CROSS-CULTURAL ADAPTATION
AND VALIDATION OF THE
JUVENILE ARTHRITIS
MULTIDIMENSIONAL ASSESSMENT
REPORT
(JAMAR)

Prof. Angelo Ravelli, MD PI of the study

Prof Alberto Martini, MD      Dr Nicolino Ruperto, MD, MPH

Alessandro Consolaro, MD study coordinator
Marco Garrone, BsA, research assistant

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CROSS-CULTURAL ADAPTATION, AND VALIDATION OF THE JUVENILE ARTHRITIS MULTIDIMENSIONAL ASSESSMENT REPORT

Introduction. In recent years there has been an increasing interest in parent/patient-reported outcomes (PROs) in juvenile idiopathic arthritis (JIA). Inclusion of these measures in patient assessment is deemed important as they reflect the parents’ and children’s perception of the disease course and effectiveness of therapeutic interventions. It has been suggested that PROs should be incorporated into routine paediatric rheumatology care. A number of measures for the assessment of PROs in children with JIA have been developed over the years, including questionnaires for the evaluation of functional ability and health-related quality of life (HRQL), and visual analogue scales for parent/patient rating of well-being and pain. However, most of these measures have remained essentially research tools and are not routinely administered in most paediatric rheumatology centres. One of the problems with the use of current measures is that they address only one aspect of child’s health and, therefore, do not provide a sufficiently comprehensive information on the disease status.

A multidimensional questionnaire was recently developed for the assessment of children with JIA in standard clinical care, which incorporates the traditional PROs (functional ability, HRQL, overall well-being, pain) and some PROs not assessed by conventional measures (morning stiffness, rating of disease course over time, proxy- or self-assessment of joint involvement, description of side effects of medications, and assessment of therapeutic compliance and satisfaction with the outcome of the illness). Administration of this questionnaire provides a physician with a thorough and systematic overview of the patient status to be scanned at the start of the visit. This facilitates focus on matters that require attention, leading to more efficient and effective clinical care. This tool is named Juvenile Arthritis Multidimensional Assessment Report (JAMAR). A parent proxy-report version of the JAMAR for ages 2-18 and a child self-report version of the JAMAR for ages 7-18 are available. In our experience, the JAMAR has been found very user-friendly, easy to understand, and readily responded by parents and patients. It is quick, taking 5-10 minutes to complete and can be scanned by a health professional for a clinical overview in a few seconds. Scoring of its components can be accomplished in less than 5 minutes. Some components of the JAMAR have been published in separate papers (1-3). The paper on the JAMAR itself is now in the Journal of Rheumatology. We believe that this new instrument may contribute to improve the quality of care of children with JIA.

For this reason, we have planned to promote its use internationally. This requires translation into different national languages of its two versions (parent’s and patient’s) and its validation in diverse patient series. This task will be the chief roles of the National Coordinating Centre of the PRINTO network (see list at www.printo.it).

All data will be handled anonymously and parent’s/patient’s consent for the participation in the study is indicated at the end of the questionnaires. Ethics Committee/Institutional Review Board approval will depend on the national laws requirement. Please notify PRINTO if you need ethics committee approval for the whole project (translation, probe technique, data collection) by sending an email to printo@ospedale-gaslini.ge.it. We anticipate that, at least for the translation work, ethics committee approval will NOT be necessary.
ALL DOCUMENTS CAN BE DOWNLOADED AT:
www.printo.it/JAMAR.asp

Please note that the files are numbered from 0 to 28, so they can be ordered easily

Phase I: Translations and Cross-Cultural Adaptation

Before starting the translations please read the following references:


The original English versions of the JAMAR for both parents and children are in the following files:

- 3_JAMARpar_English_orig.doc (original standard English version of the JAMAR parent)
- 4_JAMARchi_English_orig.doc (original standard English version of the JAMAR child)
**Forward translations into National Languages.** At least 2 (preferably 3) literal translations from English will be done by 2-3 independent translators into their native language. The 2-3 translators will be fluent in English and in the local language, will be of different educational levels, background and sex, will use wording to be understood by a 8-10-year old child (for the patient version of the JAMAR), and at least 1-2 of them will be unaware of the purpose of the translations (e.g. should not be health professionals).

See Word files to be completed locally:
- 5_JAMARpar_Forw_A.doc (forward translation version A of the JAMAR parent)
- 6_JAMARpar_Forw_B.doc (forward translation version B of the JAMAR parent)
- 7_JAMARpar_Forw_C.doc (optional) (forward translation version C of the JAMAR parent)
- 8_JAMARchi_Forw_A.doc (forward translation version A of the JAMAR child)
- 9_JAMARchi_Forw_B.doc (forward translation version B of the JAMAR child)
- 10_JAMARchi_Forw_C.doc (optional) (forward translation version C of the JAMAR child)

**IMPORTANT:** a copy of all files listed above has to be sent back to PRINTO at: printo@ospedale-gaslini.ge.it

**First unified forward translation.** The 2-3 forward translators and 1 or 2 other persons not involved in the translation procedures (e.g. the local principal investigator and a nurse/physical therapist), will then meet to reach a consensus (that is, to reconcile differences in the forward translations) among the members of the group in order to obtain a first unified version from the 2-3 forward translations. Use the **quality of the forward translation** forms to compare the 2-3 translations. **IMPORTANT: the National Coordinator is asked in this phase to add examples of commercial names for the drugs listed in lines 64-67 of the parent’s version and lines 62-65 of the child’s version.** Moreover, the National Coordinator is asked to modify the footnotes, providing his/her name (yyy) and the national language in which the questionnaire is translated (xxx) in the page footer of the JAMAR or both parent’s and child’s version. The questionnaire will be copyrighted by PRINTO but the name of the National Coordinator will appear as local project coordinator.

See word file to be completed locally:
- 11_JAMARpar_Qual_forw.doc (quality control forms for the JAMAR parent forward translations)
- 12_JAMARpar_Forw_unified_1.doc (first unified version of the JAMAR parent)
- 13_JAMARchi_Qual_forw.doc (quality control forms for the JAMAR child forward translations)
- 14_JAMARchi_Forw_unified_1.doc (first unified version of the JAMAR child)

**IMPORTANT:** a copy of all files listed above has to be sent back to PRINTO at: printo@ospedale-gaslini.ge.it
**Back-Translations into English.** The first unified version of the questionnaires will be back-translated by at least 2 (preferably 3) independent back-translators with English as their first language and fluent into the idioms and colloquial form of the source National language. The 2-3 back-translators must not have taken part in the previous step. Back-translation is aimed at improving the quality of the final version of the questionnaires, by pointing out any misunderstandings of the first translation. Back-translators will be unaware of the purpose of the concepts underlying the material and will be of different educational level, background and sex.

See file named:
- 15_JAMARpar_Back_A.doc (backward translation version A of the JAMAR parent)
- 16_JAMARpar_Back_B.doc (backward translation version B of the JAMAR parent)
- 17_JAMARpar_Back_C.doc (optional) (backward translation version C of the JAMAR parent)
- 18_JAMARchi_Back_A.doc (backward translation version A of the JAMAR child)
- 19_JAMARchi_Back_B.doc (backward translation version B of the JAMAR child)
- 20_JAMARchi_Back_C.doc (optional) (backward translation version C of the JAMAR child)

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printo@ospedale-gaslini.ge.it

**Review of backward translations.** The 2 to 3 backward translations will be reviewed by PRINTO Coordinating Centre staff to check their correspondence with the original English version. The aim of this phase is to make sure that the introductory material, instructions for the questionnaires and all the items are still relevant based upon the final version, that the translation is fully comprehensible, and finally to verify the cross-cultural equivalence of the source and final versions by comparing their semantic, idiomatic, experiential and conceptual equivalencies.

PRINTO staff will send to the National coordinator the following 2 files with their comments on the backward translations

See file named (these files are not included in the main packet and will be send by PRINTO staff)
- 21_JAMARpar_Qual_back.doc (quality control forms for the JAMAR parent backward translations)
- 22_JAMARchi_Qual_back.doc (quality control forms for the JAMAR child backward translations)

**Second unified forward version.** All the forward and backward translators will finally meet to discuss the comments received from the PRINTO staff on the backward translations. The purpose of this meeting is to reach a consensus among the translators for a second unified version of the questionnaires in each National language. **Please highlight with different colors (e.g. in yellow) all changes with respect to the previous version**

See file named:
- 23_JAMARpar_Forw_unified_2.doc (second unified version of the JAMAR parent)
- 24_JAMARchi_Forw_unified_2.doc (second unified version of the JAMAR child)

**IMPORTANT:** a copy of all files listed above has to be sent back to PRINTO at:
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Pre-Testing in Target Population Using Probe Technique. Before proceeding to the validation procedure, the second unified version of the questionnaire (files named 23_JAMARpar_Forw_unified_2.doc and 24_JAMARchi_Forw_unified_2.doc) will be administered to 10 parents of patients with JIA and 10 children, of different educational level and background, using a probe technique to ensure parents’ and children’s understanding in the target population. The probe method works as follows: a health professional, familiar with the intent of each question, will administer the questionnaires to the parents and children, asking to consider each question, and elucidate their understanding of each item in an open-ended manner. The health professional will judge if the question is perfectly understood by each parent and child. Questions that are misunderstood by 20% or more of the parents or children will be reviewed by the National Coordinating Centre and revised appropriately.

See file named:
- 25_JAMARpar_Probe.doc (probe technique form for the JAMAR parent)
- 26_JAMARchi_Probe.doc (probe technique form for the JAMAR child)

Final unified forward version. In case modifications to the Second unified forward version are needed (files named 23_JAMARpar_Forw_unified_2.doc and 24_JAMARchi_Forw_unified_2.doc), all the forward and backward translators will finally meet to discuss the results of the probe technique. The purpose of this meeting is to reach the final consensus among the translators for a final unified version of the questionnaires in each National language. Please highlight with different colors (e.g. in yellow) all changes with respect to the previous version.

See file named:
- 27_JAMARpar_Forw_unified_3.doc (third unified version of the JAMAR parent)
- 28_JAMARchi_Forw_unified_3.doc (third unified version of the JAMAR child)

IMPORTANT: a copy of all files listed above has to be sent back to PRINTO at: printo@ospedale-gaslini.ge.it

Once the final unified version will be received by PRINTO, a booklet for data collection will be sent to the PRINTO coordinator with the related instructions.
**Phase II: Validation**

Following the process of cross-cultural adaptation, a large-scale data collection phase will be set up using the third unified forward version of the questionnaires.

Each centre will be asked to enrol 100 non-selected consecutive patients meeting the ILAR criteria for JIA or, if the centre does not expect to see at least 100 patients within 6 months, all non-selected consecutive patients meeting the same criteria seen within the first 6 months after the study start. Moreover, each centre will be asked to enrol around 100 parents of healthy children and around 100 healthy children aged more than 7-8 years. This sample can be represented by the healthy brothers and sisters, other relatives (e.g. cousins), or friends of JIA patients included in the study. In case of healthy brothers and sisters of JIA patients, the parent will be asked to complete the JAMAR for either the patient and the healthy sibling(s) at the time of the visit. The healthy sibling(s) can complete the JAMAR at the time of the visit (if present) or at home.

Each patient in each centre will undergo the following clinical assessments:

**Retrospective data: demographic data, detailed registration of the ILAR criteria, including descriptors/exclusions and occurrence of iridocyclitis, results of ANA determinations, drug therapies received by the patient from disease onset to cross-sectional assessment (only the indication of the name of medications or therapeutic interventions will be required).**

**Cross-sectional data:**
- Physician-centred measures: full joint count, physician’s global assessment of disease activity, physician’s rating of disease status (remission, flare, continued disease activity) on categorical scales, Juvenile Arthritis Damage Index (JADI).
- Parent-centred measures: parent’s version of the JAMAR.
- Patient-centred measures (for children aged > 8-10 yrs): patient’s version of the JAMAR.
- Acute phase reactants if clinically indicated.

All data collection forms and the questionnaires will be printed at the PRINTO Coordinating Centre and sent by DHL to each participating centre. The completed forms and questionnaires will be subsequently sent back to PRINTO Coordinating Centre by DHL. All shipping costs will be charged to PRINTO.

Full protocol and case report forms for data collection will follow, once the third unified version of the questionnaires is available.

**IMPORTANT:** please let us know which other centres in your country may want to participate to the project. These centres will be required to collect just the JIA patients’ data (100 non-selected consecutive patients meeting the ILAR criteria for JIA or, if the centre do not expect to see at least 100 patients within 6 months, all non-selected consecutive patients meeting the same criteria seen within the first 6 months after the study start).
FILE NAMES INDEX

0_instructions.pdf

1_1993_JCE_Guillemin translation guidelines.pdf
2_2001_CER_Ruperto_CHAQ-CHQ_validation.pdf
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CROSS-CULTURAL ADAPTATION CHECK LIST
Please check the appropriate box when the task is completed.

<table>
<thead>
<tr>
<th>FORWARD TRANSLATIONS from English to your language</th>
<th>Parent</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Do the 2-3 forward translators have your country language as their first language?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2 Do the 2-3 forward translators have English as their second language?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3 Are both genders represented among the translators?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4 Are the 2-3 forward translators fluent in the English idioms and colloquial forms of English?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5 Is one of the translators an health care provider (not mandatory) AWARE of the process purposes?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6 Are the remaining translators professional translators UNAWARE of the process purposes?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7 Have the 2-3 forward translators worked INDIPENDENTLY from each others?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8 Have the translators written down their translation in the enclosed blank files? SEND A COPY OF ALL FILES to PRINTO at <a href="mailto:printo@ospedale-gaslini.ge.it">printo@ospedale-gaslini.ge.it</a></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9 Have you convened a meeting along with another member of your group not involved in the cross-cultural adaptation procedures and the three forward-translators (total 4-5 people), in order to rank with them for the quality of the 2-3 forward translations, for semantic, idiomatic and conceptual equivalence (file 11_JAMARpar_qual_forw.doc and 13_JAMARCHI_qual_forw.doc) ?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10 Did you arrive at a preliminary unified version?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11 Have an Investigator inserted in the appropriate text field the commercial names of the most used drugs?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12 Has an Investigator properly modified the footnotes with his/her name and indication of the national language? SEND A COPY OF ALL FILES to PRINTO at <a href="mailto:printo@ospedale-gaslini.ge.it">printo@ospedale-gaslini.ge.it</a></td>
<td>☐</td>
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</tr>
<tr>
<td>BACKWARD TRANSLATIONS (of the unified version at point 10) from your language into English</td>
<td>Parent</td>
<td>Patient</td>
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<tr>
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<tr>
<td>13 Have the 2-3 backward translators English as their first language?</td>
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<td>☐</td>
</tr>
<tr>
<td>14 Have the 2-3 backward translators your country language as their II language?</td>
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<td>☐</td>
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<tr>
<td>15 Are both genders represented among the translators?</td>
<td>☐</td>
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<tr>
<td>16 Are the 2-3 backward translators fluent in the idioms forms of your language?</td>
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<tr>
<td>17 Are the translators UNAWARE of the process purposes?</td>
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</tr>
<tr>
<td>18 Have the 2-3 backward translators worked INDIPENDENTLY from each others?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19 Have the translators typed on paper their work using the enclosed blank files? SEND A COPY OF ALL FILES to PRINTO at <a href="mailto:printo@ospedale-gaslini.ge.it">printo@ospedale-gaslini.ge.it</a></td>
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</tbody>
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<table>
<thead>
<tr>
<th>UNIFIED FORWARD TRANSLATIONS</th>
<th>Parent</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Have you received the comments from the Genova co-ordinating center for equivalence of the backward translation with the original?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>21 Have you convened a meeting along with another member of your group not involved in the cross-cultural adaptation procedures, the 2-3 forward-translators, and the 2-3 backward translators (total 6-8 people) to modify the first unified version and arrive at the second unified version?</td>
<td>☐</td>
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</tr>
<tr>
<td>22 Have you administered the questionnaires using the probe technique described in the grant proposal to the first 10 parents of JIA patients and 10 JIA patients of more than 8 years that come to your clinic for a follow-up visit?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>23 Have you convened a meeting along with another member of your group not involved in the cross-cultural adaptation procedures, the 2-3 forward-translators, and the 2-3 backward translators (total 6-8 people) to modify the second unified version and arrive to the third unified version (not mandatory)? SEND A COPY ALL FILES ABOVE TO PRINTO at <a href="mailto:printo@ospedale-gaslini.ge.it">printo@ospedale-gaslini.ge.it</a></td>
<td>☐</td>
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</tbody>
</table>