Developing core sets for patients with obstetric brachial plexus injury based on the International Classification of Functioning, Disability and Health

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Background
Symptoms of obstetric brachial plexus injury (OBPI) vary widely over the course of time and from individual to individual and can include various degrees of denervation, muscle weakness, contractures, bone deformities and functional limitations. To date, no universally accepted overall framework is available to assess the outcome of patients with OBPI. The objective of this paper is to outline the proposed process for the development of International Classification of Functioning, Disability and Health (ICF) Core Sets for patients with an OBPI.

Methods
The first step is to conduct four preparatory studies to identify ICF categories important for OBPI: a) a systematic literature review to identify outcome measures, b) a qualitative study using focus groups, c) an expert survey and d) a cross-sectional, multicentre study. A first version of ICF Core Sets will be defined at a consensus conference, which will integrate the evidence from the preparatory studies. In a second step, field-testing among patients will validate this first version of Core Sets for OBPI.

Discussion
The proposed method to develop ICF Core Sets for OBPI yields a practical tool for multiple purposes: for clinicians to systematically assess and evaluate the individual’s functioning, for researchers to design and compare studies, and for patients to get more insight into their health problems and their management.

Key messages
- A systematic literature review, a qualitative study, an expert survey and a cross-sectional study will be performed to identify ICF categories important for OBPI
- The first version of ICF Core Sets will be defined at a consensus conference
- Field-testing among patients will validate this first version of Core Sets for OBPI

Introduction
An obstetric brachial plexus injury (OBPI) is caused by traction on the brachial plexus during delivery and can result in severe disabilities in arm function. The incidence varies between 0.4 and 2.9 per 1000 live births. The severity of the injury may vary from...
neuropaxia and axonotmesis to neurotmesis and avulsion of rootlets from the spinal cord. The upper part of the brachial plexus is most often affected, resulting in variable weakness of the shoulder and elbow flexion. Extension of the elbow and function of the hand and wrist are additionally impaired when the C7, C8, T1, medial trunk and inferior trunk are involved. An isolated injury of the lower brachial plexus (C8-T1) is rare. Depending on the severity and extent of the OBPI, the overall quality of life of patients is very much affected due to impaired upper-limb function. Symptoms of OBPI can vary widely between individuals, and clinical studies have been performed to identify the natural history and to improve treatment. Several outcome measures are used to evaluate the natural history and the effect of treatment, but there is no consensus on which outcome measures are the most appropriate.

An important base for the optimal management of OBPI is the in-depth understanding, systematic consideration and sound measurement of the impact of OBPI on health and health-related domains. The International Classification of Functioning, Disability and Health (ICF) is a worldwide accepted model of the World Health Organization (WHO) providing a universal language for the description of functioning and includes the domains Body Structures, Body Functions, Activities and Participation as well as Personal and Environmental Factors (Fig. 1). These ICF domains, which contain together more than 1400 categories, can serve as a reference for purposes in the clinical practice. ICF Core Sets are generally agreed on lists of ICF categories and contain as few as possible but as many ICF categories as necessary to describe the typical spectrum of problems of functioning and health of patients with a specific condition. To date, ICF Core Sets have already been or are being developed for more than 20 health conditions, including neurological, musculoskeletal and cardiovascular diseases. However, ICF Core Sets for OBPI are not available so far. The objective of this paper is to outline the proposed developmental process for internationally accepted, evidence-based, reliable and valid ICF Core Sets for OBPI.

Materials and Methods
The development of the ICF Core Sets for OBPI is a collaborative project of the Leiden University Medical Center (LUMC) and the ICF Research Branch of the Collaboration Centre of the Family of International Classifications (DIMDI) at the Ludwig-Maximilian University (Munich, Germany). Figure 2 shows the three phases in the development of the ICF Core Sets for OBPI: the preparatory phase with the international consensus conference (phase I) and the testing and implementation phase (phase II). A summary of the methods is shown in Table I. The project will be conducted in conformity with the ethical principles of Declaration of Helsinki. All appropriate study-related documents will be presented to the Medical Ethics Committees for review and approval.

Preparatory phase. The preparatory phase aims at identifying concepts relevant to patients with OBPI from four different points of view. Therefore, this phase consists of four different preparatory studies: 1) a systematic review; 2) a qualitative study; 3) an expert survey; and 4) a cross-sectional study.

1. Systematic review. The objective of this study is to capture the researchers’ perspective, a) by identifying outcome measures cited in published studies with the focus on individuals with OBPI; and b) by identifying and quantifying the concepts contained in these measures using the ICF as a reference. Electronic databases regarding the measures used in clinical trials and in observational studies identifying concepts from the researchers’ point of view. The data collection process comprises three steps: i) the parameters used in published studies are identified; ii) the items of all retrieved parameters and their underlying concepts are specified; and iii) finally, these concepts will be linked to the categories of the ICF using standardised linking rules. Absolute and relative frequencies of the parameters and the linked ICF categories will be reported.

2. Qualitative study. The objectives of this study are: a) to explore and understand the perspective of patients with OBPI on functioning and health; and b) to identify and quantify the concepts of functioning and health important to patients with OBPI using the ICF as a reference. It is important to include the patients’ perspective because
personal values for outcomes vary between and within patients. In order to identify the prototypical spectrum of problems of patients with OBPI, small groups with ≤ eight individuals between the ages of eight and 18 years are interviewed. These focus groups are likely to generate more concepts than individual interviews, as the interaction and group process can enrich the information generated within a group of patients.28,29 A topic guide based on the components Body Structures, Body Functions, Activities and Participation, Environmental Factors and Personal Factors of the bio-psycho-social model will be applied. All interviews will be digitally recorded, transcribed verbatim and evaluated again by two independent researchers. Participants will be included in the study until saturation is reached, which is defined as the point during data collection when the linking of the retrieved concepts to the second level of the ICF classification is < 5% of the number of second-level ICF category nominated so far. The frequencies of the parameters and the linked ICF categories from the focus groups will be reported.

3. Expert survey. An internet-based expert survey will be conducted with the aims of: a) collecting the health professionals’ perspective on relevant problems of patients with OBPI; and b) identifying and quantifying the concepts contained in these problems using the ICF as a reference. As the ICF was developed to facilitate communication between different groups of people and to be used globally, the aim is to include experts from all six WHO regions: Eastern Mediterranean, South-East Asia, Western Pacific, The Americas, Africa and Europe. In order to maximise the number and range of ideas and opinions, the aim is to include experts from different health professions including neurosurgeons, orthopaedic surgeons, plastic surgeons, rehabilitation physicians, neonatologists, neurologists, pediatricians, physical therapists, occupational therapists, nurses and social workers. In order to contribute to the survey, the health professionals must have a minimum of two years’ experience in the treatment of OBPI and must be fluent in English. In the expert survey a five-item open-ended questionnaire is used, which requests that experts list all body structures, functions, activities and participation aspects in which patients with OBPI encounter problems, as well as all contextual factors that have a facilitation and/or hindering influence on the problems of patients with OBPI. The answers of the health professionals are linked to the ICF categories and the frequency of ICF categories are reported.

4. Cross-sectional study. In order to obtain the clinical perspective, a multi-centre cross-sectional study will be conducted. The aims of this study are: a) to describe functioning and health of patients with OBPI; b) to identify the most common problems using the ICF; and c) to identify the categories that explain most of the variance in currently used outcome measures. This multicentre study will be conducted in the different WHO regions and patients with OBPI who are literate in the primary language of the study site will be consecutively included in the study. Data will be collected with a case record form (CRF), which is made up of two parts. The first part is an ICF checklist, which comprises the 31 first-level categories and a selection of 123 from the 362 second-level categories of the whole ICF classification system. It provides a relatively simple questionnaire, which can be filled out by the physician
or other health professional. The ICF checklist makes it possible to classify the most important ICF categories in clinical practice. The second part includes the EuroQol (EQ-5D), \(^{30}\) five questions of the WHO Quality of Life Questionnaires (WHOQoL) \(^{31}\) to assess the subjective appraisal of health and well-being, the Short-Form (SF)-36 health survey, \(^{32}\) the Disability of Arm, Shoulder and Hand Questionnaire (DASH), \(^{33}\) and the self-administered Co-morbidity Questionnaire (SCQ). \(^{34}\)

Furthermore, sociodemographic variables will be collected. For the ICF components body functions, body structures, activities and participation, absolute frequencies and relative frequencies of impairment will be reported along with their 95% confidence intervals. For environmental factors, absolute frequencies and relative frequencies of persons who regarded a specific category as either barrier or facilitator are reported.

**Consensus conference.** The results of the preparatory phase will be presented at an international consensus conference. At this conference, experts in the field of OBPI will work actively together to deal with the complex problem of arriving at an international consensus on the most adequate ICF categories to be included on the ICF Core Sets for OBPI. The “Nominal-Group Technique” will be applied to regulate the group dynamic and the teamwork during the conference. \(^{35}\) Since the results of the preliminary studies are all expressed in ICF language, they can be compiled in tables that contain (for each category addressed) the percentage with which the categories were named in the preparatory studies. First, the experts will be asked to select ICF categories for the comprehensive ICF Core Sets, which is a list of ICF categories long enough to describe the prototypical spectrum of functioning and health of patients with OBPI. Secondly, the experts will be asked to select ICF categories from the comprehensive ICF Core Sets lists that are sufficient to describe the prototypical spectrum of functioning of patients with OBPI, with this list being short enough for feasible use in clinical practice. This process will lead to a brief list of ICF Core Sets.

**Validation phase.** The next step is to test the validity and feasibility of the proposed brief and comprehensive ICF Core Sets for patients with OBPI. This will be conducted in a multicentre cohort study at a network of cooperating organisations. The objectives are to analyse the frequency of patients’ problems in different subsets, including

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**Table I. Summary of the methods for the development of International Classification of Functioning, Disability and Health (ICF) Core Sets for obstetric brachial plexus injury (OBPI)**

| Methods                        | Objectives                                                                 | Specifics                                                                 |
|--------------------------------|---------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Systematic review               | A systematic review uses explicit methods to systematically search, critically appraise, and synthesise the world literature on OBPI | a) To identify outcome measures cited in published studies with the focus on patients with OBPI; b) To identify and quantify the concepts contained in these measures using the ICF as a reference |
| Qualitative study               | Focus group technique is a qualitative method valid to explore the perspective of those who experience OBPI, i.e. the so-called patient perspective | a) To explore and understand the perspective of patients with OBPI on functioning and health; b) To identify and quantify the concepts of functioning and health important to patients with OBPI using the ICF as a reference |
| Expert survey                   | A survey involving experts experienced in the treatment of individuals with OBPI | a) To identify the most relevant problems of patients with OBPI from the perspective of clinical experts; b) To identify and quantify the concepts contained in these problems using the ICF as a reference |
| Cross-sectional study           | A multicentre, cross-sectional study that involves data collection at one time point | a) To describe the prevalence of problems in functioning of patients with OBPI; b) To identify the categories that explain most of the variance of external standards |
| Consensus conference            | The ‘Nominal-Group Technique’ is a consensus-planning process that helps to prioritise issues during an expert’s conference | To develop ICF Core Sets for OBPI in a formal decision making and consensus process, integrating evidence gathered from preliminary studies and expert opinion |
| Implementation and testing      | Worldwide Empirical studies, including external standards, such as the Short-Form 36 | To study the content validity and feasibility of the Comprehensive and the Brief ICF Core Sets for OBPI |

To obtain the researchers perspective, electronic databases will be searched using keywords including ‘Brachial plexus neuropathies’, ‘Brachial plexus injury’, ‘Erb paralysis’, ‘Klumpke paralysis’ and ‘Obstetric brachial plexus’.

To obtain an international perspective, focus groups are conducted with people with OBPI in different countries.

To obtain a worldwide perspective, experts from all over the world and from different health professions will be included.

To obtain an international perspective, centres in different countries will be involved.

To obtain the researchers perspective, centres in different countries will be involved.

A network of organisations and institutions from all over the world that are interested in the implementation and testing of the pilot ICF Core Sets will be established.
functioning and relevant environmental factors. The ICF has been proposed to develop ICF Core Sets for OBPI. The ICF offers a framework and classification for the patient and clinical perspective both at the individual and the population level. It integrates long known concepts and provides a universal and standardised language. ICF Core Sets are necessary to make the ICF useful to describe functional limitations and disabilities of patients with OBPI.

Currently, ICF Core Sets have been, or are being developed for more than 20 health conditions, including neurological traumas and musculoskeletal diseases such as traumatic brain injuries, spinal cord injuries, osteoarthritis and low back pain. ICF Core Sets may well serve as the basis for multi-professional patient assessment, goal setting, intervention management and evaluation. For a correct interpretation of the patient’s problems, it is important to first describe the concerns of the patient and/or parents in their own words. Physicians can use the ICF Core Sets to describe and classify patients’ symptoms and findings of clinical examinations. Professionals could describe at least all categories from a brief Core Set and use the comprehensive Core Set as a source of additional relevant items. Using the ICF Core Sets supports multidisciplinary and comprehensive assessment of functioning. It helps all team members to consider every potentially relevant aspect of functioning of a patient. The use of ICF Core Sets can assist health care professionals in explaining the necessity of a certain procedure for a patient and for their parents, thereby creating more insight into the health problems and treatment. It is by no means the aim of the ICF to replace validated existing instruments. In contrast, it is likely that they will have an essential role to measure particular parts of the ICF. Most measurement instruments do however cover only a limited number of ICF categories.

Next to the clinical application, ICF Core Sets will be used by researchers and healthcare providers in many ways. ICF Core Sets make it possible to classify and describe an individual’s functioning using widely accepted terminology, which facilitates the comparability of international studies. It can also be used to rate the content validity of health-status measures and to select appropriate instruments for the specific needs for patients with OBPI. In the future, ICF and the ICF Core Sets may become the new basis not only for the further development of such measures, but also for the creation of an item list with parameters relevant to patients with OBPI. Furthermore, ICF facilitates linking medical data across different conditions or interventions for efficient, transparent and cost-effective health care. Other benefits could also arise from compiling a functionality assessment for OBPI from a common set of indicators (a common bio-psycho-social framework) used for all health conditions. For example, a common language would facilitate communication among health professionals and also between health professionals and patients with OBPI, as well as their family or caregivers. In addition, because the ICF is aetiologically neutral, it is easily possible to combine the ICF Core Sets for OBPI with other ICF Core Sets in a non-redundant and useful way when describing and classifying functioning and disability of persons with more than one condition. Worldwide comparisons will also be possible for any health condition, not only for OBPI. This will enable policy makers to make informed decisions with regard to such issues as resource allocation, new legislation and modification of care provision policies.

A few limitations have to be resolved during the developmental process of ICF Core Sets. The assessment of functioning and quality of life data is highly sensitive to ethno-cultural differences. In order to come up with a first version of ICF Core Sets for OBPI that integrates information from different cultural backgrounds, the preparatory studies will gather data on patients being treated at centres from different countries and from professionals in an international expert survey. Another limitation could be that the preparatory studies collect information only from published papers in English and English-speaking participants. This is done to ease comparability of results from different countries, but on the other hand will contain a structural bias for countries in which English is not the native language. The extent and relevance of this issue will be addressed in the validation phase following the consensus conference. An issue to be addressed is the possible need for stratification by a number of variables including the extent of brachial plexus injury and the age of the growing children. The preliminary studies will provide the necessary information to guide these decisions. It is important to realise that the ICF Core Sets Consensus Conference will provide only a first, best possible version of ICF Core Sets for OBPI, which will then need to be tested worldwide.

In conclusion, this is a big step forward in the development of an internationally acceptable and standardised tool for assessing disability in OBPI. Establishing standardised ICF Core Sets will be useful for research, clinical practice and teaching. The ICF Core Sets will then also form the basis for the development of assessment instruments to quantify the severity of OBPI to measure change over time and the effectiveness of interventions. They could also serve as the basis for setting clinical significance thresholds in diagnostic assessment systems. Finally, it is
our hope that such research will lead to interventions and accommodations that improve the restoration and maintenance of functioning and minimise disability among patients with OBPI throughout the world.

Invitation for participation. The development of the ICF core sets is an inclusive and open process. Therefore, the authors of this article encourage clinical experts and patients with OBPI throughout the world to actively participate in the process. Anyone who wishes to actively participate is invited to contact the Leiden ICF brachial plexus team (brachialplexus@lumc.nl).

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