responses will be analyzed following the method of meaning condensation [25,26] and linked to ICF categories according to the aforementioned linking rules [24]. Descriptive statistics will then be used to calculate the frequency of the reported categories across all expert respondents. ICF categories that are reported by at least 5% of the experts will be included in the list of candidate categories.

#### 2.1.4. Multi-Center, Cross-Sectional Study (Clinical Perspective)

An empirical, cross-sectional study will be conducted to identify the most common functioning problems experienced by female patients in peri- and post-menopause that are documented in a clinical setting, preferably in all six WHO regions. The local study centers will be identified through the scientific network of the project Steering Committee and the main study team at the University Hospital of Bern. In addition, a request will be made to diverse national and international menopause societies to place a call for participation on their respective websites. Guidelines for appointing local study center investigators will be developed before issuing the call. The study population includes women 40+ years old who are receiving health services for menopausal symptoms. The study centers will conduct semi-structured interviews with patients using a modified version of the ICF Checklist 2.1a for data collection [11,32]. ICF Checklist 2.1a contains a selection of 127 categories covering all ICF components that the WHO considered most

relevant for documentation in clinical practice. To ensure that ICF Checklist 2.1a captures patient functioning specific to menopause, it will be supplemented with the candidate categories resulting from the systematic literature review and expert survey if the candidate categories are not yet included in ICF Checklist 2.1a. Descriptive statistics will be employed to analyze the frequency with which specific ICF categories are reported as a problem, barrier, and/or facilitator. An ICF category that is considered a problem, barrier, and/or facilitator by at least 20% of the participants (the cut-off will depend on the data collected) will be included in the list of candidate categories. The recruitment of the participants takes place during a regular menopausal consultation. It does not cause any additional effort for the participants and the recruiter. Recruitment is terminated when new participants no longer contribute any new information to the study. The estimated number of recruited participants required is about 100, as in previous studies with this design.

This study has been approved by the local ethics commission (KEK Bern 2019-01329 Version 2, October 2019). Registration at the Insel-spital (the University Hospital of Bern, Switzerland) is still pending.

#### 2.2. Phase I: Consensus Conference

The ICC is central to the development of an ICF Core Set. In this phase, the consolidated list of candidate ICF categories resulting from the preparatory studies will be provided to the ICC participants with the objective of deciding which ICF categories will be included in the ICF Core Set for Climacteric Syndrome. Participants from different WHO regions and disciplines will be invited. Experience from previous consensus conferences verifies that the optimal number of participants to include in the ICC is between 21 and 24 experts [15]. Participants will be introduced to the essentials of the ICF that they need for informed participation in the ICC. Furthermore, the process of developing ICF Core Sets, the results of the preparatory studies, and the consensus and decision-making process of the ICC will be presented. The decision-making process to be used at the ICC follows the established process implemented in previous ICF Core Set projects [15]. It involves discussion and voting that take place in alternating working group and plenary sessions, leading to a final agreement on which ICF categories to include in the ICF Core Set for Climacteric Syndrome

#### 2.3. Phase II: Implementation of the ICF Core Set for Climacteric Syndrome

Phase II will include the validation and implementation of the ICF Core Set for Climacteric Syndrome. It aims to evaluate whether 1) the included categories describe the limitations that patients with climacteric syndrome suffer from, and 2) all relevant categories have been included. Additionally, the feasibility of the ICF Core Set in different contexts will be examined. Phase II will also include as many WHO regions as possible to guarantee global applicability.

### 3. Discussion

This paper proposes a rationale for the development of an ICF Core Set for Climacteric Syndrome and details the process of developing that tool. The proposed project will be the first research endeavor in the field of menopause health care that systematically examines a broad spectrum of factors beyond the limitations in body functioning that impact the lived experience of women in peri- and post-menopause. The development of an ICF Core Set for Climacteric Syndrome will provide the foundation for a comprehensive and holistic assessment of the limitations and needs of peri- and post-menopausal women [15]. A better understanding of what matters to peri- and post-menopausal women — in terms of functioning and the impact of their physical, social, and attitudinal environment in daily life — can lead to symptom relief, higher patient satisfaction, and improved quality of life [9,33].

The ICF Core Set for Climacteric Syndrome will be developed in consideration of evidence resulting from four preparatory studies following an established, evidence-based process developed by the ICF Research Branch in Nottwil in collaboration with the WHO Collaborating Centre for the Family of International Classifications in Germany. Therefore, we expect it to support evidence-informed medical care for women in peri- and post-menopause [15]. Furthermore, we anticipate that the ICF Core Set for Climacteric Syndrome will help change the paradigm in menopause health care practice from a purely biomedical perspective to an integrative psycho-social perspective [9,10]. To foster acceptance and implementation of the ICF Core Set for Climacteric Syndrome in routine clinical practice, it will be developed in cooperation with a multidisciplinary group of health professionals working in this medical field and with affected patients. It will also undergo validation and testing to demonstrate its robustness and reliability.

The ICF Core Set for Climacteric Syndrome will serve as the starting point for a user-friendly, discipline-independent, standardized assessment instrument that other gynecologists outside the menopause competence centers — as well as general practitioners and other health providers — can use in their daily routines. Collecting and sharing information on a patient's menopausal health and functioning using a mutually recognized assessment instrument could facilitate comparability of information and support transparency. It could also improve the communication between different stakeholders involved in the continuum of menopause health care, including the patient herself.

The ICF Core Set can be translated into various assessment tools such as the ICF Categorical Profile or the ICF Evaluation Display that can facilitate patient-to-health-professional interaction, help shared goal-setting, and identify targets for intervention [34–37]. A further tool, the ICF Intervention Table, can support interdisciplinary collaboration by providing a comprehensive overview of all intervention targets [36, 38,39]. These tools would provide clinicians a standardized method for assessing specific aspects of peri- and post-menopausal women's health and functioning that were not previously capable of assessment. Among these aspects are mood swings that affect a woman's social life and the impact of peri- and post-menopause on her lifestyle in general. It has been shown that a comprehensive functioning assessment captures more of a patient's real-life, health-related problems that otherwise go unnoticed by a conventional medical assessment alone [40]. In addition, the ICF enables comparisons over time of data between countries and disciplines of the health care system or health service.

Eventually, the ICF Core Set for Climacteric Syndrome could be applied in other research endeavors. For example, it could be applied in studies examining the effectiveness of preventive and treatment strategies in menopause health care and other areas of health care. Specifically, the categories of the ICF Core Set for Climacteric Syndrome could be employed to define the outcomes of randomized controlled trials (RCTs) examining two or more intervention strategies. Long-term, the results of such RCTs and other studies could inform the (further) development of interventions, including pharmacological interventions [39], and may provide insurers and policymakers with evidence for decision-making.

There are uncertainties involved in this project that can only be addressed and resolved in the process of this scientific endeavor. It must be emphasized that the ICF Core Set for Climacteric Syndrome developed in this process will be a first, prototypical version. It will have been agreed upon by the ICC, but will still need to be validated globally and tested for applicability. Thus, if needed, it could be revised.

In conclusion, the ICF provides a globally accepted framework for the assessment of problems in functioning related to health conditions. The ICF Core Sets are developed to facilitate the application of the ICF Classification. An ICF Core Set for Climacteric Syndrome could provide for a holistic assessment of limitations encountered by peri- and post-menopausal women by integrating the psycho-social perspective into health care practice. It could further facilitate communication between health care providers, be useful for research and teaching, and support

transparency as well as comparability of information.

### Contributors

Martina Zangger contributed to conceptualization, methodology, writing the original draft, and visualization.

Christin Weber contributed to methodology, and writing the original draft.

Petra Stute contributed to review and editing of the manuscript, and supervision.

### Declaration of Competing Interest

The authors declare that they have no conflicts of interest.

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### Ethical approval

The studies have been approved by the local ethics commission (KEK Bern 2019-01329 Version 2, KEK Bern 2019-01330 Version 2, October 2019). The qualitative study has been registered at the Inselspital, University Hospital of Bern, Switzerland (Nr. 4160). Registration for the quantitative study at the Inselspital University Hospital of Bern, Switzerland, remains pending.

### Provenance and peer review

This article was not commissioned and was externally peer reviewed.

### Research data (data sharing and collaboration)

There are no linked research data sets for this paper. Data will be made available on request.

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### Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.maturitas.2020.10.014>.

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