**Ileal orthotopic neo-bladder (IOB): how Quality of Life (QoL) of recipients can be measured**

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**A. Background**

IOB allows recipients to void naturally through their urethra. Although most of the advantages of such solution in comparison to others (i.e. stoma) are self-evident IOB may have negative impacts on Quality of life (QoL) of patients. This is due to the difficulties they meet during rehabilitation and to the related attempts to adapt to living with neo-bladder. Very few articles in literature are dedicated however to the QoL of IOB recipients and the few empirical studies have been conducted by applying current QoL instruments. Among these: the MOS SF-36; the FACT-B1; the Hospital Anxiety & Depression Scale (HAD); the QLQ from EORTCL (see for example Mansson, Davidsson et al 2002; Hara, Miyake et al.2002; Mansson, Caruso et al.2000). Such scenario seems to suggest that QoL in IOB recipients is not considered of main concern. Nevertheless the need for a valid and reliable QoL instrument is claimed in urology for testing IOB surgery outcomes, monitoring recipients during follow-up and supporting them in their normal lives. The present document outlines a procedure in order to envisage the most suitable strategy for QoL measurement in IOB recipients including the development of a specific QoL questionnaire. The initial project will take place by involving 4 Italian centres, before undergoing international development.

**B. Research strategies**

Several possible strategies of instrument development in international backgrounds have been discussed preliminarily. The one seen as most suitable for the present project is described in the following.

The QOL questionnaire development was seen as including the following 4 phases:

1) Item generation;  
2) QoL instrument design;  
3) International adaptation;  
4) Psychometric property testing survey (for reliability, validity testing);  
5) Dissemination and further research planning.

**Phases 1-2) Item generation and instrument design**

Phases 1-2 will be performed in Italy with the participation of the centres of urology of the universities of Trieste, Verona, Padova, Brescia, Genova and Modena. Items will be generated trough in depth techniques of inquiry. A number of 35-50 interviews should be performed on patients from the participating clinics. Interviewers will use a specifically prepared interview guide, will tape record their interviews which will be transcribed subsequently. Scripts will undergo content analysis in order to draw significant sentences which could be suitable to be transformed into possible items of QoL questionnaires.
In the instrument design phase (2), an hypothesis of instrument development will be formulated: decisions about either using parts of existing questionnaires or developing brand new instrument, will be considered.

3) International adaptation

A systematic translation from Italian into English will take place first including the following steps:
1) two translators native in English and bilingual in Italian will translate independently the rough questionnaire into English;
2) comparison of the two translations will be made and a first English version will be produced;
3) a native Italian translator bilingual in English will translate the English version into Italian (backtranslation);
4) comparisons between the first Italian original version and the backtranslation will be made and possible changes to the translation discussed;
5) In the field testing (or cognitive debriefing) step local questionnaires will be administered to 5-10 IOL recipients for each country by asking whether items are understandable, sound and suitable to describe their condition. IOL recipients have to be selected by making sure that also low education persons are included. Response scales will also be checked. An standardized interview guide will be prepared for local team interviews;
6) steps 1-5 will be repeated in the other participating countries by assuming the English version as the source for further international adaptations.
7) Each country is encouraged to produce some cultural specific items. Such Items will be roughly translated from a language into the other before the final harmonization.
8) During international harmonization item discussion will take place between representatives of all local teams participating in the project. The locally produced questionnaires will undergo the subsequent psychometric testing step and decision on the possible items suggested by each country will be made.

4) Psychometric testing

A number of IOB recipients will undergo a protocol including:
 a) the clinical CRF and patient demographics;
 b) the QoL questionnaire so far produced;
c) concurrent measures for psychometric testing (other questionnaires related to the QOL concerns under scrutiny).
The protocol will indicate inclusion as well as exclusion criteria, ethic requirements a.s.o. and ethical requirements will be met.
Psychometric properties will be tested on a sample whose size will be assessed once the number of participant countries will be assessed.
A half of the sample should be re-tested after 8 days for test-retest reliability. EDP will be performed on order to test internal consistency reliability and construct validity, by crossing results with other current measures on the same very aspects considered by the new questionnaires.
Although the precise requirement of QoL measures for IOB will be decided ad the project go along easy to handle and short forms will be produced.

5) Publication and research plan

Each phase will give place to publications. Nevertheless a systematic plan will be drafted on the last meeting of the participating teams.
Steps and timeline are drafted in appendix 1.

C. Further suggestions

The following suggestions could be of utility for the management of the project.
1) Although not mentioned so far decision-making meetings among researchers will be important. In appendix 1 some proposals have been drafted. In order encourage sponsors to support the project, day conferences open to experts could be kept. In any case, the use of video-conference technologies will help for minor importance meetings.

2) Each team should include a non-medical practitioner for the management of both interviews and field testing of the first preliminary version.

3) Each team should be in contact with 2 translators native in the local mother language and with a translator native in English for the step (backtranslation) of the systematic translation procedure.

4) A preliminary overall team meeting should be dedicated to the areas of concern that patient use to refer from to in his/her conversations with the clinician, by collecting experiences of the participant clinicians about the main QoL concerns.

5) Although QoL on IOB is not popular in literature a deep search on Medline or dedicated journals should be performed.

D. References


Marciniak A, NIERO M, Integrating patients’ views into the measurement of quality of life: examples from peri-post menopausal periods*, Quality of Life Research, 2000, 7: 775-784.


# APPENDIX 1. OUTLINE AND TIMELINE

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<tr>
<th>ITEM GENERATION PROCEDURE</th>
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<td>INTERVIEW - GUIDE PREPARED</td>
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<td>INTERVIEWS SCRIPTS OBTAINED FROM TPE RECORDINGS</td>
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PER PARTECIPARE AL PROTOCOLLO RIVOLEGERSI AL PROF SIRACUSANO - TRIESTE