

ITEM BANKING

Call for papers

Quality of Life Newsletter Special Issue on "Item Banking"

The strategy to pool PRO/QoL measures into item banks has found supporters worldwide, looking for more relevant and reliable information, identifying problems and solutions for health outcomes assessment. To outline a vision of this new practice, we invite you to contribute to the Item Banking Special Summer Issue of our Quality of Life (QoL) Newsletter. Your article should address issues on: the interest of item banking to the field, the development and/or practical use, and applications and perspective. Likewise our bi-annual QoL Newsletter, the Item Banking Special Issue will be circulated to over 8000 people around the world.

Deadline for submission:
28 May 2004

We look forward to hearing from you. Submission information will be sent on request. For requests and questions, please contact Leticia Lobo Luppi: llloboluppi@mapi.fr

QOLID Discounts for ISOQOL's Members

ISOQOL Board of Directors recently approved a plan that will enable the ISOQOL's members to take advantage of a generous discount on yearly subscriptions to QOLID (the Quality of Life Instruments Database) through the MAPI Research Institute. ISOQOL members can now take advantage of a discount from 20% to 25% on annual subscriptions to this information-packed online database available at www.QOLID.org

See QOLID insert on p 11-14 of this QoL Newsletter

Gender and Age Based Differential Item Functioning in the AMC Linear Disability Score Project

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Background

An important assumption in item banking is that the items included in a calibrated item bank have the same measurement characteristics for all subgroups in the population. Differential item functioning occurs when patients in two groups have different probabilities to respond to an item in a given way, even though they have the same level of health status or quality of life. If differential item functioning is ignored, inaccurate measurements are obtained and true differences between patient groups may be obscured and non-existent differences 'created'.

Differential item functioning has been identified in a wide range of instruments, designed to quantify aspects of health related quality of life. Items from the Mini-mental State Examination have been

shown to function differently for education and gender based groups in a community-based sample¹. Items from the RAND-36, based on the SF-36, had different measurement characteristics for patients with multiple sclerosis, rheumatic diseases and COPD², while items from the SF-12 function differently in age and education level based groups in respondents to the 2000 Medical Expenditure Panel Survey³. The Rivermead Mobility Index items functioned differently for age based but not for gender based groups in a sample of lower limb amputees⁴. The Bath Ankylosing Spondylitis Functional Index and Revised Leeds Disability Questionnaire both demonstrated differential item functioning with regard to age and perceived duration of illness⁵. The items from the National Health Interview Survey Disability Supplement in a sample of

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civilian, non-institutionalised persons requiring help or supervision with at least one activity⁶ and the items from the PDQ-2 39 and Nottingham Health Profile in a sample of patients with Parkinson's disease⁷ function differently with respect to age and gender based groups. The conclusions drawn in the studies discussed indicate that it is essential to examine items, in instruments to quantify health related quality of life, to see whether they have the same measurement properties for subgroups of respondents.

The **AMC Linear Disability Score project** aims to construct and calibrate an item bank to measure functional status, as expressed by the ability to perform 'activities of daily life'⁸. Each item in the item bank describes an activity of daily life essential for living independently or in an appropriate care setting. Necessarily, a large proportion of items describe domestic activities, which are traditionally, and currently, primarily performed by either men or women. This paper uses non-parametric item response theory methods^{9,10} to compare the measurement properties of the items from this item bank across gender and age based groups in the responses given by residents of nursing and care homes in and around Amsterdam, The Netherlands. The results will extend knowledge of differential item functioning in the items in this and similar item banks¹¹.

Respondents and items

The data described in this article comes from the responses of long-term residents of sheltered housing schemes, care and nursing homes in Greater Amsterdam, The Netherlands, to sets of items presented in an interview carried out by specially trained nurses. The interviews were conducted between December 2002 and July 2003. Of the 551 respondents, 440 (80%) were female and 277 (50%) were aged 84 years or under. Furthermore, 525 (95%) of the respondents were aged 70 or older.

Each of the 160 items described an activity of daily life. Participants responded to each item in one of the categories 'I can carry out the activity', 'I cannot carry out the activity' or 'This item is not applicable to me'. The final category was only used if the respondent had never experienced the activity. For example, respondents, who had never had a full driving licence, responded in this way to the item 'driving a car'.

Four sets of 80 items were used. The sets of items were compiled in such a way that they were equally difficult and were allocated to patients randomly. Each set was linked to two other sets using 39 or 40 common items⁸. In order to obtain the maximum amount of information on the measurement properties of the items described in this paper, four data arrays, based on the common items between pairs of sets of items, were constructed. Each item appears in a single data array, but about half of each patient's responses appear in one data array and the other half

in another data array. Full details of the methodology employed have been given elsewhere^{8,12}.

Statistical analysis

Although most instruments measuring health related quality of life are analysed using sum score based methods, interest in item response theory (IRT) based methods, including item banking, is currently increasing¹³. The majority of research using IRT concentrates on the well-known parametric models, such as the Rasch and the two-parameter logistic models.

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TABLE 1: types of item, for which the majority have the same measurement characteristics for men and women and for respondents aged 84 or younger and respondents aged 85 or older. The letter 'M' denotes that the item is easier for men than for women, the letter 'F' that the item is easier for women than for men and the letter 'Y' that the item is easier for respondents aged 84 or younger.

Mobility and agility – 27 items	Dressing and self-care – 19 items	Activities outside the home – 16 items
Walking up a flight of stairs	Putting on a coat	Eating in a restaurant
Standing for 10 minutes	Putting on a blouse or shirt	Visiting an outpatients' clinic
Walking up two flights of stairs	Putting on a T-shirt or vest	Visiting a dentist
Going for a long walk	Putting on a scarf and gloves	Voting in an election
Going down a flight of stairs	Putting trousers on	Visiting a general practitioner
Getting out of bed into a chair	Washing upper body at sink (taken to sink)	Travelling by bus
Walking for less than 15 minutes	Washing lower body at sink (taken to sink)	Going to the bottle bank
Sitting up in bed	Washing upper body at sink	Travelling (not driving) in a car
Sitting on the edge of the bed	Washing lower body at sink	Going to a concert
Moving between two dining chairs	Rubbing in body lotion	Shopping for clothes
Moving between two easy chairs	Shaving or putting make-up on	Going to a birthday party
Reaching into a high cupboard	Using a public toilet	Visiting a hairdresser
Putting a dining chair up to a table	Going to the toilet in your own home	Fetching groceries
Locking a door	Using a lift	Visiting the neighbours
Cutting finger nails	Taking oral medication	Going to the pharmacy (Y)
Opening and closing a door	Pulling a blanket around oneself	Crossing the road (Y)
Whipping feet on doormat	Showering and washing hair (M, Y)	Having a drink in a cafe (F)
Getting a book off a shelf	Cutting toe nails (M)	
Answering the door bell	Putting on lace-up shoes (M)	
Reaching into a low cupboard		
Picking something up off the floor		
Opening and closing a window		
Opening a high window		
Opening and closing curtains		
Going for a walk in the woods		
Getting into a car (M)		
Walking up a hill or high bridge (M)		
Caring for plants – 4 items		
Re-potting a houseplant		
Putting flowers in a vase		
Watering a houseplant		
Caring for plants on a balcony		

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However, non-parametric IRT models have also been developed. Non-parametric models have the advantage that it is easier to differentiate between differential item functioning and item misfit. In this article, the probability of persons with a particular level of functional status responding to a given item in the category 'I can carry out this activity' is plotted against their functional status. These probabilities are then smoothed using a kernel method. Differential item functioning is quantified as the mean of the distance between the smoothed probability for the reference group, say women, and the smoothed probability for

the focus group, say men, weighted by the distribution of the latent variable in the reference group⁹. This type of model can be fitted using the TestGraf software¹⁰, although the standard errors for the estimates of differential item functioning are too small by a factor of 0.4 [personal communication – J.O. Ramsay, 2003]. Before the IRT analysis commenced, items with more than 90% or fewer than 10% of responses in the category 'cannot' were excluded from further analysis. Responses by patients in the category 'not applicable' were treated as if the item had not been presented to the patient¹⁴. Items were regarded as demonstrating differential

item functioning if the *P*-value of the appropriate statistic was less than 0.01.

Results

A total of 160 items were included in this study. Two items (1%) were excluded because they were only in a single data set, meaning that there were not enough responses to evaluate them. In addition, 35 items (22%) were excluded because more than 90% or less than 10% of the responses were in the category 'cannot'. This means that there was little information on the behaviour of these items and that they were unsuitable for quantifying the functional status of residents of care and nursing homes. A total of 15 items (9%) were easier for women and 18 items (11%) were easier for men. A further 4 items (3%) were easier for respondents aged 84 or under and 2 items (1%) were easier for men and easier for respondents aged 84 or under. The remaining 86 items (54%) did not display statistically significant amounts of differential item functioning.

The types of item, for which the majority have the same measurement characteristics for men and women and for respondents aged 84 or younger and respondents aged 85 or older are given in Table 1. Of the 27 items reflecting mobility and agility, 25 have the same characteristics for all groups and 2 are easier for men than women. All 4 items on caring for plants have the same characteristics for all groups. Of the 19 items reflecting dressing and self-care, 16 have the same characteristics for all groups and three are easier for men than for women. Two of these three items are particularly interesting: 'showering and washing ones hair' and 'putting on lace-up shoes'. When considering these items, it is useful to note the large proportion of women in this age group, who have a highly coiffured hairstyle requiring 'setting' by a hairdresser, and the unpopularity of lace-up shoes in women of this age group. Furthermore, of the 16 items reflecting activities outside the home, 14 have the same characteristics for all groups and two are easier for respondents aged 84 or younger. One of these, 'going to the pharmacy', may be explained by the fact that pharmacies in the Amsterdam region provide a free delivery service.

The types of item, for which a large proportion do not have the same

TABLE 2: types of item, for which a large proportion do not have the same measurement characteristics for men and women or for respondents aged 84 or younger and respondents aged 85 or older. The letter 'M' denotes that the item is easier for men than for women, the letter 'F' that the item is easier for women than for men and the letter 'Y' that the item is easier for respondents aged 84 or younger.

Housework, cleaning and laundry – 24 items
Cleaning a bathroom
Mopping the floor
Sweeping the floor
Using a dustpan and brush
Cleaning a fridge
Clearing the table after a meal
Vacuum cleaning
Washing up
Shaking a table cloth out
Polishing shoes
Hanging clothes in a cupboard
Putting crockery away
Cleaning a toilet (F)
Changing the sheets on a bed (F)
Changing a duvet cover (F)
Making a bed (F)
Cleaning kitchen worktops (F)
Cleaning a bathroom sink (F)
Dusting (F)
Using a washing machine (F)
Washing underwear by hand (F)
Hanging the washing out (F)
Ironing clothes (F)
Folding clean laundry up (F)

Household maintenance – 5 items
Changing the bulb in a side lamp
Plugging in an electrical appliance
Tightening a screw (M)
Hanging something on a nail (M)
Unblocking a sink (M)

Eating and food preparation – 13 items
Eating a meal
Making a fried egg sandwich
Making coffee or tea
Preparing a bowl of cereal
Peeling an apple
Warming tinned soup up
Making a cheese sandwich
Preparing porridge
Preparing a light meal (F)
Preparing a warm meal (F)
Opening a bottle of fizzy drink (M)
Pulling a cork out of a wine bottle (M)

Lifting and carrying – 7 items
Lifting a box weighing 10kg (M)
Lifting a toddler up (M)
Doing weekly grocery shopping (M)
Putting a bag of rubbish out (M)
Carrying a tray (M)
Moving a bed or table (M)
Picking up something from under table (M)

Household administration – 10 items
Setting an alarm clock
Reading a newspaper
Writing a letter
Fetching and opening letters
Wrapping up a present
Filling in an official form (M)
Going to the post office (M)
Using an automatic teller machine (M, Y)
Replacing a passport (Y)
Posting a letter (Y)

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(continued from p 3)

measurement characteristics for men and women or for respondents aged 84 or younger and respondents aged 85 or older, are given in Table 2. Of the 24 items reflecting housework, cleaning and laundry, 12 are easier for women. It is interesting to note that all five items reflecting washing clothes are easier for women than men. Of the 5 items reflecting household maintenance tasks, 3 are easier for men than women. Furthermore, of the 12 items reflecting eating and food preparation, 2 are easier for women and 2 are easier for men. Women appear to find preparing a whole meal easier and men find preparing drinks easier. All 7 items reflecting activities with a large element of lifting or carrying are easier for men than women. Finally, of the 10 items reflecting household administration, 2 are easier for men, another 2 items are easier for respondents aged 84 or younger and one item is easier for both men and respondents aged 84 or younger.

Discussion

Due to the relatively small sample size and the low significance level used in this study, only items with a substantial amount of differential item functioning have been identified. It is plausible that even more items would have demonstrated different measurement characteristics for subgroups if a larger sample had been available or a higher significance level used.

A lot of items in instruments to assess functional health status reflect activities traditionally performed primarily by either men or women. These items are likely to have different measurement characteristics for men and women. Examples include: housework, particularly items relating to laundry; preparing meals; lifting and carrying heavy objects; and household maintenance. A number of items will describe activities, which have only become common place in recent years. These items are likely to have different measurement characteristics for younger and older respondents. Examples are: withdrawing money using an automatic teller machine; using a mobile telephone. Notice should be taken of local customs when interpreting results. These results were obtained from a sample of respondents from the Netherlands. Activities of daily life seen as the preserve of men or of women differ, even between countries with very similar cultures,

meaning that a sample from another country or culture may result in very different results. The items, which behave in different ways for different subgroups, will either be removed from the item bank or included with different measurement properties for different subgroups. The latter approach may seem complicated, but is straightforward in the framework of a computerised item bank. •

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WARD

~~~ REMINDER ~~

#### Catherine Pouget Research Award

Deadline for submission: 31 May 2004

The **Catherine Pouget Research Award** is intended to encourage young investigators to study the impact of quality of care on, or improve the quality of life of the terminally ill. Applicants may include students, degree candidates, fellows, or faculty members early in their research. The selection committee will consider a wide range of research projects whose results are likely to improve the quality of life and/or the health care of the terminally ill. Appropriate research projects would include studies of the impact of interventions on the quality of life of the terminally ill and studies of measures and determinants of quality of life and patients and/or families perspectives about the quality of care and/or life experiences. The maximum amount that will be funded will be \$10,000 for work to be completed over a 1 or 2 year period.

Application Form available on the MAPI Research Institute website at [www.mapi-research-inst.org](http://www.mapi-research-inst.org)

Please submit proposal to Mrs Leticia Lobo-Luppi, MAPI Research Institute, 27, rue de la Villette, 69003 Lyon, France E-mail: [llobo-luppi@mapi.fr](mailto:llobo-luppi@mapi.fr)

# WORK IN PROGRESS

## SPARCLE – Study of PARticipation of Children with Cerebral Palsy Living in Europe

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**This study whose full title is 'The Influence of Environmental Factors on the Participation and Quality of Life of 8-12 Year Old Children with Cerebral Palsy in 6 EU Countries' is funded by the European Commission Research Framework 5 Programme - Grant number QLG5-CT-2002-00636.**

### Background

Cerebral palsy is the commonest cause of physical impairment in childhood and associated with cognitive and sensory impairments. It occurs in 1 in 500 births, or 10,000 new cases a year in the E.U. Children with cerebral palsy continue to be seriously disadvantaged with respect to social relationships, education and employment prospects, even though there are infrastructures and systems in place in every European country to respond to the child's and families' needs. Such arrangements are called Environmental Factors in the International Classification of Functioning, Disability and Health: Final Draft ICIDH-2<sup>1</sup> and are defined as the physical, social and attitudinal environment in which people live and conduct their lives. Environmental factors include factors such as arrangements for educational provision, social attitudes and norms, legislation on access to buildings, anti-discrimination legislation, transport design, rehabilitation and therapeutic services and assistive technology. Within any one locality or even country, environmental factors are relatively constant but between countries they vary considerably. A preliminary survey amongst the collaborating partners has confirmed that there are major differences in environmental factors between the participating EU countries. For instance, one third of the centres must provide wheelchair access to trains by law; one third must allow access to cinemas but they are different centres to those previously mentioned. There are also wide variations in financial benefits and availability of specialised services.

However, a systematic description and assessment of relevant environmental factors across different countries has not been undertaken before. In order to determine which actually work it is necessary to evaluate environmental factors against a well-defined outcome.

A collaboration of 14 cerebral palsy registers in European countries exists, funded by the EU. Each register covers all children in a defined geographical area, and each child is categorised for impairment, by type and extent. Those involved in the collaborative register realised that children with similar severity of impairment progress very differently and that this appears to relate to some obvious environmental factors such as educational provision and possibly to others not systematically studied or recorded. There are two outcomes that can be used to assess different models of provision for children with disability. The first is what the child does (participation) and the second is how the child feels (quality of life). Participation is an objective measure of health status whereas quality of life is a subjective measure of health status.

Although the concept of participation has been well articulated for over 20 years, there have been few attempts to operationalise it, and particularly so for children. This was partly because ICIDH was criticised for being too medical and not taking the social construction of disability sufficiently into account<sup>2</sup>. However, the Final Draft of ICIDH-2 has largely reconciled this by the formal introduction of contextual factors. The Final Draft ICIDH-2 classifies participation as follows: learning and applying knowledge, general tasks and demands, communication, mobility, self-care, domestic life, interpersonal interactions and relationships, major life areas and community, social and civic life.

Past research has tended to rely on parents' perceptions of their child's quality of life, but it is now recognised that children's view should be sought directly rather than being inferred from indirect reports. Measurement of quality of life in children has also lagged behind because

of conceptual and practical difficulties such as the reliability of children's self reports, and the different values which children place on particular health states as compared to adults<sup>3,4</sup>. Early work has also tended to develop measures specific to particular diseases such as cancer<sup>5</sup> and asthma<sup>6</sup> for the purpose of contributing to the evaluation of medical interventions. There is now the need to measure quality of life in children with relatively stable impairment whose health status and quality of life are likely to be influenced more by social and educational environmental factors than by medical interventions. In addition, although a number of qualitative studies asking disabled children and their families to report their experience have yielded important insights into the lives and views of such children<sup>7,8</sup>, larger populations of disabled children should now be studied to determine how much participation and quality of life varies between children with comparable severity of impairment, and compared to children without impairment. This study will take advantage of the European collaboration of cerebral palsy registers so that relationships identified between environmental factors and outcome (participation and quality of life) can be compared across different countries. It will be epidemiologically sound because the registers cover all children in particular areas and involve sufficient numbers of children on which to base statistically sound conclusions.

### Aim

The study aims to identify which environmental factors, if improved, will yield the greatest benefits for children with disabilities and their families. This knowledge will inform EU policy in the health, educational and social sectors and generate protocols to optimise outcomes. The principal hypothesis is that children with similar severity of impairment will experience variable outcomes in different countries due to variation in environmental factors.

# WORK IN PROGRESS

## SPARCLE – Study of PARticipation of Children with Cerebral Palsy Living in Europe

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### Sample

Children aged 8-12 years will be drawn from cerebral palsy registers in 8 centres in Europe: Denmark, France (2 centres), Ireland (2 centres), Italy, Sweden and UK. Those on the register within the age range will be stratified in advance according to severity of impairment.

The study will also collect data on non-disabled children in each country to determine how much participation varies between disabled and non-disabled children, and whether there are differences between countries.

### Instruments

The following aspects will be investigated:

#### Personal factors

The study will measure personal factors, which are potentially confounding such as parental stress and life events, and the child's personal characteristics.

#### Environmental factors

The study will measure environmental factors that are relevant to the majority of children with cerebral palsy, and that can be used in an analysis where the factors are used as explanatory independent variables. The study will describe and quantify environmental factors at two levels:

- National level;** for example anti-discrimination legislation. A literature and publications review will be conducted between June 2003 and June 2004 by a sub-contracted social scientist at Edinburgh University, UK. It will examine environmental factors at a national macro level by reviewing research literature, EU publications, international reports and European government publications. It will bring together up-to-date information about how environmental factors vary between European countries, mainly concentrating on the countries in the study but will include all those in the EU and those seeking membership.

- Local level;** for example availability of respite care or family experience such as cinema accessibility. Following a literature review<sup>9</sup> and pilot study completed in April 2003, focus groups were conducted with parents in each country to discuss environmental factors relevant to their child's disability. This information was used to generate items for an instrument to measure the experiences of families on these factors – an instrument now being used in our study.

### Participation

SPARCLE will use the LIFE-H instrument which has been developed within the ICDH-2 framework and has been used in children with cerebral palsy<sup>10</sup>. The LIFE-H was validated in 2002 on 8-12 year old children by researchers in Quebec.

#### Quality of Life

Quality of life will be reported by the children themselves wherever possible using a generic instrument, KIDSCREEN<sup>11</sup> so that quality of life can be assessed in the same context and with the same instrument in all children. KIDSCREEN is ideal for SPARCLE, because it has been developed in a European context and its items are derived from children's own reports. Children with severe cognitive difficulties will not be able to self-report, and work at Hôpital Paule de Viguier, Toulouse in France has determined the most appropriate proxy measures to use. For this group of children, we will use the parent-completion KIDSCREEN and CHQ-PF50<sup>12</sup>, and the child's teacher/therapist will also be asked to complete these questionnaires. There is debate as to whether proxy report is appropriate for measuring quality of life, but it is preferable to get a proxy measure than to exclude this group of children from the study.

#### Child impairment

A descriptive instrument for child impairment has been developed which combines the classification presently used by the cerebral palsy collaborative group and the Gross Motor Classification System<sup>13</sup>.

### Dissemination

Local dissemination in each country will begin to parents, children, voluntary organisations and health and social service departments in year two. Central dissemination with findings will take place later to key EU committees, international conferences and journals, and in all the languages of the centres taking part in SPARCLE

### What we hope to achieve

We will have assessed the participation and quality of life of 1200 children with cerebral palsy across Europe.

We will have described and quantified environmental factors relevant to children with cerebral palsy across Europe.

We will have developed a statistical model to represent how these environmental factors influence participation and quality of life.

We will be able to make recommendations about the optimal environment, and these will hopefully influence social policy development by the European Commission. Data collection will begin in April 2004 and be completed by June 2005. Results will be published in 2006. Further information can be accessed on the website (<http://www.ncl.ac.uk/sparcle/>) or from the contact address. ●

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# WORK IN PROGRESS

Canada

## Quality of Life and Perceived Communication between Patients and Health Care Providers among Women with Breast Cancer

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### Current Knowledge and Rationale of the Study

#### Quality of life among women with breast cancer

Breast cancer is a major public health problem, with 570,000 new cases diagnosed worldwide every year<sup>1</sup>. In 2003, breast cancer continues to be the leading form of cancer diagnosed among Canadian women, with an estimated 21,100 newly diagnosed cases. However, due to early screening programs and effective treatments, women with breast cancer can foresee living longer, and a large number of them can even hope for total recovery<sup>2</sup>. Now that medical interventions offer new hope to many women, their quality of life during the various phases of the disease's evolution needs to be addressed. Women with breast cancer have to deal with numerous short- and long-term somatic, psychological and social difficulties that may compromise their quality of life. It is therefore of prime importance to evaluate their quality of life in order to implement appropriate psychosocial interventions that will promote to the utmost their quality of life, now and in the future.

A large number of studies<sup>3-11</sup> have been published on the quality of life of women suffering from breast cancer. However, 1) none of these studies has examined the longitudinal change in the quality of life of these women in relation to the various phases of the disease; 2) no researcher has attempted to identify the main determinants of quality of life as a function of the quality of communication between patients and health care providers throughout the clinical evolution of the disease.

Several studies have looked at the quality of life of breast cancer patients at a specific moment in the disease's trajectory, either during treatment or during long-term remission<sup>5,8,9,11</sup>. But only a few studies, all cross-sectional<sup>12,13</sup> have attempted to describe quality of life trajectories in women with breast cancer, that is, to describe the evolution in their quality of life in relation to the different phases of the disease, such as the diagnostic, treatment and post-treatment

phases. Furthermore, no study has examined the association between quality of life trajectories and socio-demographic characteristics of these women (age, education, income). To develop effective and better-focused interventions, new studies should be designed and conducted so as to fill this knowledge gap.

#### Quality of life and communication among women with breast cancer

Clinical observation and a number of published reports show that communication between patients and health care providers is considered one of the most important aspects of quality of life among cancer patients<sup>14,15</sup>. Good communication between breast cancer patients and health care providers offers many advantages. First, Northouse and Northouse<sup>16</sup> note that, through effective communication with health care providers, these patients can reveal their feelings, share their fears and regain control of their lives. Moreover, some researchers<sup>17,18,19</sup> have demonstrated that the quality of communication between cancer patients and those who care for them greatly influences their health. Specifically, these researchers have asserted that the psychological and physical adaptation of breast cancer patients toward their disease improved with good communication between them and health care providers. In short, the studies concerning communication in the health care setting<sup>17,18,19,20</sup> show the significance of effective communication between patients and health care providers on the patients' well-being. The variable "communication" is all the more important in the current context of health care services on account of the accrued number of women diagnosed with breast cancer, shorter stays at the hospital and the scarcity of health care providers such as doctors and nurses. Therefore, communication between patients and health care providers appears to be a determining factor to consider in quality of life studies among women suffering from breast cancer. In addition, few researchers<sup>17,19,21</sup> have evaluated how breast cancer patients perceived their communication with health care providers.

Moreover, all of these studies were restricted to only one phase of the breast cancer trajectory - the diagnostic period<sup>17</sup>, treatments<sup>21</sup> or post-treatment<sup>19</sup>. To our knowledge, there is no research that examines communication between patients and health care providers along a trajectory, that is, according to many phases of the disease's evolution. Thus, it would be useful to ascertain whether communication between breast cancer patients and health care providers is defined as a static phenomenon or that changes over time. Likewise, it would be useful to determine whether the quality of communication between breast cancer patients and health care providers influences quality of life for these women at various phases during the disease's trajectory. To our knowledge, no study yet available documents this link.

### Research Objectives

The present research is based on the idea of trajectories as described by Holland<sup>22</sup> and Corbin & Strauss<sup>23</sup>. The proposed study has **three main objectives of an exploratory nature:** **1)** to describe the quality of life of women with breast cancer during three phases of the disease's evolution, namely diagnosis, radiation therapy and post-treatment; **2)** to describe how breast cancer patients perceived communication with various health care providers (doctors, nurses, radio-oncology technicians) at the three phases described above; **3)** to examine the degree and direction of the link between quality of life and perceived communication between patients and health care providers among women suffering from breast cancer during the diagnosis, radiation therapy and post-treatment phases. The study's secondary objectives will consist of exploring trajectories of quality of life and trajectories of perceived communication between breast cancer patients and health care providers with respect to the socio-demographic data of breast cancer patients (age, education, income) and those of health care providers (sex and role of health care provider).

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# WORK IN PROGRESS

## Quality of Life and Perceived Communication between Patients and Health Care Providers among Women with Breast Cancer

(continued from p 7)

### Method

#### 1. Subjects

Subjects for this study will be 120 French-speaking women with breast cancer recruited at two hospital centers affiliated with Université de Montréal. Their eligibility for the study is based on the following criteria: being 18-75 years of age; having an early cancer diagnosis (stage 1 and 2), specifically tumors of 5 cm or less with auxiliary nodules of N0 or N1 and no metastasis; undergoing a future lumpectomy as a surgical procedure. The following exclusion criteria apply: previous cancer; chemotherapy as initial treatment; total mastectomy as a surgical intervention and finally, evidence of serious psychiatric illness (psychosis) or suicidal tendencies during the study period.

#### 2. Design

A longitudinal design will be used. The study will require an approximately one-year commitment, during which the women will have to fill out questionnaires three times: 1) around the diagnostic period, that is, between the time of diagnosis and surgical intervention; 2) about half-way through the scheduled radiation therapy, specifically between 3 to 4 weeks after the start of radiation therapy, should it lasts 6 weeks 3) between 2 to 3 months following the end of their radiation therapy.

#### 3. Procedure

Recruitment: After obtaining authorization from the ethics committees of the two hospitals affiliated with Université de Montréal, the principal investigator (JGT) presented her study to all oncology surgeons in both hospitals in order to have access to their patients. The oncology nurse working at the CRID (Centre de Référence pour l'Investigation Désigné) of each hospital identifies the women who meet all selection criteria and gives a pamphlet describing the study to each one after her visit with the oncology surgeon. The nurse asks whether the patient accepts being called by the principal investigator. The research project is then explained; if the women agree to take part in the study, they sign a consent form. They have to fill out self-administered questionnaires at the three specified time periods stated above in a standardized order with the help of the principal

investigator to minimize omission of data. Women fill out the questionnaires either in a private room at the CRID clinic or, if they prefer, at home. The time required for completing all questionnaires is in the order of 60 minutes.

### Measuring Instruments

The women complete the following questionnaires in a standardized order: a questionnaire pertaining to demographic and medical data, the MOS Social Support Survey<sup>24</sup>, two Quality of Life questionnaires namely the EORTC QLQ-C30 plus its BR23<sup>25,26</sup> and the FACT-B<sup>27,28</sup>, two questionnaires that evaluate the perceived communication between patients and health care providers that is the Medical Communication Competence Scale<sup>29</sup> and the Perceived Physician's Communication Style Scale<sup>30</sup>, and finally a Visual Analog Scale is administered to assess the women's overall perception of communication between themselves and the health care providers.

### Relevance of this Study

By studying the quality of life of women with breast cancer at different phases of the disease, we will be better able to identify the various difficulties encountered at different points, and better focused psychosocial interventions could be developed to help these women at different times. Also, by better understanding how communication affects the quality of life of these women throughout the clinical evolution of their disease, it should enable health care providers to change their approach towards their patient by using better communication strategies in order to improve the quality of care and quality of life of women afflicted with breast cancer. Finally, the results of the present study will provide useful information on which decision-makers in the health care system can base their priorities for money and resource allocation towards effective psychosocial programs for patients diagnosed with breast cancer along the disease's trajectory.

### Progress Report

The present study has been approved by the ethics committees of two hospitals affiliated with Université de Montréal. All

oncology surgeons (n=9) have agreed to participate in it. Data collection started in November 2003. As of the beginning of January 2004, 45 women with breast cancer have been invited to participate in the study and 40 accepted, a response rate of 88%. So far, the women had no difficulty completing the questionnaires and there were almost no missing data. We plan to recruit 120 women in the first phase of the disease's trajectory by the beginning of the Summer 2004. We estimate that we will have collected complete data on 120 patients (3 phases) by the Summer of 2005. •

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# WORK IN PROGRESS

## Quality of Life and Perceived Communication between Patients and Health Care Providers among Women with Breast Cancer

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## PUBLICATION

### Coping Strategies and Health-Related Quality of Life in Persons with Traumatic Spinal Cord Lesion

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**Aims:** The overall aims of the thesis were to investigate coping strategies employed by persons with traumatic spinal cord lesion (SCL) to cope with the lesion and its consequences, and to study the relations between coping strategies and health-related quality of life (HRQoL). Further, specific contributions to SCL-related scale development were given.

**Methods:** Participants were recruited among community-residing persons with SCL from a typical rural/urban Swedish area. Characteristics of the participants were comparable to the general Swedish SCL population. In a cross-sectional design, items in a pool derived from in-depth interviews, literature reviews and the transactional theory of stress and coping were tested. Standardised instruments were used to assess general coping strategies, social support, and HRQoL. A rigorous psychometric procedure was used. First, 274 persons participated in the development of SCL-related coping strategies and emotional well-being measures. Second, a sub-sample of 256 persons participated in studies of relations between SCL-related coping strategies and a wide range of HRQoL domains. Third, a further sub-sample of 181 persons participated in a comparison of SCL-related and general coping strategies. Three reference groups were used: 167 persons with SCL from the same catchment area, 110 age- and sex-matched persons from the Swedish norm group (SF-36), and a general population sample of 264 persons.

**Results:** The SCL-related Coping Strategies Questionnaire (SCL CSQ) and SCL-related Emotional Well-being Questionnaire (SCL EWQ) both met basic psychometric standards for reliability and validity. The SCL CSQ comprises three factors: Acceptance (i.e. revaluation of life values); Fighting Spirit (i.e. efforts to minimise the effects of the lesion); Social Reliance (i.e. a tendency towards dependent behaviour). The SCL EWQ included three factors: Helplessness (i.e. feeling perplexed, out of control and low self-esteem); Intrusion (i.e. bitterness and brooding); Personal Growth (i.e. positive outcomes of life crisis). There were clear limitations in participants' generic HRQoL compared to age- and sex-matched references. Two SCL-related coping factors were clearly associated with all HRQoL domains when social support and a wide range of socio-demographic and disability-related variables were controlled for. Persons scoring high on Acceptance reported better HRQoL whereas high scores on Social reliance were related to decreased HRQoL. SCL-related coping strategies were psychometrically more stable and stronger related to overall quality of life than general coping strategies.

**Conclusion:** SCL-related coping strategies are distinct correlates of HRQoL. Revaluation of life values is associated with better HRQoL whereas unconditional reliance on other people is linked to unsatisfying HRQoL. The results suggest the importance of coping strategies in further research studying factors that may mediate the effect of stress on HRQoL among persons with SCL. Continued and emphasised focus on individuals coping strategies and evaluation of HRQoL outcome in rehabilitation and follow-up is proposed.

**Key-words:** spinal cord injuries, scale development, coping behaviour, distress, mental health, quality of life, psychometrics, validation, cross-sectional.

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## INSTRUMENTS

### Italy

# Development of the Italian Version of the Quebec Back Pain Disability Scale, Adapted for Inmates

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### Background and Objectives

The healthcare budget allocated to the Italian prison system has been steadily reduced over the last few years, and a reversal in this trend is not foreseen.

Given this dire budgetary situation - not to mention general ethical considerations - the improvement of the inmates' health should be a priority.

Since it is well known that back pathologies constitute one of the main reasons for medical intervention in prison, the Faculty of Motor Science of the "Carlo Bo" University of Urbino (Marche, Italy) is now involved in a project together with the Ministry of Justice and the "Casa di Reclusione" prison in Fossombrone (Marche, Italy) to validate an easy-to-use tool for evaluating the degree of disability due to back pain in inmate subjects, and to promote its use in Italian prisons.

### Methods

We chose the Quebec Back Pain Disability Scale (QBPDS) by applying the following criteria:

The measure should be suitable for use with inmate patients.

The measure should have well-known psychometric properties, such as reliability, validity, responsiveness, and a definition of the least relevant clinical difference, in accordance with the World Health Organization's psychological and social recommendations.

The QBPDS is a modular questionnaire developed in Canada (Montreal and Toronto) and the United Kingdom (London)<sup>1</sup> for measuring the degree of disability in patients with back pain.

The QBPDS is a 20-item questionnaire with 6 different domains (bed/rest; sitting/standing; ambulation; movement; bending/stooping; handling large or heavy objects). For each of the 20 items, the patient indicates the perceived difficulty associated with completing basic daily physical activities by choosing a score from 0 to 10 on a numerical (not a continuous) scale. Each score is then converted in a 5-point scale, from 1 to 5, so that the final total score ranges from 20 to 100.

The higher the score is, the greater the disability.

The percent of maximal disability (PMD) can be easily computed through the formula: PMD = ((score-20)/80)\*100%.

Kopec et al<sup>2</sup> and Davidson & Keating<sup>3</sup> demonstrated the high level of effectiveness of

QBPDS in discriminating among different levels of disability; furthermore, they validated the QPDS through the analysis of its reliability, responsiveness, and consistency.

In addition, the QBPDS translations in French and Dutch have already been validated<sup>4,5</sup>.

Our project is composed of the following stages:

- Adaptation of the QBPDS to the prison environment and inmates' lifestyle, through the elimination or modification of some items, e.g. those regarding sitting in car or carrying groceries.
- Translation into Italian and validation of the translated QBPDS. This phase includes a series of pilot studies on small samples of inmates suffering from back pain, recruited from the "Casa di Reclusione" prison in Fossombrone (Marche, Italy).
- Administration of QBPDS to a sample of healthy same-age, same-sex subjects (i.e. equivalent to those in our patient sample) in order to assess the psychometric properties of the Italian version/inmate-population of the QBPDS.
- Administration of QBPDS to a larger sample of inmate patients suffering from back pain for a long time follow-up, to evaluate the predictive properties of the questionnaire.

Once the QBPDS has been psychometrically validated, we plan to use it in order to evaluate the outcomes of a clinical trial designed to test the role of a physical activity protocol in the prevention of back pain in a prison population. ●

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## INTRODUCING

### MAPI Research Institute's Enhanced Presence in Asia

**S**ince November 2003, Mapi Research Institute has enhanced its presence in the Asian region through the opening of an Asian office in Singapore and the establishment of a "Correspondent", Dr. Mark E. Barrett.

Mark is serving as a regional contact person for clients that are interested in learning more about services such as translating PRO/QoL instruments, accessing QOLID and obtaining instruments in Asian languages.

Mark obtained his degree in social psychology at the Texas A&M University in 1988. After managing epidemiological studies in drug abuse at the Addiction Research Institute in Chicago, he joined the National University of Singapore where he taught Psychology from 1991 to 2003. During this time he has worked in many Asian healthcare settings doing studies related to drug addiction, HIV/Aids risky behaviour, and evaluation of health care programmes. He has also done linguistic validation research on PRO/QoL instruments in Chinese, Thai and Malay languages. Mark has been living in Asia for over 12 years and currently holds the position of Research Fellow at the Faculty of Psychology, Chulalongkorn University in Bangkok, Thailand.

Due to his background and experience, he will also contribute to the dissemination of information in the PRO field in our bi-annual Quality of Life Newsletter, which is sent at no charge to over 8000 experts worldwide. ●

For further information, please contact Mark E. Barrett, PhD, Correspondent in Asia, MAPI Research Institute's Offices in Asia, Level 21, Centennial Tower, 3 Temasek Avenue, Singapore 039190. Tel: +65 6549 7402 - Fax: +65 6549 7001 - E-mail: mebarrett@yahoo.com



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MAPI Research Institute's  
correspondent in Asia

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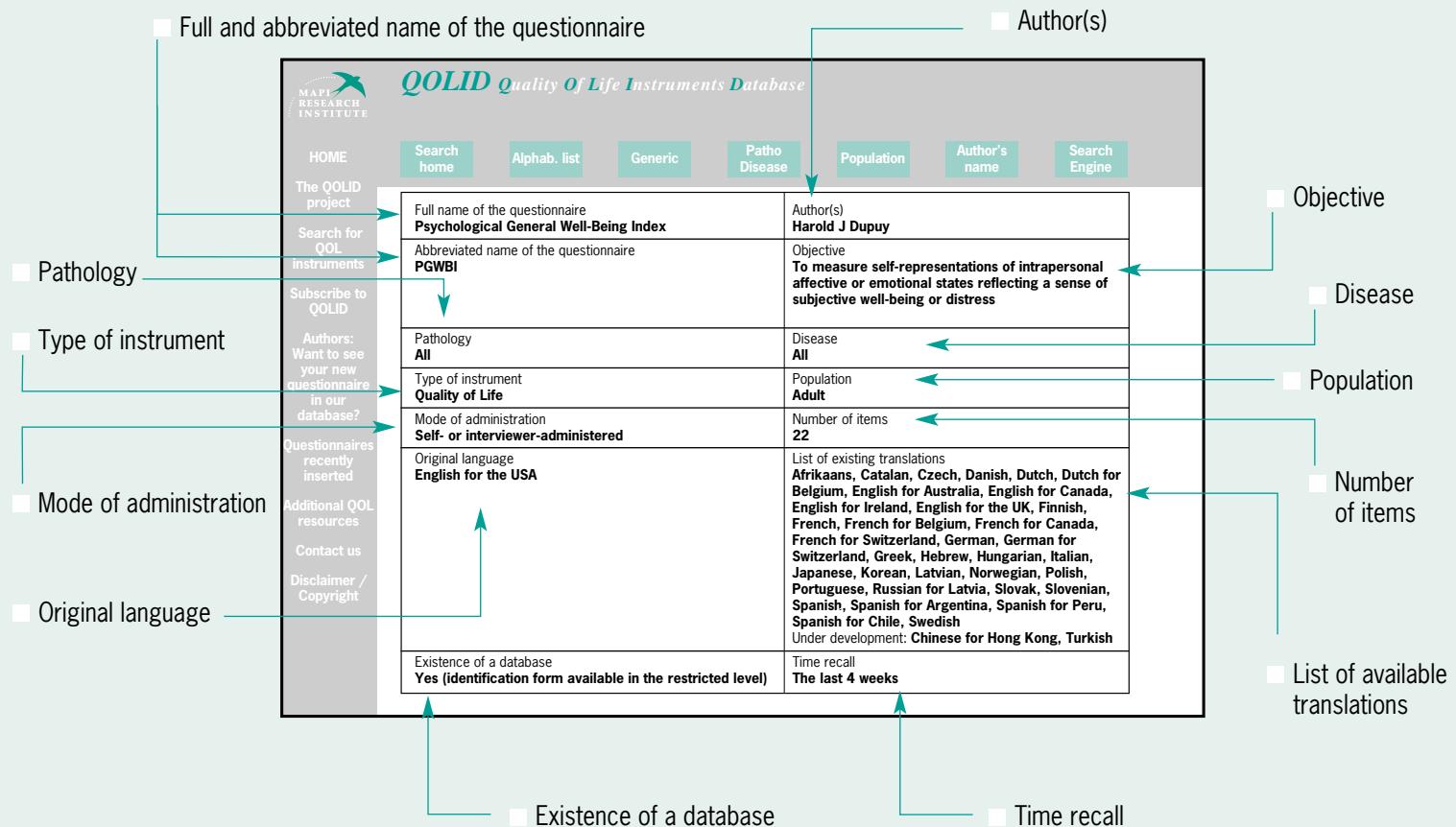


Fig.1: Basic form of the Psychological General Well-Being Index (PGWBI)

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## INSTRUMENTS

**Measuring the Dimension of Psychological General Well-Being by the WHO-5**

Per Bech, M.D., Professor of Psychiatry, WHO Collaborating Centre for Mental Health, Psychiatric Research Unit, Frederiksberg General Hospital, Hilleroed, Denmark

**Historical Background**

Health-related quality of life is a multidimensional subjective concept including the three basic WHO dimensions of physical, psychological and social well-being. When trying to cover these different dimensions simultaneously, the WHOQOL<sup>1</sup> should be considered.

The dimension of psychological well-being was considered the most responsive in the classical paper by Croog et al<sup>2</sup> who tested several instruments covering diverse quality of life dimensions in patients treated for hypertension. The measure of psychological general well-being (PGWB) was found to have a higher responsiveness than the general distress scale (Symptom Checklist, SCL).

In the mid-1980s, questionnaires analogous to the PGWB were released, such as the Hospital Anxiety Depression Scale (HAD) and the WHO Well-Being Scale. While the number of items in the PGWB was 22, the WHO Well-Being Scale in its first version had 28 items and the HAD 14.

All three scales, however, contain both items measuring positive well-being and items measuring negative well-being. Psychometric analyses of the WHO Well-Being Scale isolated five items, the sum of which was a sufficient measure of the dimension of positive, psychological well-being<sup>3</sup>.

**Description of the WHO-5**

Table 1 shows the final version of the WHO-5.

The internal validity of the scale tested by use of the non-parametric Mokken analysis has shown that the Loevinger coefficient of homogeneity was 0.50 or higher, indicating a strong evidence for scalability. The theoretical total score range of WHO-5 goes from 0 to 25 (Table 1). However, for comparison with other scales such as the SF-36, the WHO-5 is conventionally transformed to a 0 to 100 scale in which 0 = worst thinkable well-being and 100 = best thinkable well-being. It is simply a matter of multiplying the raw score by 4 (Table 1).

The WHO Collaborating Centre at Frederiksberg General Hospital in Denmark was asked by the WHO European Office in Copenhagen to consider the WHO-5 as a screening instrument in the primary care setting for the recognition of

**TABLE 1 WHO-5 Well-Being Scale**

Please indicate for each of the five statements, which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

| Over the past two weeks                                      | All of the time            | Most of the time           | More than half of the time | Less than half of the time | Some of the time           | At no time                 |
|--------------------------------------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| 1 I have felt cheerful and in good spirits                   | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> 0 |
| 2 I have felt calm and relaxed                               | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> 0 |
| 3 I have felt active and vigorous                            | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> 0 |
| 4 I woke up feeling fresh and rested                         | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> 0 |
| 5 My daily life has been filled with things that interest me | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 | <input type="checkbox"/> 0 |

**Scoring:**

The raw score is calculated by totaling the figures of the five answers. The raw score ranges from 0 to 25, 0 representing worst possible and 25 representing best possible quality of life.

To obtain a percentage score ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.

depression in the DepCare study. However, it was the German centre in Munich<sup>4</sup> that performed the first validity study of the WHO-5 in this respect. Henkel et al<sup>4</sup> used the CIDI as index of validity. They compared WHO-5 with the General Health Questionnaire and the Patient Health Questionnaire. The results<sup>4</sup> favoured the WHO-5, which showed a sensitivity of 93% and a specificity of 64%.

When used as a screening test for clinical depression, it is recommended to administer a specific depression scale such as the Major Depression Inventory (MDI) or the Hamilton Depression Rating Scale (HAM-D), when the raw score of the WHO-5 is below 13, i.e. < 50 on the 0 to 100 scale<sup>5</sup>.

In training programmes for general practitioners in Norway for recognizing depression, Bakke<sup>6</sup> has found WHO-5 to be very successful. He uses the WHO-5 to monitor outcome of antidepressive therapy.

General populations studies have indicated that the mean score of WHO-5 is around 70<sup>7</sup>. The goal of antidepressive treatment is to obtain endpoint scores of around 70. Before therapy, depressed patients typically have scores of around 40.

The WHO-5 has been compared to the Sickness Impact Profile (SIP) by Folker and Jensen<sup>8</sup>. When monitoring treatment

outcome in patients with mental disorders, they found that the WHO-5 was much easier to complete and more valid than the SIP in patients with mood disorders and schizophrenia.

In a large European study<sup>9</sup> on people with diabetes, the WHO-5 has been shown to have a high degree of acceptability and applicability. It was shown that the WHO-5 was a unidimensional scale for the measurement of positive, psychological well-being.

**Discussion and conclusion**

The WHO-5 has been derived from a larger pool of items, which constituted the 28-item WHO Well-Being Scale. This scale, like the PGWB and the HAD, consisted of items measuring both positive and negative well-being. The WHO-5 was developed for the measurement of the dimension of positive well-being. The classical scale in this field is the Affect Balance Scale<sup>10</sup>, which contains five items measuring positive well-being and five items measuring negative well-being. However, the WHO-5 is much more overlapping with the PGWB than with the Affect Balance Scale. Thus, the five WHO items in Table 1 can be found in the following PGWB items [the original PGWB

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### Measuring the Dimension of Psychological General Well-Being by the WHO-5

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numbers in brackets]: cheerful [20]; calm and relaxed [19]; active and vigorous [16]; fresh and rested [12]; and interested in things [15]. Recently, Martiny et al<sup>11</sup> have shown that this 5-item PGWB subscale was more sensitive than the complete 22-item PGWB in discriminating between active light therapy and placebo light therapy when combined with sertraline in patients with major depression.

Similarly, a 5-item subscale has been derived from the Hospital Anxiety Depression Scale (HAD) to cover the WHO-5. This 5-item HAD subscale was able to discriminate between venlafaxine and placebo, both in patients with major depression and in patients with generalized anxiety disorder<sup>12</sup>. These results with subscales of the PGWB and the HAD, covering the contents of WHO-5, support the validity of positive psychological well-being as endpoint in clinical trials.

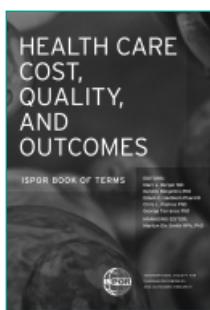
In conclusion, the WHO-5 is a patient-friendly short scale for the measurement of positive psychological well-being. Its psychometric properties are acceptable both when used as a screening instrument for depression and when used to measure quality of life in different patient populations. General population norms can be used to define the goal of therapy. •

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## INSTRUMENTS

Spain

### Resistance to Illness Index (IRE® Questionnaire)

Juan Antonio Fernández-López<sup>1</sup> and María Fernández-Fidalgo<sup>2</sup>

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#### Introduction

The standardized self-administered psychometric approach "Resistance to Illness Index (IRE®)" attempts to conceptualize and operationalize the personal and social resources increasing or decreasing the resistance to illness. Basically we argue that this approach provides a representation of sociological, interpersonal dimensions in addition to intrapsychic resources.

This conceptualization underlines a notion of human life and its components proposed most convincingly by the Spanish philosopher José Ortega y Gasset (1883-1955), i.e. the essential in life is the future<sup>1</sup>. According to this idea each human being first imagines what he would like his life to be. As future is something that enthuses us and at the same time anguishes us, we emphasize the "anguish-illusion" binomial as an important determinant of quality of life and of coping skills. The Spanish concept of "illusion" has not a negative sense as it commonly has in most languages but a positive sense, something similar to what we could convey into English as "optimism"<sup>2</sup>. Both dimensions "anguish-illusion" appear faced one to another, as in a pair of scales, where one dimension determines the level of the other one (see Chart 1). Of course, through life, in different ages, each dimension changes and so may have an unequal weighting. However, as the relationship between the two basic dimensions is a dialectic connection, such dialectic will always appear and only the point on the line of this relationship will vary. Sometimes this point will be closer to a pole of the scale and another times it will be closer to the opposite pole.

Thus the combination of two basic dimensions –summarized in a global index– would represent the variable individualized judgment and answer to face similar vital events or objective states of health or illness. It is assumed that this judgment is based on an individual's mental representation of their personal health that consists of semantic and episodic knowledge, as well as information about change. In addition, respondents must form a mental representation of some standard against which they evaluate their health. This

standard is context-dependent and may include an individual's previous experience, the experience of others, what one thinks one's health status is or should be, or future expectations<sup>3</sup>.

In this sense, our binomial "anguish-illusion" might be closely related with "optimism" and "pessimism" conceptualizations defined as relatively stable, generalized expectations that good/bad outcomes will occur across important life domains<sup>4</sup>. The important part of the definition is the stability of the expectation. People maintain their optimism and pessimism over time and across different situations<sup>5</sup>. A large body of research has demonstrated that dispositional optimism has beneficial effect on people's well-being and health<sup>6</sup>. Outcome expectancies have also been linked to objective indicators of quality of life, such as good health<sup>7</sup>, and mortality<sup>8</sup>. Likewise an individual's general conviction regarding overall status is assumed to predict future crucial health events including morbidity, the decision to seek help, and mortality<sup>9</sup>.

According to this we might assume that a high value obtained with the IRE® global index corresponds with high overcoming capacity or resistance to illness. Thus the standardized self-administered IRE® questionnaire represents an approach towards assessing resistance to illness in healthy and chronically ill people.

In its methodological development the goal was essentially pragmatic i.e. to design a short instrument easily understandable, feasible in setting and with a clear prognosis pointing. Likewise, the instrument should be used in different types of study, namely: a) epidemiological studies, b) clinical studies dealing with the effects of individual overcoming capacity on therapeutic measures applied to acute and chronically ill patients, and c) in prevention and rehabilitation programs, looking into the effects of individual resistance to illness on health or on the disease course.

#### Structure of the IRE®-Questionnaire

It is composed of a general, non-specific part that measures two basic coping related dimensions: "anguish-illusion" by means of 20 Likert-scaled items. In addition, a socio-demographic general module (6 items) and

one global question have been included (item 21). The 20 items of the IRE® questionnaire are grouped in two subscales representing the two defined basic dimensions: anguish subscale (10 items) and illusion subscale (10 items). The two subscales can be combined to outcome a total score (= global index of resistance to illness). Every item in the IRE® questionnaire has a Likert type scaling (ranging from 0 to 4), so the categories of answers to the items cover 5 levels (0 = not at all, 1 = slightly, 2 = moderately, 3 = strongly, 4 = very strongly).

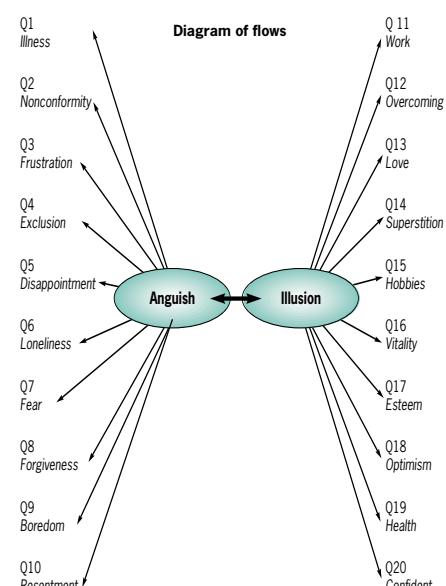
The 'anguish' subscale is composed of 10 items considered with a negative sense (items 1-10, marked with an asterisk in the questionnaire) and the 'illusion' subscale covers 10 items considered with a positive sense (items 11-20). By adding the scores from the two subscales the "resistance to illness index" is produced.

#### Psychometric properties of the IRE® Questionnaire

The scale structure of the IRE® questionnaire was tested using the MAP-analysis approach<sup>10</sup>. The hypothesised scale structure could be perfectly confirmed. The

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#### CHART 1. Nominated Structure of the Resistance to Illness Index (IRE® Questionnaire)



## INSTRUMENTS

### Resistance to Illness Index (IRE<sup>®</sup> Questionnaire)

(continued from p 17)

itemfit was 100% for both sub-scales and also for the total scale, and indicates satisfying convergent and discriminant validity on item-level<sup>11</sup>.

In addition the scales reliability was calculated using Cronbach's alpha coefficient for internal consistency (see Table 1). Inter-scale-correlation was  $r=.20$  and both scales were similar correlated with the total-scale (corrected  $r=.20$ ).

In spite of few redundancies in the scales, we assume a one-dimensional latent structure of the whole construct of "resistance to illness" due to the high item-total correlation of the items (Table 2). In this sense the 20-item total-scale displayed satisfying internal consistency with Cronbach's alpha =.85 To test the know-group validity of the questionnaire three studies have been carried out in Asturias (Spain) on 232 subjects (healthy people, hemodialized and depressive patients) recruited from primary care/hospital environment. The reliability for single scales was higher than 0.83.

A prospective study, enrolling coronary heart disease patients, to test the predictive validity of the questionnaire is currently carrying out. Results will be presented at a later stage.

#### Administration of the IRE<sup>®</sup>-Questionnaire

Administration of this measure requires 5 minutes, and in specific target groups (e.g. impaired sight or disabled condition), an interviewer-form can be applied. The test is intended for adult people excluding children. We did not observe high non-response rates or significant differences in response according to age, gender or socioeconomic status. Thus, the test can be applied widely among chronically ill and healthy people. •

#### Summary

In brief, the Resistance to Illness Index (IRE) questionnaire appears to provide a psychometrically measure of illusion & anguish binomial, defined in terms of the favorability of a person's generalized outcome expectancy. The IRE would seem to possess an adequate level of internal consistency, convergent and discriminant validity and known-group validity to make it suitable for use in practice when such a measure is desired. Nevertheless, further investigations are needed to test repeatedly its predictive validity.

**TABLE 1: Psychometric properties & structure of the IRE<sup>®</sup>'s scales (N=232)**

| IRE <sup>®</sup><br>Scales | n<br>items | Mean<br>0-100 | SD<br>0-100 | Lowest<br>0-100 | Highest<br>0-100 | %<br>at floor | %<br>At ceiling | Alpha | Scale<br>fit |
|----------------------------|------------|---------------|-------------|-----------------|------------------|---------------|-----------------|-------|--------------|
| Anguish                    | 10         | 60,05         | 21,95       | 5               | 100              | 0%            | 0,4%            | 0,87  | 100,0%       |
| Illusion                   | 10         | 50,03         | 18,13       | 2,5             | 92,5             | 0%            | 0%              | 0,83  | 100,0%       |
| Total                      | 20         | 55,04         | 15,59       | 3,75            | 96,25            | 0%            | 0%              | 0,85  | 100,0%       |

**TABLE 2: Pearson Item-Scale Correlation**

| Items          | Mean | sd   | r    | r    | r    | SE(r) |
|----------------|------|------|------|------|------|-------|
| Illness        | 2.10 | 1.25 | .48* | .10  | .38* | .07   |
| Nonconformity  | 2.32 | 1.20 | .64* | .24  | .50* | .07   |
| Frustration    | 2.47 | 1.21 | .65* | .11  | .50* | .07   |
| Exclusion      | 2.74 | 1.32 | .63* | .15  | .52* | .07   |
| Disappointment | 2.39 | 1.22 | .58* | .03  | .41* | .07   |
| Loneliness     | 2.55 | 1.48 | .49* | .16  | .43* | .07   |
| Fear           | 2.48 | 1.32 | .65* | .15  | .53* | .07   |
| Forgiveness    | 1.96 | 1.28 | .44* | -.03 | .28* | .07   |
| Boredom        | 2.39 | 1.43 | .61* | .34  | .63* | .07   |
| Resentment     | 2.63 | 1.28 | .67* | .11  | .52* | .07   |
| Work           | 1.34 | 0.83 | .12  | .44* | .34* | .07   |
| Overcoming     | 2.08 | 1.28 | -.12 | .50* | .18* | .07   |
| Love           | 4.00 | .96  | .10  | .43* | .31* | .07   |
| Superstition   | 2.10 | 1.36 | -.01 | .52* | .25* | .07   |
| Hobbies        | 1.80 | 1.31 | .21  | .55* | .46* | .07   |
| Vitality       | 1.52 | 1.20 | .38  | .57* | .60* | .07   |
| Esteem         | 2.27 | 1.19 | .00  | .52* | .28* | .07   |
| Optimism       | 1.98 | 1.21 | .26  | .48* | .46* | .07   |
| Health         | 1.99 | 1.08 | .18  | .59* | .46* | .07   |
| Confident      | 1.92 | 1.00 | .23  | .61* | .51* | .07   |

\*corrected for overlap

#### Scoring of the IRE<sup>®</sup>-Questionnaire

Four modes are proposed to analyze the scores collected with the IRE<sup>®</sup>questionnaire:

##### 1. To reduce the scores collected with all items to a sum score.

The sum score of both subscales (= global index) ranges between -40 and +40, with -40 meaning the minimum resistance capacity to face up to illness, and +40 the maximum possible capacity. In such a manner we can discriminate among subjects according to the level of resistance to illness as following:

- Sum scores lower -14 = Very low resistance to illness
- Sum scores between -14 and 0 = Low resistance to illness
- Sum scores between 0 and 7 = Minimal resistance to illness (limit zone)
- Sum scores between 7 and 14 = High resistance to illness
- Sum scores higher 14 = Very high resistance to illness

This mode is the simplest way of applying the questionnaire. A quick manual analysis of the questionnaire is possible, and therefore the incorporation of the results into clinical decision process.

##### 2. Calculation of the "illusion/anguish" ratio.

This calculation is based on the previous one. To compute the ratio the illusion score is put in the numerator and the anguish score in the denominator without considering their sign. By applying this algorithm a standardized summary of the model is defined where a threshold of 1.0 discriminates between a high risk group (values <1.0) and a group at lower or no risk (values >1.0).

##### 3. To reduce the sub-scale score and the global index to a mean value between 0 and 4.

The items with a negative sense (items 1-10) should be recoded in the following way: 0 = 4, 1 = 3, 2 = 2, 3 = 1, 4 = 0, with the 0 value meaning the minimum resistance capacity, and the 4 value the maximum possible resistance.

##### 4. Calculation of scores of every subscale and global index transformed to 100.

The mean values of the subscales and the global index are transformed to values from 0 to 100, where 0 = minimum value, 100 = maximum value of resistance.

All scoring methods can detect large differences between several clinic groups. The total scale displays the largest effect-size " $f$ " = .89, followed by the anguish scale " $f$ " = .70 and the illusion scale " $f$ " = .63.

(continued on p 19)

## INSTRUMENTS

**Resistance to Illness Index  
(IRE® Questionnaire)**

(continued from p 18)

## ACKNOWLEDGMENTS

We would like to thank Bärbel Knäuper (McGill University, Montreal) for helping with English version and Michael Erhart (Robert Koch Institute, Berlin) for providing statistical assistance.

*The IRE® questionnaire is available from the authors on request. The IRE® represents a copyrighted work. Therefore all translations, scoring algorithms, norms, guidelines and other work described in this article remain the intellectual property of the IRE® developers.*

*If you have any questions about the IRE® questionnaire we will be happy to assist you.*

For further information, please contact Juan Antonio Fernández-López, MD, PhD, Centro de Salud de Riosa, Servicio de Salud del Principado de Asturias (SESPA), 33160- Asturias-Spain. Tel: +34 985 76 66 14- E-mails: jaflopez@wanadoo.es

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## INSTRUMENTS

United Kingdom

**A Scale to Measure the Impact of Faecal Incontinence in Inflammatory Bowel Disease: a Patient-Centred Approach**Chris Speed BSc<sup>1</sup>, Elaine McColl MSc<sup>1</sup>, Mark Welfare MD<sup>2</sup><sup>1</sup>Centre for Health Services Research, University of Newcastle, Newcastle upon Tyne, UK, <sup>2</sup>North Tyneside General Hospital, Northumbria Healthcare NHS Trust, UK

Readers of this newsletter may remember that in edition 27 we described the Quality of Life in Faecal Incontinence (QoLiFI) study. For readers unfamiliar with the work, Box 1 highlights the aims of QoLiFI. QoLiFI was funded in the UK by the National Association for Colitis and Crohn's disease (NACC). Faecal incontinence (FI) has been defined as the "involuntary or inappropriate passage of faeces"<sup>1</sup>. However, in this study we used a broader definition, to include the involuntary passage of liquid matter or gas (anal incontinence). FI is under-reported by patients and rarely asked about by clinicians; one study showed that less than 5% of patients with FI have this problem recorded in their medical notes<sup>2</sup>. Many people with a diagnosis of IBD – Ulcerative Colitis (UC) and Crohn's Disease (CD) – have episodes of FI, though estimates of the number of such people who experience FI are quite vague.

**Aims**

The primary aims of QoLiFI were to define the impact of Faecal Incontinence (FI) upon the Quality of Life (QoL) of patients with Inflammatory Bowel Disease (IBD) and to develop a questionnaire to assess the QoL of this patient group. The secondary aims (assessment of prevalence of FI in IBD and ascertainment of patients' knowledge and use of aids and services) will not be covered here, but details are available from the first author.

**Methods**

Any attempt to define what a chronic condition means to a particular group of people needs to be informed by those experiencing that condition. This is very much the essence of the patient-centred approach we adopted throughout the study. Whilst the literature on chronic illness suggests potential impact upon physical, social and psychological well-being, the bottom-up approach of asking individuals with the condition about the aspects of their life that are affected, enables a broad range of experiences to be covered without limitation from the researcher's imagination or agenda. The frequency and severity of FI was initially assessed using items from currently

available instruments<sup>3-4</sup>. A purposive sample of nine individuals with IBD who had experienced FI in adulthood took part in a series of in-depth qualitative interviews. Transcripts from the interviews were systematically analysed and the emerging themes recorded. This rich and detailed information was used to inform the choice of domains and themes for inclusion in the initial QoL question pool. Newsletter 27 details these themes.

An initial item pool of questions was generated from the contents of these in-depth interviews. This pool contained 190 items. These were reduced and refined to omit wordy, double-barrelled, vague or duplicate items. The reduced item pool then underwent a further round of cognitive interview pre-testing. These methods were used frequently during the study with the aim of producing high quality questionnaires. We used patient feedback to ensure that all questionnaires were easy to comprehend, that the information we required was possible to recall, and that our response categories were logical and 'user friendly'. The 75 remaining items were then drafted into a postal questionnaire and subjected to impact rating<sup>5</sup> by a sample of 79 IBD patients.

In the impact approach to item selection<sup>5</sup> patients were asked to identify which of the 75 items were 'true of them'. For each item that was positively identified, the patient was asked to rate it for 'importance' or

**BOX 1 The aims of QoLiFI****Main aims**

1. To define the physical, social and psychological impact of FI in people with IBD, including coping strategies and lifestyle adaptations.
2. To develop a validated instrument to assess QoL in this patient group.

**Subsidiary aims**

1. To assess the prevalence of FI in a large sample of patients with IBD, including those under hospital follow-up and those being cared for in primary care.
2. To investigate awareness and use of incontinence services and aids by patients with IBD.

(continued on p 20)

# WORK IN PROGRESS

## A Scale to Measure the Impact of Faecal Incontinence in Inflammatory Bowel Disease: a Patient-Centred Approach

(continued from p 19)

'troublesomeness'. Results were expressed as 'frequency' (the proportion of patients experiencing a particular item), 'importance' (the mean importance score attached to each item), and 'impact' (frequency multiplied by importance). We then ranked the items by the impact score. The 36 highest-ranking. The 36 highest-ranking items were drafted into a postal questionnaire for the final rounds of analysis and validation. In addition to these 36 QoL questions we produced a further set of items relating to 'sex and relationships'. Due to their complexity (they covered current, future, platonic and sexual relationships and reasons behind relationship choices) these items did not undergo impact rating. They were however, subjected to rigorous cognitive interviewing to ensure that they fulfilled the criteria described above. Although these questions do not necessarily measure the impact of FI, we believe that they have a place in a QoL questionnaire as they provide rich and detailed information about intimate and personal circumstances in a non-intrusive and non-threatening manner.

### The construction and preliminary validation of the QoLiFI scale

For the final phase of validation, questionnaires were posted out at two time points (2 weeks apart). 261 responded at time 1 and 127 at time 2.

Exploratory factor analytic techniques were used to 1) detect structure in the relationship between the variables and 2) reduce the number of variables. We used "varimax" rotation during this process. Examination of the screen plot suggested a two-factor solution. However, there were high numbers of double loadings indicative of a lack of independence. Using the criterion of an eigenvalue  $>1$ , we extracted four factors. Again, double loadings were an issue. As we tested solutions involving the extraction of a greater number of factors (11, 12 etc) the number of items loading on each factor decreased. The danger of such a solution was that any emerging factor would have a low level of internal reliability.

Ultimately, we settled on a 'one factor' solution: an indication that quality of life is unidimensional in this group. On the grounds of face validity, we dropped one item. For ease, we shall now refer to the full 35-item scale as "the QoLiFI35 scale". Internal reliability was assessed using Cronbach's alpha ( $\alpha=0.98$ ). This suggested that there could be a level of redundancy in the scale. We therefore constructed a shorter QoLiFI18 scale. The main inclusion criterion for the

**TABLE 1 Correlations between QoLiFI scales and existing measures**

| Scale                      | QoLiFI35 | QoLiFI18 |
|----------------------------|----------|----------|
| IBDQ Total                 | 0.662**  | 0.639**  |
| IBDQ Symptom               | 0.671**  | 0.652**  |
| IBDQ Social/Emotional      | 0.695**  | 0.659**  |
| Previous 4 Vaizey          | 0.656**  | 0.665**  |
| Previous 4 weeks Pescatori | 0.396**  | 0.357**  |
| HADS Depression            | 0.464**  | 0.423**  |
| HADS Anxiety               | 0.530**  | 0.494**  |

(All \*\* significant at 0.01 level - 2 tailed)

QoLiFI18 scale was face validity. This meant that we were able to select a smaller number of items from a collection of equally good items but still cover the breadth of impact of FI on QoL. Cronbach's alpha score for the QoLiFI18 scale was  $\alpha = 0.96$ , therefore, we can assume that the QoLiFI18 scale is also internally reliable. Indeed, we could shorten the scale even further, however in doing so there is a danger of reducing the richness of the impact it measures.

Two week, test-retest correlation coefficients of 0.93 for the QoLiFI scale and 0.91 for the QoLiFI18 scale suggest stability over time.

When respondents completed the QoLiFI items, they also completed the questions to assess their FI in the previous four weeks (these being a Pescatori<sup>3</sup> score for FI and a Vaizey<sup>4</sup> score for FI). In table 1, we present the correlations of the two QoLiFI scales with several existing measures from the first round of validation for the final scale.

The correlations suggest that our scales do in fact tap into what we claim. If we consider both the Pescatori<sup>3</sup> and Vaizey<sup>4</sup> scales for FI, we have significant correlations between them and the two QoLiFI scales. This means that the greater the level of FI (i.e. the more severe the condition) a person experiences, the greater the impact upon QoL. This belief is further supported by the correlations with various Inflammatory Bowel Disease Questionnaire (IBDQ)<sup>6</sup> scale scores. The symptoms score in the IBDQ measures the level of bowel and systemic symptoms; the worse these are, the greater the impact upon QoL. The social and emotional impact of FI was also apparent from our interviews. Combining the IBDQ Social and Emotional subscales, it is apparent that we have captured this also. We know too, from our in-depth interviews, that episodes of FI can be accompanied by higher levels of anxiety and depression. Again, we find significant correlations between these scores as measured by the HADS<sup>7</sup> and our QoLiFI

scales. This relationship is interesting although we must be aware that it is not suggestive of causation. We are not claiming that FI causes depression or anxiety causes FI. We are simply confirming what was apparent from the interviews. The fact that the correlations between the QoLiFI scales, the FI severity measures, IBDQ and HADS scores are not perfect, however, indicates that the QoLiFI scales are not simply measuring something that can be captured completely by one or more of these existing measures; rather, they serve as complementary measures to the more specific measures of disease severity and the somewhat broader measure of the impact of IBD in its totality.

We now have two scales that measure the impact of FI on QoL. These scales have been created from a patient's perspective. The responsiveness to change of the scales remains to be tested, but the findings presented above are encouraging. We would be happy to share these scales with other researchers. ●

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## INTRODUCING



## Patient-Reported Outcomes Validated Instruments Database: A Valuable New Information Resource on PRO

As Patient-Reported Outcomes have become an essential variable in clinical and outcomes research, it has become increasingly important that one is able to identify and choose which linguistically validated instruments in a certain disease area best fit specific objectives.

Based on the spirit of QOLID, MAPI Research Institute and Adelphi have thus teamed up to develop a unique concept that will enable pharmaceutical companies to provide their investigators with a wide range of information on PRO instruments that is specific to a disease, geographical area, and presented in a targeted language.

The PROVIDE databases will offer their users the latest information on PRO questionnaires developed for a

specific disease and translated in a specific language. Information on methodology of translation, psychometric properties, conditions for use and other valuable parameters will also be available.

The PROVIDE online databases will feature a password-protected user login or will also be available as CD-ROMs.

For a free demo of the PROVIDE database visit [www.adelphisystems.com/preview/provide/index.htm](http://www.adelphisystems.com/preview/provide/index.htm). You will need a user name and password for the demo, which we will be pleased to provide. Please contact Marie-Pierre Emery, Director of Information Resources Centre, MAPI Research Institute, [mpemery@mapi.fr](mailto:mpemery@mapi.fr)

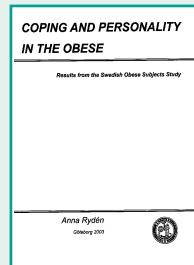


## PUBLICATION

## Sweden

### Coping and Personality in the Obese Results from the Swedish Obese Subjects Study

Anna Rydén, Göteborg University, Sweden



**Aims:** The overall aims of this thesis were to evaluate coping and personality in obesity and the relation to weight change. Specific aims were to validate methods for assessing condition-specific coping and distress; to evaluate coping, distress, and personality in relation to treatment preference before and 2 years after treatment start; and compare personality profiles with reference subjects.

**Methods:** All study samples comprised participants in the Swedish Obese Subjects Intervention or Reference studies. In study 1 the Obesity-related Coping (OC) and Obesity-related Distress (OD) questionnaires were developed and evaluated in 2,510 patients, using multi-trait, exploratory and confirmatory factor analysis procedures. Study 2 is a 2-year follow-up of 1,146 surgically and 1,085 conventionally treated patients that completed the OC and OD at baseline. Within- and between-group differences were significance tested. Study 3 assessed personality, using the Karolinska Scales of Personality, in 3,270 patients. In study 4 personality traits were assessed prior to treatment and after 24 months in 1,380 surgically treated and 1,241 conventionally treated. In studies 3 and 4 results were compared with data obtained from 1,135 reference subjects. Within and between-group differences were significance tested and effect sizes (ES) were calculated.

**Results:** Three coping (two adaptive/one maladaptive) and two distress factors were identified. Patients who preferred surgical treatment reported more maladaptive and less adaptive coping and, hence, more distress. Regarding personality traits at baseline, obese patients were more anxiety prone, impulsive and irritable (particularly the surgical candidates) when compared to a reference group. In ES terms, though, these differences were trivial to moderate and the greatest differences could be traced to items tapping condition-specific symptoms. However, the difference in Impulsiveness could not be explained by item

composition. Both obese and reference females reported more anxiety proneness compared to men (ES: small). Two years after treatment start, weight gainers decreased in both adaptive and maladaptive coping, leaving distress levels unchanged and personality traits remained mostly stable. Among patients that lost  $\geq 20$  kg a decrease was noted in maladaptive coping, distress and anxiety proneness together with an increase in Monotony Avoidance. Patients that lost  $\geq 20$  kg also increased in adaptive coping, displayed even greater reduction of distress, anxiety proneness, Irritability and increase in Monotony Avoidance. However, the elevated levels of Impulsiveness remained stable in both patient groups.

**Conclusions:** The use of certain coping strategies may partly explain psychological distress in obese patients and influence treatment choice. Despite the lack of coping intervention, participation in a weight program seems to reduce maladaptive coping, irrespective of treatment or weight change. Improvements in adaptive coping, however, are not as easily achieved. Concerning personality, our results did not provide any evidence of a general obese profile. Long-term weight reduction was associated with changes on practically all scales, particularly Psychastenia. The one exception was in Impulsiveness that remained unaffected by weight change. Possible explanations are that Impulsiveness is not reflected in weight-related behaviour or that weight-reducers have found alternative ways to canalise this trait.

**Key words:** obesity, coping, distress, personality, anxiety, depression, factor analysis, multi-trait analysis, structural equation modelling, clinical trial, treatment preference, treatment outcome, gender differences, reference subjects.

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## MEETINGS

### Agenda

#### June 21-23, 2004

##### **ENABLE final conference: Challenges in dementia care: can technology help people with dementia?**

##### **To be held in Oslo, Norway**

The ENABLE project aims at facilitating independent living of people with early dementia and to promote their well-being through access to enabling systems and products. Pleasure, memory support, entertainment and own activity are key words in the project. The project is funded under the EC Programme Quality of Life and Living Resources.

More information on internet at [www.enableproject.org](http://www.enableproject.org)

#### June 24-25, 2004-03-30

##### **Conference On Improving Health Outcomes Assessment Based On Modern Measurement Theory And Computerized Adaptive Testing**

The National Cancer Institute and the Drug Information Association (DIA) are co-sponsoring the conference, "Advances in Health Outcomes Measurement: Exploring the Current State and the Future of Item Response Theory, Item Banks, and Computer-Adaptive Testing." Scheduled for June 24-25, 2004, in Bethesda, MD, this conference will focus on new, innovative techniques for patient-reported outcomes assessment based on item response theory (IRT) modeling. Of special interest will be an open discussion among representatives of

public and private organizations on the utility of developing and supporting public domain item banks and computerized adaptive tests for measuring key health domains such as physical functioning, depression, fatigue, and pain. Members from academia, industry and government will outline a research agenda for the future of health outcomes and behavioral science measurement.

An introductory IRT workshop, taught by Dr. Steve Reise, UCLA, will be offered the day prior to the start of the conference

To register for the conference or view the conference program, please visit the DIA website: [www.diahomes.org/docs/Events/events\\_search\\_detail.cfm?EventID=04015](http://www.diahomes.org/docs/Events/events_search_detail.cfm?EventID=04015). For preliminary content and related information, visit the NCI conference website: <http://www.outcomes.cancer.gov/conference/irt/>, or contact Bryce Reeve by e-mail at [reeveb@mail.nih.gov](mailto:reeveb@mail.nih.gov)

#### June 27-29, 2004

##### **ISOQOL 2004 Symposium**

##### **Stating the Art: Advancing Outcomes Research Methodology and Clinical Applications**

##### **To be held at the Boston Park Plaza Hotel Boston, MA, USA**

Chairs: William Lenderking, PhD (USA) and Dennis Revicki, PhD (USA)

Join other QoL colleagues and immerse yourself in the latest advances in the field of outcomes research as they pertain to patient-reported outcomes. This meeting is organized into two tracks: methodology and clinical applications, so that you can stay within a single track throughout the meeting or switch according to your preference. ISOQOL, 6728 Old McLean Village Drive, McLean, VA 22101-3906 USA. Phone: (703) 556-9222 - FAX: (703) 556-8729 - Email: [info@isoqol.org](mailto:info@isoqol.org) - Website and online registration: [www.isoqol.org](http://www.isoqol.org)

#### August 19-21, 2004

##### **2nd Ibero-American Congress of Quality of Life**

##### **To be held in Porto Alegre, South Brazil.**

In the framework of the XXII Congress of Dynamic Psychiatry of the State of Rio Grande do Sul, researchers and clinicians interested in HRQOL will have the opportunity to attend a high standard meeting in their native language. Portuguese and Spanish will be the official languages of the meetings. Guest speakers: Dr. Beny Lafer (Brazil), Dr. John Ware (USA), Dr. Jordi Alonso (Spain), Dr. Guus van Heck (Netherlands), Dr. Martin Eiseman (Norway), Prof. Mick Power (Scotland), Dra. Monica Bullinger (Germany), Dra. Silke Schmitt (Germany), Dr. Valentim Gentil Filho (Brazil), Dr. Vicente Galli (Psychiatrist, Psychoanalyst, Argentine)

Please consult [www.ufrgs.br/psiq](http://www.ufrgs.br/psiq) for more information

#### October 24-26, 2004

##### **ISPOR 7th Annual European Congress**

##### **To be held in Hamburg, Germany**

The congress will focus on health care costs and outcomes in health-care decision making. For more information, please visit the ISPOR website at [www.istor.org](http://www.istor.org)

## Health Outcomes 2004: Perspectives on Population Health



Australian Health Outcomes  
Collaboration (AHOC)

### 10<sup>th</sup> Annual National Conference

**15-16 September 2004, Canberra, Australia**

Convened by the Australian Health Outcomes Collaboration

**Health Outcomes 2004** will focus on evaluation issues and challenges in the planning, development and implementation of population health initiatives aimed at improving health outcomes for the general population and for particular population groups.

Research on the global and national burden of disease provides the background to this theme. What are the health needs of Australians (and of neighbouring nations) in the context of changing demographic patterns that include not only an ageing population but also an increasing divide between rich and poor? How responsive is our health system, with its mix of public and private care, to the present and future requirements of the population? Where should we be placing health resources in order to get the best health outcomes - for our society and for the individual? Governments will ultimately choose which health areas receive priority, but how can health practitioners and health consumers influence this decision making? What evidence is required to support policy development and service provision in the population health field, and how and by whom is this evidence to be collected and evaluated? Health care is an area with limited funds but with the potential for limitless expenditure. There are large disparities in health status between different population groups - how do we ensure that equity concerns are central to the processes outlined above?

The conference will examine outcomes evaluation in relation to specific population groups (for example Indigenous peoples, health consumers from non-English speaking backgrounds, the elderly, youth, women, rural communities, consumers managing chronic diseases, the socio-economically disadvantaged and the terminally ill) and 'populations' receiving care for disorders falling under the designated National Health Priority Areas.

The conference will also explore methodological aspects of outcomes measurement in this field. For example, what are the most appropriate indicators and measures for outcome assessment? How do we select which ones to use? It is notoriously difficult to evaluate the intermediate stages of long term population health strategies - is it valid to use proxy measures to assess progress? What might these measures be? When assessing either an individual clinical intervention or a population health program, what constitutes a 'significantly meaningful' improvement in practical terms? How do we account for cross-cultural differentials in outcomes assessment? Is there a need to place greater priority on clinical benchmarking - at both health system and treatment levels?

**Further information about the conference (including registration details) may be found at the AHOC website at [www.uow.edu.au/commerce/ahoc](http://www.uow.edu.au/commerce/ahoc)**

## MEETINGS

## Agenda



## International Quality of Life Conference Set for Hong Kong

The International Society for Quality of Life Research (ISOQOL) is pleased to announce that the 11<sup>th</sup> Annual Scientific Meeting, entitled "Harmonizing International Health-Related Quality of Life (HRQOL) Research" will be held in Hong Kong, from October 16 to 19, 2004.

ISOQOL's annual scientific conference always offers an interesting and informative mix of conceptual, methodological and practical sessions. This theme of this year's conference is *Harmonizing International HRQOL Research*. With so many cultures and languages around the globe, so many ways of defining and conceptualizing HRQOL, with so many instruments and scales to measure HRQOL, and so many different uses and users of HRQOL measures, this theme provides a timely focus for what promises to be a fascinating and rewarding conference.

The plenary sessions and special symposia will address many topics and questions, including:

- Harmonizing International HRQOL Research - What do we need to achieve and how will we do it?
- Conceptualization of HRQOL - differences across cultures
- Item Response Theory (IRT) and cross-cultural equivalence of HRQOL instruments
- Integration of Western and Traditional Chinese Medicine (TCM) & HRQOL in TCM
- Value and use of HRQOL measures in different countries and health care systems
- Individualised goal attainment scaling - Do HRQOL measures reflect the treatment goals?

The conference keynote speaker, John Ware, has long provided leadership in harmonizing international HRQOL research, with his efforts in cross-cultural and cross-instrument calibration, and

more recently in dynamic instruments bridging the gulf between individual patient management and population surveys.

Plenary speakers David Andrich and Alan Tennant will discuss the role of Item Response Theory in determining the cross-cultural equivalence of HRQOL instruments. This is a wonderful opportunity to see these world leaders, each with a long and distinguished career in the development and application of Rasch measurement models.

During the three conference days, many other distinguished speakers will provide their insights and opinions. The conference will be preceded by workshops, covering a range of topics from introductory to advanced levels.

All submitted abstracts will undergo international double-blind peer review with respect to significance and scientific quality. Abstracts accepted for presentation will be published in a supplement of the journal *Quality of Life Research*, which will be distributed to all delegates.

We invite submissions for scientific papers and workshops from all countries, including the Asia-Pacific region. To assist authors whose first language is not English, we will provide linguistic assistance in the preparation of abstracts prior to submission. In addition, a range of scholarships will be available, and an optional Ambassador Program will match participants with local QOL researchers, based on research interests and specialties. A range of social and travel events will be offered to complete the conference experience!

To submit an abstract for consideration, and to learn more about the Conference, please visit [www.isoqol.org](http://www.isoqol.org) or send an email to: [info@isoqol.org](mailto:info@isoqol.org). Abstract submissions will be accepted at [www.isoqol.org](http://www.isoqol.org) through 11:59 pm EST on May 4, 2004.

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Dedicated to Your Information & Advancement  
www.diahome.org

May 10-11, 2004 - Hotel Sofitel Paris Forum Rive Gauche, Paris, France



## Assessing Treatment Impact Using PROs: Challenges in Study Design, Conduct and Analysis

**This DIA workshop is being organised in cooperation with the ERIQA Group**

**Background**

In the past 20 years, the growth of patient-reported outcome (PRO) instruments being used in multinational clinical trials has increased dramatically. As a result, regulatory authorities are increasingly faced with having PROs as an additional outcome measure for the evaluation of new therapies. Moreover, PROs are being recognized as an important evaluation criteria. However, there are key issues that need to be addressed between manufacturers, health care providers and regulatory authorities

**Conference Objectives**

- To discuss CPMP, national regulatory authorities, and FDA's experience in PRO data review to support medical product approval
- To explain challenges in PRO study design, conduct analysis and interpretation when assessing treatment impact
- To recognize when PROs may add value to the evaluation of treatment effectiveness and thereby strengthen an application for registration
- To generate discussions between regulators, academics and members of pharmaceutical industry

**Overview**

This workshop will provide an overview of current issues in clinical trial research using patient-reported outcomes (PROs). Examples of industry use of patient-reported outcomes to support European and FDA medical product approval decisions will be presented. Sessions will focus on the following:

- Tutorial: Educational Programme on Patient Reported Outcomes in Clinical Trials (limited to 15 participants)
- Session 1: Patient Reported Outcomes: When Do They Add Value?
  - Overview: examples of when PRO add values
  - Examples in respiratory diseases
  - Examples in oncology
- Session 2: How to integrate Patient Reported Outcomes in International Trials? Regulatory Issues
  - Importance of guidance in PRO: PROS and CONS
  - Practical experience from a reviewer: reviewers - what do they expect?
- Session 3: How to integrate Patient Reported Outcomes in International Trials? Methodological Issues
  - Clinical trial design and cross-cultural issues for PRO
  - Statistical issues: missing data, multiplicity
  - Interpretations: clinical significance: what does it mean?
- Session 4: Use of Patient Reported Outcomes to Support European and FDA Approval Decisions
  - QoL from a regulatory perspective
  - The role of Patient Reported Outcomes in US drug approval and labeling decisions

Please note that this programme is being updated on a regular basis on the DIA Home Page [www.diahome.org](http://www.diahome.org) or via <http://www.diahome.org/Content/Events/04105.pdf>

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**VISIT OUR WEBSITE [WWW.DIAHOME.ORG](http://WWW.DIAHOME.ORG)**

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**The primary goal of Mapi Research Institute's Quality of Life Newsletter is to encourage and facilitate the rapid dissemination and exchange of information on health outcomes within the scientific community.**

**The views expressed in this Newsletter are those of the authors and do not necessarily represent those of Mapi Research Institute.**

### Call for Papers

QoL Newsletter 33

**Deadline for submission:**

**30 July 2004**

Any news and information on Quality of Life are invited (e.g. short articles on on-going Quality of Life research, announcements of publications, meetings, websites etc.)

Please refer to Mapi Research Institute website at [www.mapi-research-inst.org](http://www.mapi-research-inst.org) for submission information.

Please send your paper by post, fax or E-mail to Caroline Anfray, Mapi Research Institute, 27 rue de la Villette, 69003 Lyon, France. Fax: +33 (0)4 72 13 66 82 - E-mail: [canfray@mapi.fr](mailto:canfray@mapi.fr)



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