Editorial

PROs are now playing a substantial role in drug development. However, many clinicians and researchers still struggle and wonder: “Does the right PRO measure exist and, if so, how do I find it?”...

It is time now for a new generation of PRO instruments.

Researchers, clinicians, regulators, payers, and patients all need standard assessments to improve their ability to understand, assess, compare, and make decisions. These standards should be grounded in patients’ experiences to address specific questions. They should combine well-documented developments, excellent measurement properties, and have ability to measure the same thing across a population of patients living all around the world.

Where are these new standards most urgently needed?

In a couple of weeks, we will invite the readers of the PRO Newsletter to answer a short online survey designed to highlight the priorities of researchers and clinicians. We plan to publish the results of this survey in the newsletter’s fall edition.

I hope many of you will take the brief time needed to answer this important survey. I am sure it will reveal emerging trends and may uncover some interesting comparisons between the views of researchers and clinicians.

Bernard Jambon
Director of Publication
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The Head and Neck Cancer Patient Concerns Inventory (PCI): A Practical Holistic Assessment Tool in Outpatient Setting pp. 1-4

Psychosocial dysfunction and psychological distress is prevalent in this cohort\(^4\) and is experienced as depression,\(^5\)\(^,\) anxiety,\(^6\)\(^-\)\(^9\) mood disorders,\(^7\)\(^,\)\(^8\) worries relating to fear of recurrence\(^8\) and also experience other psychosocial concerns, like employment\(^9\)\(^,\)\(^10\) and financial worries.\(^11\) Caregivers of HNC patients often shoulder the load of the care-giving burden\(^9\)\(^,\)\(^12\) and also experience psychological distress.\(^13\) These problems may be compounded by pre-diagnosis conditions, namely, poor socioeconomic circumstances,\(^14\) substance addiction\(^9\) and medical comorbidities.

The challenge of providing supportive care that is appropriate, adequate and timely for HNC patients begins by being able to identify the concerns and perceived needs of these patients, including their desire for supportive care. Oncology patients experience high levels of unmet needs in and across various areas of their life.\(^15\)\(^,\)\(^16\) Indeed, serious psychological distress and appearance issues in HNC patients are often unrecognized and unmet.\(^12\)\(^,\)\(^17\)\(^,\)\(^18\) It can be difficult to identify the patient who “suffers in silence” as many are unwilling to complain and often have lowered self-esteem.\(^19\) Others are reticent to discuss sensitive and embarrassing issues like intimacy and sexual dysfunction.\(^20\)

The Patient Concerns Inventory

THE HEAD AND NECK PATIENT CONCERNS INVENTORY

Please choose from the list of issues you would specifically like to talk about in their consultation / while at clinic today. You can choose more than one option. (Check the box ☑)

- Activity
- Anger
- Anxiety
- Appearance
- Appetite
- Bowel habit (diarrhea or constipation)
- Breathing
- Carer
- Chewing/eating
- Dental health/teeth
- Depression
- Energy levels
- Fatigue/tiredness
- Fear of the cancer coming back
- Financial / benefits
- Hearing
- Home care/district nurse support
- Intimacy
- Lifestyle issues (smoking/alcohol)
- Memory
- Mobility
- Mood
- Mouth opening
- Nausea
- Pain in head and neck
- Pain elsewhere
- PEG tube
- Recreation
- Regret about treatment
- Relationships
- Salivation
- Sex
- Shoulder
- Sleeping
- Smell
- Speech/voice/being understood
- Spiritual/religious aspects
- Support for my family
- Swallowing
- Swelling
- Taste
- Temperament and personality
- Vomiting/sickness
- Weight
- Wound healing
- Anything else

Please indicate the people you would specifically like to talk with either in clinic or by referral. You can indicate more than one person. (Check the box ☑)

- Chaplain
- Clinical nurse specialist
- Dental hygienist
- Dentist
- Dietician
- Family doctor
- Nursing staff
- Occupational therapist
- Oral rehabilitation team
- Physiotherapist
- Radiotherapist/oncologist
- Social worker
- Speech and language therapist
- Surgeon
- Anyone else

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Some find the clinical setting intimidating may not feel able to vocalize their concerns despite attending regularly part of their cancer surveillance program. The outpatient clinic setting can be busy, frenetic and demanding for both the patient and clinician. Patients may be anxious, unwell, and experience long waiting times before being seen while clinicians are under pressure to perform cancer surveillance tasks, examine prosthesis/wounds and provide information, advice, and reassurances during a small window of opportunity. Thus, some issues of patient concerns may be missed completely while others are addressed superficially due to a combination of time and logistical constraint, a patient’s reticence, and perhaps, the clinician’s unwillingness to broach challenging and sensitive issues that they may feel inadequately skilled or trained in. Inadequately addressed concerns and unrecognized issues form the undercurrents of unmet needs and can lead to poorer overall health, inefficient use of healthcare, and dissatisfaction.

Apart from these described obstacles, other barriers in assessing the patient needs exist, including the absence of best practices in initially identifying needs. The Head and Neck Patient Concerns Inventory (PCI) was introduced as a site-specific needs assessment tool for use in the outpatient setting. It was developed together with the Merseyside Region HNC support group and is designed to be a holistic, patient-reported instrument that aims to identify patients’ needs and concerns, which they wish to discuss during an outpatient clinic visit. The PCI is a list of 55 items of concerns (Figure 1), ranging from problems of dysfunction, appearance, and symptoms to psychosocial issues relating to the HNC and its treatment. It is a simple questionnaire that takes an average of eight minutes to complete prior to their consultation. Furthermore, the PCI also allows patients to choose individuals they wish to see or be referred to and these may range from core members of the HNC multidisciplinary team to others like financial advisors and chaplain. Utilizing the PCI empowers patients to take charge of their health concerns and needs.

Flow chart of the practical working of the PCI in a typical head and neck oncology outpatient clinic.
When the PCI is completed routinely in successive outpatient clinics, it presents a unique record of an individual patient’s needs over time. Longitudinal PCI data is important because studies have shown that unmet needs in cancer patients persist over time. The information gathered is more useful when the PCI is coupled with a health-related quality of life measure, such as the University of Washington Quality of Life Version 4 (UW-QOL), where the impact of unmet needs can be related to health-related quality of life.

Nevertheless, data collection in a busy outpatient setting can be difficult, cumbersome and may potentially interfere with the delivery of care expected in the outpatient setting. Utilizing computer touch-screen technology, both the PCI and UW-QOL can be self-completed and the data is collated and summarized instantaneously for immediate use during consultation without causing interference or delay to the organization and running of clinic. The summarized PCI data sheet can also be printed and attached with the customary clinic letter to the general practitioner, facilitating continuity of oncology care in the primary setting. Figure 2 illustrates the practical working of the PCI in a typical head and neck oncology clinic.

Ongoing work is being done to evaluate the implementation of the PCI in a wider head and neck context by including otolaryngology patients in the outpatient setting, evaluation of the PCI by both patients and clinicians as users of this tool, the possibility of incorporating other tools with the PCI-UW-QOL touch-screen computer package and developing a PCI-directed ladder of intervention and supportive care. The potential of the PCI as a holistic tool in screening for unmet needs in a busy outpatient setting may provide the basis for creating a supportive care service that places the patient and their carer’s needs in at its heart and utilizes healthcare resources appropriately and efficiently.

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The winner of the Catherine Pouget Award in 2009 was Shyla Mills.

**Progress report**

**To Live, To Love and To Leave a Legacy**

_Shyla Mills_

_Melbourne, Australia_

A public health palliative care photographic exhibition investigating the impact of enhanced dialogue, awareness, understanding, preparation and ownership of death in the community.

After working in palliative care for over a decade in both developed and developing countries, I came to observe that staff, volunteers, carers and families often describe their time spent with the dying as a “privilege”. This intrigued me, as I felt exactly the same, however it is commonly believed that the general population fear death and hence do not like to be in close proximity to the dying.

In 2007, I began to explore this divide further and informally asked many colleagues, volunteers and carers why they felt “privileged”. I received similar responses - people felt that when most patients are faced with their own mortality they see the world and those around them in a different way; they prioritize things differently and speak about less mundane topics which offers us a rare opportunity to bare witness and hopefully learn from it.

There was nothing new about this concept that palliative patients have a wisdom to share with others. One of my favourite books is “Tuesdays with Morrie”, the story of a young man regularly visiting an old man dying and listening to him share his wisdom. However, I realized that in our busy everyday professional roles we rarely take the time to reflect on this “privilege” and consider what wisdom is being shared with us, let alone share this wisdom with others.

Thus began my journey, which has taken me around the world twice and into the homes, hospices, hospitals, nursing homes and daycare settings of some immensely wise people who entrusted me with their images and stories, in the hope that it would be of benefit to others.

**The birth of a project**

With a photography, travel and palliative care nursing background, I decided to combine these skills and create an international narrative palliative care photographic exhibition, based around a theme often discussed at management, leadership, and personal development seminars:

“We need to live, love and leave a legacy – and a legacy is more than just money in your bank account.”

In 2008, Phase 1 of my “To Live, To Love and To Leave a Legacy” project began, with a narrative photographic exhibition established during a personal study, work, and holiday tour of hospices and palliative care units in India, Thailand, France, the UK and Australia. The original objective was simply to collate and share the experiences and legacies of palliative patients, families, carers and healthcare professionals by asking the project participants to answer the following questions based on the exhibition title – “To Live, To Love and To Leave a Legacy”:

1. To Live: What is your first name, age and the country you are from?
2. To Love: What does love mean to you?
3. To Leave a Legacy: What is a message you would pass on to the next generation?
4. Lessons Learned (question for non-patients only): What is a lesson you have learned from being with the dying?

I self-funded the exhibition’s printing and exhibited the small exhibition at three palliative care conferences. The feedback was fantastic and my university professors (I am studying a Master of Public Health) encouraged me to extend the exhibition and conduct research around the impact it has on the people exposed to it, to see how it could be beneficial as a public health palliative care (also known as health promoting palliative care) project.

In 2009, Phase 2 of the project was developed and I sought funding to investigate the public health palliative care significance of this initiative. This would involved a three-pronged strategy:

- Expanding the narrative photographic exhibition
- Exhibiting the existing photographic exhibition at conferences internationally
- Conducting a pilot study on the public health palliative care impact of the exhibition

To my delight, in late 2009 I received an e-mail at midnight (Australian time) stating that I had been successful in my application for the MAPI Catherine Pouget Research Award and that it would fund Phase 2 of my project.

**Project expansion**

In late 2010, with my original exhibition, camera equipment, dictaphone, consent forms, contact lists, and computer firmly packed in my luggage I jet-setted off to the USA, Canada, and Malaysia to once again visit local palliative care teams, introduce them into the project, and collect narratives and images. It never ceases to amaze me how profound peoples’ responses are to my seemingly simple questions and how interested they were in the project.

The original Phase 1 exhibition has been translated into French and Spanish so it could be exhibited at several international conferences throughout my travels, including: the inaugural International Advanced Care Planning Conference; Happiness and its Causes Conference and the International Congress on Palliative Care.

I also piloted a small study which indicated that after viewing the exhibition 72% of participants discussed their legacy and/or
meaning with a friend or family member within 24 hours of viewing the exhibition and 22% either created or reviewed their advance care plan within a month of viewing the exhibition. Participants also identified that the exhibition reduced their fear of communicating about dying and promoted a deeper dialogue in discussing death between patients, families and health care workers. These are very positive public health palliative care indicators for the project.

Project precis

Thanks to MAPI and the project participants, the exhibition now boasts over 80 pieces from ten countries, it has been translated into three languages and receives regular requests to exhibit internationally at conferences and public venues. It is amazing to realize that this venture has grown and come full circle from a simple word back in 2007 - “privilege”.

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The ISOQoL Translation and Cultural Adaptation Special Interest Group (TCA-SIG)

Katrin Conway, MAPI Research Trust, Lyon, France
Donald Patrick, University of Washington, Seattle, WA, USA
Sonya Eremenco, United BioSource Corporation, Bethesda, MD

In 2004 the International Society for Quality of Life Research (ISOQoL) created a special interest group in the field of translation and cultural adaptation (TCA-SIG). The aim of the group is to identify and advance research in the fields of translation and cultural adaptation of PRO measures. The 25-member TCA-SIG has three subgroups pursuing individual objectives to meet the overall aim:

- The Cross-Cultural Issues subgroup addresses issues related to the access of copyrighted instruments, the translation of PROs and their use in e-format,
- The Translation Methodology subgroup pursues a research agenda for the development of methodologies in the field of translation and cross-cultural research,
- The PRO Translation Certification subgroup aims at establishing an international certification program for PRO translations.

At last year’s ISOQoL conference in London, the TCA-SIG had 37 attendees at its annual meeting. During this gathering members of the group presented the key elements of three publications the TCA-SIG is currently preparing:

- Caroline Anfray from MAPI Institute in Lyon, France, summarized the main ideas of a manuscript about the rules and applications regarding copyright of translations of PRO measures.
- Mona Martin from Health Research Associates in Seattle, Washington, USA outlined the key aspects of a publication centered on the type of certification needed for the translation of PRO measures.
- Michael Koller from the University of Regensburg in Germany presented the major elements of an article on the evaluation of existing procedures, criteria, and outcomes used during the process of reconciliation employed in the translation of QoL questionnaires.

The three articles are scheduled to be submitted for publication in 2011. Two additional articles on the value of back translation in reducing translation errors and on translation difficulties, respectively, are planned to be submitted in 2012. To review the complete list of the TCA-SIG publications please consult www.isoqol.org/SIGs/translation.htm.

The objective of the subsequent discussion was to generate new ideas for the TCA-SIG. To review the complete list please consult www.isoqol.org/SIGs/translation.htm.

The objectives of the TCA-SIG for 2011 are the publications of the above articles as well as the organization of the annual meeting during the conference in Denver, Colorado, USA.

If you wish to find out more about our activities, submit a new idea for our group or take on a project, please contact Tatiana Gauchon (tgauchon@mapigroup.com) and meet us in October at the ISOQoL’s conference in Denver.
The SPVU-5D: A Preference-based Measure of Health Related Quality of Life for Use with Venous Leg Ulceration

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Abstract

The SPVU-5D is a new condition-specific preference-based measure of health-related quality of life for use in the assessment of the impact of venous ulceration. It has five dimensions encompassing physical, psychological and social aspects. The dimensions have between three and five levels. The measure was developed from the bottom-up and incorporates items generated from patients. The measure has been shown to have good practicality and validity. Preference-weights and a scoring algorithm were produced based on valuations from the UK population.

Background

A leg ulcer is a wound on the lower leg that fails to heal within six weeks. Around 80% of all ulcers occurring on the leg are venous ulcers. They are relatively common, especially in the elderly, having an incidence of between 1.5 and 3.0 per 1000. The presence of an ulcer can result in a number of symptoms including pain, restricted mobility, excessive leakage of wound exudate, depression, and an offensive smell emanating from the wound. The best treatment for venous ulcers is the application of compression bandages. These have to be worn for a week and can be uncomfortable and restrict normal activities. Many patients rate the easing of symptoms and improved quality of life as higher priorities than the actual healing of their wound.

A recent systematic review found a total of seven condition-specific Patient-Reported Outcome Measures (PROMs) that had been applied to people with venous leg ulcers. However, all of the existing instruments showed limitations in relation to their applicability to venous ulcer patients due to flaws in their design or validation. Furthermore none of the instruments were preference-based. This article briefly describes the process of development and validation of a new preference-based instrument.

Development of the SPVU-5D

Generation of items and descriptive system

The first stage of the project was the identification of items for inclusion and the development of the descriptive system. Individual interviews with patients (n=19) and clinicians (n=12), and a focus group of patients were carried out to describe the important impacts of having a venous ulcer on quality of life. The interviews and focus groups were used to identify as many items as possible for incorporation into dimensions of a health-related quality of life instrument. Checks were performed in the analysis of this qualitative data to ensure that data saturation had been reached, and that no new items were identified. These included re-interviewing participants and using the focus group to validate the analysis of the interviews.

The items identified were grouped into physical, psychological and social dimensions. Within these dimensions it was clear from the qualitative interviews that severity and frequency were an issue and so questions should be asked about both the frequency and severity of the impact on quality of life. For example, people were concerned with how severe and frequently pain occurred, and how offensive and frequently their legs smelled. For other items, the decision to include both a severity and a frequency question was not so well defined. An example could be seen related to clothing where the emphasis was not on the severity of their restrictions with wearing clothing but regarding how frequently they were unable to wear particular clothes. The final consideration was the recall period that preference-based. This article briefly describes the process of development and validation of a new preference-based instrument.

The SPVU-5D

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1</td>
<td>I have pain none of the time</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>I have pain a little or some of the time</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>I have pain most of the time</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>I have pain all of the time</td>
</tr>
<tr>
<td>Mobility</td>
<td>1</td>
<td>I do not have problems with mobility at any time</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>I occasionally or very occasionally have problems with my mobility</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>I have problems with my mobility most of the time</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>I have problems with my mobility all of the time</td>
</tr>
<tr>
<td>Mood</td>
<td>1</td>
<td>I am not down or depressed any of the time</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>I am down and depressed a bit of the time</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>I am down or depressed some of the time</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>I am down or depressed most of the time</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>I am down or depressed all of the time</td>
</tr>
<tr>
<td>Smell</td>
<td>1</td>
<td>There is no smell from my ulcer/ I do not have an ulcer</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>I notice the smell from my ulcer a little bit or some of the time</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>I notice the smell from my ulcer most or all of the time</td>
</tr>
<tr>
<td>Social activities</td>
<td>1</td>
<td>I have no limitations with my social activities</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>I very occasionally or occasionally have limitations with my social activities</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>I nearly always or always have limitations with my social activities</td>
</tr>
</tbody>
</table>
respondents would be asked regarding the dimensions in the questionnaire. Seven days was chosen for the new instrument as compression bandages are usually left in place for a week and so patients would be used to describing how the ulcer had been affecting them since their previous application of the bandages. The wording of the questions and the ordering of the levels of the dimensions was assessed by a piloting on a convenience sample of clinicians and patients.

The draft descriptive system and the individual item performance was then assessed through testing on 162 people with a history of venous ulceration and through using factor and Rasch analysis. An additional aim of this part of the project was to refine the descriptive system so that it was amenable for use in the subsequent valuation part of the project. The factor analysis highlighted two subscales within the items which related to the direct effects of the ulcer in terms of the symptoms experienced, and indirect effects of the ulcer which focused on the effect of symptoms. The Rasch analysis allowed a detailed examination of the measurement characteristics of the instrument including confirming the instrument’s unidimensionality, the removal of poorly performing items and an assessment of the discriminative ability of the item levels. In addition, the merging and examination of the item levels performed during the Rasch analysis has been shown to improve an instrument’s sensitivity to change. The final descriptive system, henceforth to be referred to as the SPVU-5D (Sheffield Preference-based Venous Ulcer questionnaire), consisted of five items that had between three and five levels each (see Table 1).

Preference weights for the SPVU-5D
Preference weights for the SPVU-5D were obtained through a valuation survey of a representative sample of the UK general population. Time trade-off (TTO) rather than standard gamble (SG) was used for the valuation survey as TTO was thought to be more analogous to the experience of people with this condition. Time is central to the experience of having a venous ulcer. Qualitative studies have highlighted that people often worry about length of time for healing and until the next ulcer. TTO asks respondents about how many years people would be willing to give up to escape from a health state, and so it seemed to have much greater resonance than SG where decisions are related to probability and death.

Health states for valuation were selected using fractional factorial design using the “Orthoplan” module of SPSS. The valuations were then incorporated into a regression model to predict health state valuations for all of the 720 health states described by the SPVU-5D descriptive system based on the methodology used by Dolan in the valuation of the EQ-5D. The model was estimated using individual level data as this makes maximum use of data compared to mean models. The results of the model appeared credible with the coefficients being ordered on the basis of best to worse health state (see Figure 1). The predictive performance was comparable with other studies in this area.

Advantages of the SPVU-5D
• None of the existing condition specific instruments administered to venous ulcer patients are preference-based.
• It has been developed using a bottom-up approach.
• It is short and easy to complete consisting of five items with between five and three levels.
• The recall period is appropriate to the current treatment for venous ulcers.
• The SPVU-5D is the only existing measure that has preference weights on the death to full-health scale and can be used to calculate Quality Adjusted Life Years (QALYs).

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1. RCN. The management of patients with venous leg ulcers. 2006. Royal College of Nursing.


The winner of the Catherine Pouget Award in 2010 was Koen Pardon.

The following report is on the current status of the project:

**Development of an Intervention to Improve Physician-Patient Communication in Patients with Advanced Cancer**

**Koen Pardon, PhD**

**Background**

Recently, we conducted a large longitudinal multicenter study on the preferences for information and participation in medical decision-making of advanced lung cancer patients and the degree to which these preferences were met according to the patient. The results showed that patients’ information and participation preferences were often not met. More specifically, a lot of patients who wanted information about their prognosis, palliative care and end-of-life decisions shortly after the diagnosis of advanced cancer reported they were not informed. Patients who wanted to make the medical decisions together with their physician (i.e., shared decision-making) often did not achieve this and were less involved than they wanted to be.

**Objectives**

The first goal of this study is to discuss these communication problems with oncologists and to list their suggestions for improvement. The second goal is to develop a specific intervention that improves physician-patient communication at the end of life and, more specifically, information-giving and patient participation in medical decision-making in correspondence with the patients’ preferences.

**Methods**

We will use the methodology of the focus group. The focus group is a qualitative research method for eliciting descriptive data from population subgroups. Three focus groups with physicians treating seriously ill patients will be held. Sessions will be audio-taped, transcribed, and analyzed through systematic coding and comparing and contrasting themes.

**Conclusion**

This work will be successful if useful recommendations and a useful intervention model are derived from the focus groups that enable a reduction of the existing communication problems and an improvement of the patients’ well-being. To test this, we will present the recommendations and the intervention to the physicians who participated in the focus groups for their feedback. In a follow-up study, which is outside the scope of this project, the communication intervention will be tested on advanced cancer patients.

Note: Members of the project group for this study are: Prof. Dr. Reginald Descheppe, Prof. Dr. Robert Vander Stichele, Prof. Dr. Jan L Bernheim, Prof. Dr. Freddy Mortier, Prof. Dr. Luc Deliens.

For more information, please contact Koen Pardon, PhD. A focus group study of the End-of-Life Care Research Group Ghent University & Vrije Universiteit Brussel, Belgium E-mail: koen.pardon@vub.ac.be
The Cochrane Patient-Reported Outcomes Methods Group (PRO MG) was launched in 1993 as part of the Cochrane Collaboration, an international organization that aims at helping people to take well-informed decisions about health care by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions.

The focus of the PRO methods group is on patient-important outcomes self-reported by RCT participants. These outcomes may include symptoms, signs, health status, or broader perceptions and quality of life concerns included in diaries, questionnaires, or interviews. Investigators may obtain PROs using any method of data collection, including paper and pencil, telephone interviews, web-based surveys and electronic data collection.

At the last Cochrane Collaboration Annual Meeting in Keystone, Colorado, USA, the PRO Methods Group presented a workshop entitled “How to interpret patient-reported outcomes in Cochrane reviews,” facilitated by Gordon Guyatt and Donald Patrick. At our annual business meeting we reviewed collaborations with the Musculoskeletal Review Group in selecting and interpreting outcomes for trials of arthritis and other musculoskeletal diseases. Of particular interest in our work with the Musculoskeletal Review Group is how to estimate the effect on patient-important outcomes of surrogate measures and the best way of presenting results to enhance their interpretability. A broader area of inquiry that overlaps with our work with the Musculoskeletal Review Group is an exploration of methods of aggregating results from different PROs measuring similar underlying constructs. We are currently preparing an article that will summarize the available approaches. Roy Elbers, who attended from the Netherlands, reported on his work with the Parkinson’s review group and will be our liaison.

On the Cochrane website, Caroline Terwee and colleagues have provided reviews of PROs in the review areas and you can locate them at www.cochrane-pro-mg.org/index.html.

In the coming year, we shall begin modifications of the PRO chapter in the Cochrane Handbook for Systematic Reviews of Interventions, and continue to look for an existing individual patient dataset to do analyses of PROs in trials. All ideas are welcome.

The next Cochrane Collaboration Meeting will be held in Madrid, Spain between 19 and 22 October. We shall convene a conference call to get input from interested parties on activities at the Madrid meeting some time in June. Let Iliana Petkova (ipetkova@mapigroup.com) know if you would like to be in on the call.

If you wish to join our Methods Group, please complete the Membership form on this website at www.cochrane-pro-mg.org/index.html. We thank MAPI Research Trust for providing funds to support our activities and to set up our website.

Please join us at the next Cochrane Colloquium in Madrid, Spain!
A Note on Cumulative Distribution Functions for Patient-Reported Outcomes

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Abstract
Purpose: To quantify differences between cumulative distribution function (CDF) plots using percent change and simple change from baseline with original scores versus their transformed scores (0-100 scale) on patient-reported outcomes.

Method and Results: Derivations show that percent change on transformed scores can give more extreme values than percent change on original scores. Unlike simple change, percent change based on transformed scores and original scores can give different p-values in the comparison of CDF plots between treatments.

Conclusions: The choice of which type of score (original or transformed) and type of metric (percent or simple) to use should be based on how a patient-reported outcome was developed, analyzed, interpreted, and reported before CDF plots are later considered for the purpose to enhance interpretation on a patient-reported outcome.

Introduction
In terms of patient-reported outcomes, a cumulative distribution function (CDF) gives the probability that, in the data under consideration, the individual scores on a patient-reported outcomes measure are less than or equal to a given score on the same measure. A CDF is a useful graphical and descriptive display because it captures all available data. In doing so it provides a comprehensive profile on the distribution of individual scores for each treatment group. Treatment groups can then be compared in terms of their cumulative distributions to determine whether their probability distributions differ; the corresponding p-value between independent groups can be obtained from the Kolmogorov-Smirnov test.

As a tool to enrich the interpretation of a patient-reported outcome, CDF has gained prominence as a vehicle that lends insights about patient-reported outcome measures in medical product development to support labeling claims. According to the US Food and Drug Administration guidance on this subject, "Alternatively, it is possible to present the entire distribution of responses for treatment and control group, avoiding the need to pick a responder criterion. Whether the individual responses are meaningful represents a judgment, but that problem is present with almost all endpoints except survival. Such cumulative distribution displays show a continuous plot of the percent change from baseline on the Y-axis and the percent of patients experiencing that change on the Y-axis. This display type may be preferable to attempting to provide categorical definitions of responders. A variety of responder definitions can be identified along the cumulative distribution of response curve."

Consider the special case when the original (raw) scores from a patient-reported outcome are transformed onto a 0-to-100 scale for the purposes of analysis and interpretation, a not uncommon circumstance. What are the statistical implications, if any, in a CDF plot when transformed scores are used instead of the original scores in a CDF and when percent change is used instead of simple change? Does it matter? We believe that it does matter, for the reasons discussed below.

Methods and results
Let $S_1$ be the sum of the multi-item responses of a patient-reported domain that represents the original score at baseline; let $S_2$ be the corresponding original score at follow-up. If we use those original scores, then percent change will be

$$\text{Percent Change}_{\text{Original}} = \frac{100\times(S_2-S_1)}{S_1}. \quad (1)$$

Consider a scale whose lowest possible original score is at least one (greater than zero). Suppose the original scores are transformed on a linear scale from 0 to 100 using the following standard formula: transformed score = $100\times[(\text{original score} - \text{lowest possible original score}) / \text{possible original score range}]$. Then, without loss of generality, consider a domain on a patient-reported outcome that consists of 14 items with each item having ordinal response categories from 1 to 5. If we will use transformed scores, then instead of $S_1$ we should use $100\times(S_1-14)/(70-14)$ and instead of $S_2$ we should use $100\times(S_2-14)/(70-14)$. Now percent change using transformed scores will be

$$\text{Percent Change}_{\text{Transformed}} = \frac{100\times[100\times(S_2-14)/(70-14) - 100\times(S_1-14)/(70-14)]}{100\times(S_1-14)/(70-14)}. \quad (2)$$

After simple algebra we will have

$$\text{Percent Change}_{\text{Transformed}} = \frac{100\times(S_2-S_1)}{S_1-14}. \quad (2)$$

Comparing equation (1) and equation (2) we see that the only difference is that in equation (1) we divide by $S_1$ and in equation (2) we divide by $(S_1-14)$ – that is, the second formula is always divided by a smaller value. This means, therefore, that percent change from baseline with transformed scores will always be larger than percent change from baseline with original (untransformed) scores, provided that the minimum possible original score is greater than 0. In general, the equation (2) will always be divided by $(S_1 – \text{minimum possible original score})$.

As long as at least one of the items on a domain has a minimum response category of 1, and if scores are summed, then it is impossible to get a score of 0 for a domain score. If instead the minimum possible original score is 0, as it is for example on an 11-point (0-10) pain numerical rating scale, percent change on the original and transformed scales will yield equivalent results.

Consider a subject with a score of 15 in original units at baseline and score of 30 at follow-up.
Equation 1 will produce a value of 100% for this subject, but equation 2 will give an extreme improvement of 1500% (assuming higher scores are more favorable). This discrepancy becomes especially noticeable and divergent for subjects with small baseline values.

Inference based on percentage change on the original (untransformed) scale will not equate to inference based on percentage change on the transformed scale because one is not a linear transformation of the other. Hence we would expect the p-values from the Kolmogorov-Smirnov test, which is sensitive to both location and shape of the empirical CDFs from the two samples, will differ between percent change on the original scale and percent change on the transformed scale.

For CDF plots based on a simple change (rather than percent change), statistical inference will be the same between the transformed change and the original change because the transformed change is a linear transformation of the original change. In the example provided, with a baseline original score of 15 and a follow-up original score of 30, the simple change is 30 - 15 = 15 and the transformed change is (30 - 15) * 100 / (70 - 14) = 15.42857. In the case, then, the transformed score is simply the untransformed score multiplied by the constant of 100/56, which does not affect the p-value. In general, this proportionality constant is 100/(possible original score range).

**Conclusions**

Unlike simple change, percent change based on transformed scores and original scores can give different p-values in the comparison of CDF plots between treatments. When the minimum possible score exceeds zero (typically, a minimum possible score of at least one), a CDF analysis using percent change from baseline based on transformed 0-100 scale scores is different from an analysis using percent change from baseline based on original scores, leading to different results and possibly different conclusions. Transformed scores can give more extreme values on percent change than untransformed scores when baseline values are close to zero.

Which score to use: transformed score or original score? Which metric to use: percent change or simple change? The choice of which type of score (original or transformed) and type of metric (percent or simple) to use should be based on how a patient-reported outcome was developed, analyzed, interpreted, and reported before CDF plots are later considered for the purpose to enhance interpretation on a patient-reported outcome. After all, the purpose of the CDF plot in this context is simply to enrich the interpretation of scores as they were intended to be scored and were applied in the primary analysis that preceded consideration of a CDF plot.

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**ePRO: Electronic Solutions for Patient Reported Data**

Bill Byrom and Brian Tiplady  
Published: November 2010 - ISBN: 9780566087714

Patient self-reported data has become increasingly important in today’s clinical trials. Trials in some disease indications rely upon patient recorded diary data as the primary endpoint to demonstrate drug efficacy - including, for example, indications such as insomnia, migraine and pain. In addition, improvements in quality of life measured using patient questionnaires can now be included as claims on drug labelling. Traditionally these data have been collected using paper questionnaires and diaries issued to subjects. Regulators and the industry have become increasingly aware of the limitations of recording patient reported outcomes data on paper including data quality and integrity issues. As a result there is a growing interest in collection of patient reported outcomes data using electronic means (ePRO). Solutions include handheld PDAs, Interactive Voice Response (IVR) systems, and other site-based hardware such as touchscreen PCs.

Recently, there has been much open debate with the regulators around the use of ePRO in clinical drug submissions. US and European agencies have approved new drugs that have included ePRO data in the submission dossier, but there are many questions around the adoption of the technology that concern the community. These include:

- How should instruments developed on paper be adapted for electronic use, and what degree of validation should be done between paper and electronic forms?
- How can researchers ensure they are complying with regulatory requirements including the PRO guidance published by FDA in 2009 when using ePRO solutions?
- Can fewer patients be exposed in a clinical trial as a result of improved data quality obtained using electronic diaries?
- What type of solution should be used for certain patient populations and protocols, and how can ePRO solutions be designed optimally to increase patient acceptability and compliance?

The ePro book addresses all these issues, reviews the new FDA guidance, and provides a very contemporary view on this important subject.

More information at:  
www.gowerpublishing.com/isbn/9780566087714
Expression of Gastrointestinal Symptoms and Their Impact: Similarities and Differences Across Countries

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This article is based on a presentation given at:
IBS – The Global Perspective, an international symposium organized jointly by the Rome Foundation and World Gastroenterology Organization in Milwaukee, Wisconsin, USA in April 2011

Introduction and objectives

Patient-reported outcomes (PROs) of gastrointestinal symptoms are important because there are no biomarkers readily available for conditions such as irritable bowel syndrome (IBS); clinician-reports and global assessments of signs and symptoms, if used, need augmentation with the patient perspective without clinician interpretation. The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have published guidance in which they advise the use of PROs in IBS.1, 2 In addition, a variety of socio-cultural, environmental and behavioral factors are important to consider in assessing outcomes of treatment. Heterogeneity of clinical trial populations may make detection of a treatment’s benefit more problematic, requiring large sample sizes to address variability. The patient perspective has been used extensively within gastroenterology in inflammatory bowel disease and functional bowel disorders3-7 and these measures are used widely in global clinical trials.8

Translation and cultural adaptation of symptom and impact measures for gastrointestinal conditions is important, given the frequency of global trials and the concerns of regulators, patients and other stakeholders worldwide in the identification of efficacious treatments. Of particular importance is how well these measures meet regulatory requirements, such as those posed by the US FDA and the EMA.9 In Fiscal Year 2008, 80% of approved marketed applications for drugs and biologics by the FDA contained data from foreign clinical trials and over half the participants in these trials were located outside the United States (source: personal communication, FDA). The international harmonization of clinical trial endpoints remains the goal for the International Conference on Harmonization.10 Sources of heterogeneity in clinical trials are both intrinsic and extrinsic, including the cultural adaptation of PRO instruments.

The purpose of this brief report is to review linguistic and cultural differences in the expression of gastrointestinal symptoms and impacts. An important distinction is the nature of these differences, which may be linguistic (i.e., in which one cannot find a literal equivalent for a symptom or impact) or cultural (i.e., in which a conceptual equivalent cannot be found in the languages used in the global application of a measure).12-15 We reviewed these types of differences and made suggestions for future use of these measures in global clinical trials.

Methods

We reviewed the translations of the IBS-QOL (Symptoms (S) and Impact (I)) performed by MAPI Institute. The IBS-QOL6 is a self-report quality-of-life measure specific to Irritable Bowel Syndrome (IBS) that can be used to assess the impact of IBS and its treatment. The IBS-QOL was developed using a needs-based model. The IBS-QOL consists of 34 items, each with a five-point response scale. In addition to the development of the Impact measure, a Symptom measure was created consisting of 13 symptoms assessed for frequency and bothersomeness (see Tables 1 and 2).

Symptoms are sensations or feelings known only to the person who experiences them. Impacts include changes in function, perceptions, behaviors, or any state or condition linked to the medical disease (IBS) and its signs (observable by others) and symptoms (known best by the patient).16

Languages explored

For the IBS-QOL Impact questionnaire, we explored 24 translations (22 countries) in languages representing four linguistic families (Indo-European, Afro-Asiatic, Uralic, Altaic) were identified (see Figure 1).
Expression of Gastrointestinal Symptoms and Their Impact: Similarities and Differences Across Countries pp. 13-16

**Results**

For the IBS-QOL Symptoms, all difficulties were of linguistic nature:

- Symptoms such as "nausea" and "chest pain" were found to have literal equivalents.
- "Abdominal discomfort, pain or cramps", "abdominal fullness, bloating or swelling" had exact literal equivalents. Only in some languages the translation of "abdominal" required the use of the paraphrase "in the abdomen".
- Signs like "hard or lumpy stools" and "loose or watery stools" had literal equivalents except in some countries where synonyms had to be found for lumpy (pebble-like) or loose (soft, thin).

The idiomatic term "bowel movement" did not have a literal equivalent in any language, and therefore all items including this expression were translated using synonyms or paraphrases such as defecation, evacuation of stools, or stools.

For example, the item "Feeling of incomplete bowel movement" was translated as follows in French, Italian, Spanish and German:

**French:** Sensation d’évacuation incomplète des selles (Feeling of incomplete evacuation of stools)

**Italian:** Sensazione di defecazione incompleta (Feeling of incomplete defecation)

**Spanish:** La sensación de una evacuación incompleta (The feeling of an incomplete evacuation)

**German:** Gefühl einer unvollständigen Entleerung (Feeling of incomplete evacuation)
For the IBS-QOL Impact questionnaire, too, all differences were of linguistic nature (use of synonyms and paraphrases instead of literal equivalents). Most difficulties were encountered with the five following items:

1. Item 22: “I have to avoid strenuous activity because of my bowel problems”. In 18 countries, synonyms of “strenuous activity” had to be used such as the following: demanding activity, physical efforts, physical exertion, energetic, tough, laborsome, very tiring activity. In two countries, “physical” was added to qualify “strenuous” and “activity” had to be used in the plural.

2. Item 26: “I feel unclean because of my bowel problems.” “Unclean” had to be clarified in 21 countries. For instance, in 14 countries, translators added brackets around the equivalent of “unclean” to imply that the term should not be understood literally but metaphorically. In five countries (French for Belgium, Spanish for Chile and Columbia, Portuguese for Brazil and Portugal), a negative formulation was used (e.g., “I do not feel clean”). “Myself” had to be added in one country (Korea) to clarify the concept.

3. Item 29: “It is important to be near a toilet because of my bowel problems.” In 11 countries, the concept had to be clarified by the addition of “for me”. In one country (Czech Republic), “important” was replaced by “I have to”. In seven countries, “to be near a toilet” was replaced by “to have a toilet near”.

4. Item 31: “I worry about losing control of my bowels.” In seven countries, “worry” was replaced by “fear” or “afraid of”. In most countries the use of synonyms or paraphrases of “losing control of my bowels” was needed: “cannot hold faeces”, “losing control over my anus”, “cannot stop my faeces”, “not being able to hold my faeces”, “losing control of my defecation”, “not being able to control my bowels”, “not being able to hold my excrement”.

5. Item 32: “I fear that I won’t be able to have a bowel movement.”

The main differences were seen in the choice of synonym for fear: 10 languages mentioned “to be afraid”, others used “to be scared” or “to worry”. “Bowel movement” could not be translated literally in 12 languages: the terms “to evacuate”, “to defecate”, “to pass stool”, and “to empty my bowels” were used instead.

When crossing the level of differences of each item with the corresponding domain (see Table 3), we realized that dysphoria items as well as the items from the social reaction and relationships domains were the least problematic (in light blue). However, almost half of the items of the “Interference with activity” domain belonged to the category “major difference items” (in dark blue).

Example: the Item “I feel unclean because of my bowel problems.”

➤ Afrikaans: I feel “not clean” as a result of my bowel problems.

➤ Swedish: I feel like I am not completely fresh because of my bowel problems.

➤ Czech: I have the feeling that I am not “clean” because of my bowel problems.

➤ Hungarian: I feel that I am not “clean” because of my bowel problems.

➤ Korean: I feel myself unclean because of the bowel problem.

➤ Arabic: I have a “feeling of uncleanness” because of my bowel problems.

Discussion and conclusion

Results of this study indicate that there are no major differences in the expression of symptoms and their impacts across countries. Most differences were due to the use of synonyms or paraphrases in the target languages where no literal equivalents could be found. In most cases, the translations of symptoms or signs were the least problematic. On the contrary, the description of actions or feelings often needed the use of paraphrases or synonyms because of the structure of the target language(s).
Table 3.

Less and most problematic items in the IBS-QOL (domain by domain)

<table>
<thead>
<tr>
<th>Domains</th>
<th>Corresponding items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysphoria</td>
<td>1 6 7 9 10 13 16 30</td>
</tr>
<tr>
<td>Interference with activity</td>
<td>3 18 19 22 27 29 31</td>
</tr>
<tr>
<td>Body image</td>
<td>5 21 25 26</td>
</tr>
<tr>
<td>Health worry</td>
<td>4 15 32</td>
</tr>
<tr>
<td>Food avoidance</td>
<td>11 23 28</td>
</tr>
<tr>
<td>Social reaction</td>
<td>2 14 17 34</td>
</tr>
<tr>
<td>Sexual</td>
<td>12 20</td>
</tr>
<tr>
<td>Relationships</td>
<td>8 24 33</td>
</tr>
</tbody>
</table>

There are some limitations to our assessment: no African language and no Asian languages besides Korean were included in the study we analyzed.

On the basis of the present findings we would recommend the following:

When developing a new PRO measure:
- Prepare a “list of concepts” containing the description of the concept being measured, the intention of the item, and direct patient quotes.
- Follow item writing guidelines such as those posed by Brislin.17
- Use translatability assessment (TA).18
- TA can be defined as the evaluation of the extent to which a PRO measure can be meaningfully translated into another language. A “meaningful translation” in the context of international clinical trials is one that is conceptually equivalent to the source text and culturally and linguistically appropriate in the target country to facilitate comparison and pooling of data. The goal of TA is to identify translation difficulties before embarking on the translation process as such.
- Use observable signs as much as possible, or concrete behaviors, rather than more abstract concepts.

Additional qualitative work using individual interviews and cognitive interviewing is important to confirm results from linguistic analysis.

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**Objective**
Almost four years of discussion were necessary to finalize FDA guidance on the use of PRO measures in clinical trials. Our objective was to compare how the recommendations about translations and cultural adaptation of PRO measures had evolved from the 2006 draft to the 2009 final guidance.

**Methods**
The draft and final guidances were retrieved on the FDA website and analyzed.

**Results**
Recommendations on translations and cultural adaptation were moved to another section within the Evaluating PRO Instruments Part: from “IV.D. Modification of an existing instrument” to “III.G. PRO Instruments intended for specific populations.” As for the content, the text in the body of the final guidance is more concise compared to the draft guidance. See Table 1.

New is the stipulation that the FDA will review the process used to translate/culturally adapt the instruments. As a consequence, an Appendix (section VIII) was added in which the FDA explains which topics should be addressed in the PRO documents provided to the FDA for review: description of process used, patient testing, rationale for decisions made, copies of versions, and evidence about validity.

**Discussion**
The recommendations are more concise. Expectations of the FDA are clarified in the added Appendix in which a list of documents to be provided for review is

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### Table 1.
Comparison of FDA draft and final guidances on the use of PRO measures - section on translation

<table>
<thead>
<tr>
<th>2006 draft guidance</th>
<th>2009 final guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. Modification of an Existing Instrument</td>
<td>G. PRO Instruments Intended for Specific Populations</td>
</tr>
<tr>
<td>5. Changed Culture or Language of Application</td>
<td></td>
</tr>
<tr>
<td>An instrument developed in one language is adapted or translated for use in another language or culture.</td>
<td>Because many development programs are multinational, application of PRO instruments to multiple cultures or languages is common in clinical trials.</td>
</tr>
<tr>
<td>The FDA recommends that sponsors provide evidence that the methods and results of the translation process were adequate to ensure that the validity of the responses is not affected.</td>
<td>Regardless of whether the instrument was developed concurrently in multiple cultures or languages or whether a fully developed instrument was adapted or translated to new cultures or languages, we recommend that sponsors provide evidence that the content validity and other measurement properties are adequately similar between all versions used in the clinical trial.</td>
</tr>
<tr>
<td>Some examples include the following:</td>
<td>We will review the process used to translate and culturally adapt the instrument for populations that will use them in the trial.</td>
</tr>
<tr>
<td>■ PRO instruments are developed initially in one language, culture, or ethnic group and are used subsequently in another language or culture.</td>
<td></td>
</tr>
<tr>
<td>■ PRO instruments developed and validated outside the United States are applied to the U.S. population</td>
<td></td>
</tr>
<tr>
<td><strong>Sponsors should consider whether generally accepted standards for translation and cultural adaptation have been used to support the validity of data from a translated/adapted PRO instrument, including but not restricted to the following:</strong></td>
<td><strong>APPENDIX: INFORMATION ON A PRO INSTRUMENT REVIEWED BY THE FDA</strong></td>
</tr>
<tr>
<td>■ The background and experience of the persons involved in the translation/adaptation</td>
<td>A. Process used to translate and culturally adapt the instrument for populations that will use them in the trial.</td>
</tr>
<tr>
<td>■ The translation/adaptation methodology used</td>
<td>B. Description of patient testing, or language- or culture-specific concerns, and rationale for decisions made to create new versions.</td>
</tr>
<tr>
<td>■ The harmonization of different versions</td>
<td>C. Copies of translated or adapted versions.</td>
</tr>
<tr>
<td>The evidence that measurement properties for translated versions are comparable</td>
<td>D. Evidence that content validity and other measurement properties are comparable between the original and new instruments.</td>
</tr>
</tbody>
</table>
Recommendations about Translations in the Final FDA Guidance on PRO Measures: What has Changed and What has Remained pp. 17-18

provided. However, the FDA does not indicate a preference for a specific translation methodology as long as evidence shows that the methodology followed creates conceptually equivalent versions.

Patient testing is clearly indicated as a key point of the process.

The need for documenting all decisions is crucial. In view of the final guidance, it seems clear that organizations involved in the translation of PRO measures will have to develop a standardized reporting system to structure the evidence to be provided to the FDA.

The last point of the Appendix (point D) is debatable as we anticipate that it might add to the cost and timeline already involved in the production of the translations. The FDA does not indicate which criteria or methods should be used to prove that content validity is comparable between the original and translations. The necessity of quantitatively testing content validity at the end of the linguistic validation process should be considered and discussed since all the evidence gathered during the whole process is of a qualitative nature. Information about the team involved in the production of the translations might be considered as one of the criteria used to back up comparability of content validity.

Finally, another point of discussion might be the necessity of developing standardized lists of concepts including translation alternatives to make sure that the conceptual framework of the original is maintained in the translations.

Conclusion

In its final guidance on the use of PRO measures, the FDA has clarified its expectations about the evidence on the translations of PRO measures to be provided in a submission dossier. Comparability of content validity is the key issue. Sponsors will have to provide evidence in a consistent way.

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2010 Asian Chinese QOL Conference

Kwok Fai LEUNG
Chairman, Organizing Committee, 2010 Asian Chinese QOL Conference

The International Society for Quality of Life Research - Asian Chinese Chapter had organized the 2010 Asian Chinese QOL Conference from 17th-19th December, 2010 in the Li Ka Shing Faculty of Medicine at the University of Hong Kong. The conference was co-organized by the Hong Kong Society for Quality of Life and the Department of Family Medicine and Primary Care at the University of Hong Kong.

This was the sixth conference on QOL research held in Hong Kong or Guangdong Province of China since 2000. Everybody involved in organizing the conference shared a common mission of building and maintaining a platform on which people conducting QOL research or providing services for the promotion of quality of life for the Chinese population could share their work in a bilingual conference environment. This time, we were very successful in achieving such goal again.

There were 150 people attended the conference, among them 30 came from various parts of mainland China. Besides academia and researchers, a large proportion of participants are practicing clinicians and therapists, including practitioners of Chinese medicine.

We were much honored to have invited Prof. John Ware as our keynote speaker. Several renowned experts in QOL research including Ms. Mona Martin and Mr. Donald McKnight Bushnell from USA, and Prof. Ji-qian Fang from China, Prof. Cindy Lam from Hong Kong, and Dr. Sunny Lin from Taiwan shared their latest thoughts and findings on QOL research in the plenary sessions.

All the participants, especially young researchers from Mainland China, enjoyed very much the half day workshop conducted by Prof. John Ware. Ms Martin discussed the issue related to QOL claims from a conceptual perspective. Prof. Cindy Lam shared her thoughts on selecting QOL instrument to suit the nature of various QOL research. Prof. Ji-qian and Dr. Sunny discussed various aspect of QOL research on traditional Chinese medicine.

Besides the plenary sessions, there were 25 local and Mainland Chinese speakers who delivered lectures in the concurrent symposiums on a wide range of QOL topics. We had 50 free papers presented in the concurrent free paper sessions. We were much obliged to the MAPI Research Trust and Health Research Associates for their generosity in donating scholarships to young researchers. Fifteen people received awards for their outstanding free papers.

ISOQOL-ACC is planning to organize the next Asian Chinese QOL conference in mid-2012 in the Guangdong Province of China. We hope you can join us there in 2012.
Diabetes Treatment Satisfaction Questionnaire (DTSQ) for Spain and Latin America: are Multiple Language Versions Really Necessary?

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Objectives
To ascertain the need for several same-language adaptations, by comparing 12 Spanish versions of the Diabetes Satisfaction Questionnaire (DTSQ), originally developed in English by Clare Bradley (Bradley and Lewis, 1990) and now linguistically validated into over 100 languages.

Methods
The original English DTSQ has been translated into two versions for Mexico and the USA instead of adapting the existing Spanish version for Spain. Other Latin American versions were adapted mostly from the Spanish for Argentina, itself originally adapted from the Mexican Spanish. Differences and equivalents are explored: (i) among the 12 language versions; (ii) based on the three main areas of language descriptions (syntax, semantics, pragmatics); and (iii) with regard to the conceptual complexity of the items.

Results
The Castilian DTSQ has a higher register, with more formal and detached wording. The other two independent versions (Mexico and USA) include many Anglicisms, as well as a shorter and simplified syntax. Notable differences and similarities among the other Latin American versions highlight the possible impact of social factors and usage, and suggest four potential groupings by geographical area: (1) a “central” American variation (with Guatemala and Venezuela sharing linguistic features with Mexico); (2) the Antilles regions of Dominican Republic and Puerto Rico (with wording analogous to the US version); (3) the equatorial area of Colombia, Ecuador, and possibly Peru (sharing some archaic lexis, repetitive and simplified structures); and (4) the Rio de la Plata region, Argentina (with a slightly more formal register). Linguistic differences concern mainly lexis and semantics. Instructions and Qs.2/3 (perceived frequency of hyper/hypoglycemia), Q.4 (convenience) and Q.5 (flexibility) showed the most differences.

Conclusions
The analysis confirmed the contextual-specificity of questionnaire validity and the necessity for separate versions for Spain, USA, and Mexico. Further research is recommended on the possibility of four other “grouped” versions for Latin America.

NEWS FROM...

The Australian Health Outcomes Collaboration (AHOC), with associated organizations, convened an Australian seminar and workshop series with Dr. Ware. There were seminars and workshops held in Adelaide, Brisbane, Canberra, and Sydney between the 2nd and 6th May 2011. Dr. Ware spoke on “Advances in Health Outcomes Assessment: Implications for Current Practice” and offered workshops on “The Application and the Interpretation of Patient Reported Health Outcome Measures”. Dr. Ware had not presented in Australia since the 2003 Health Outcomes Conference so we all really enjoyed catching up with him again. The feedback received from the participants was excellent.

AHOC staff recently completed a report on The Effective Assessment of Social Isolation which reviews measures of social isolation, loneliness, and social function. We are also currently involved in the clinical validation of two short measures for the assessment and outcomes monitoring of incontinence (Revised Urinary Incontinence Scale; Revised Faecal Incontinence Scale) and, with A/Prof. Graeme Hawthorne, the validation of the Short Assessment of Patient Satisfaction Scale. A/Prof. Sansoni has recently written a report for the Australian Government Department of Health and Ageing on the national standardization of assessment tools for Aged Care Assessment Teams.

If you are interested in obtaining relevant reports or information from AHOC, please contact Associate Professor Jan Sansoni at janet.sansoni@grapevine.com.au
The 2010 Catherine Pouget Award

As many readers of the PRO Newsletter know, our colleague and friend Catherine Pouget died on July 3, 2001, at the age of 31, after a long illness. During the last year of her life she suffered greatly, not only from the effects of the illness and its treatment, but even more from the lack of understanding and compassion in those who were responsible for her. In her memory, MAPI Institute has for several years offered an award to support the design and implementation of projects intended to improve the quality of life of those who are terminally ill.

This year’s guidelines had been modified to encourage the submission of projects that were not necessarily “scientific” in form. Even scientifically qualified applicants were thus able to relax their usual style of presentation.

There were 14 submissions, nine of them from English-speaking countries (seven from North America). Applicants included four PhDs, four MDs, one DD, one MA, three graduate students and one who gave no professional information.

The topics chosen showed increasing sensitivity to the need for improving communication with the terminally ill. Several proposals focused on programs to teach participants how to communicate with each other.

The evaluation of intervention in terminal illness is always difficult, but defense of the criteria for demonstrating success was rare, and the formulation of testable hypotheses even rarer. One brave applicant made reference to a controlled trial design.

Of the 14 projects submitted, five were judged particularly worthy of recognition. Of these, the qualities of two were considered almost impossible to separate. Alas, only one grant could be made, and the list therefore contains the name of one winner (Koen Pardon - please refer to the article entitled “Development of an intervention to improve physician patient communication in patients with advanced cancer”) and four honorable mentions (Elaine Wittenberg-Lyles, Rafael Wainer, Jessica McFarlin, Negin Hajizadeh). These may be mentioned if their bearers wish, in future c.v.s.

Advice to Applicants for the 2011 Catherine Pouget Award:

Your proposal should present an original and relevant approach to the improvement of communication between people who are terminally ill and those who care for them.

Read the guidelines with care. Your submission should not exceed four pages in length, double-spaced. You should include: the most important features of your curriculum vitae (date of birth; maternal language; major qualification; present appointment/activity), not more than four references to your own work, and a brief justification of your budget. Include only essential background about your chosen subject: a detailed history is not necessary.
Dismal Scenario of Diabetes in India
Sanjay Kachroo
New Delhi, India

Introduction
There is no denying the fact that India has made remarkable and noticeable progress in the field of health of its citizens during the past decades. The determining parameters of a society are Infant Mortality Rate, Crude Birth Rate, Crude Death Rate, Maternal Mortality Ratio, Disease Prevalence, Morbidity and Life Expectancy. India has seen a substantial decline in all these parameters except for the Life Expectancy which grew from a dismal 36.7 years in 1951 to a robust 64.6 years in year 2000 and is still on the rise. The noteworthy successes include eradication of Small Pox and Guinea Worm Disease, near eradication of Polio and containment of Leprosy, Filariasis and Kala Azar diseases to a large extent. Sustained improvement in the public health system and the participation of an ever-expanding private sector has led in ameliorating the sufferings of the people who, until recently, were exposed to limited medical and clinical resources, mostly due to poverty.

However rosy the picture appears to be in the light of impressive progress made, quite a sizable proportion of the population living in rural India is still deprived of easily accessible health care which could be available at affordable costs. Precious lives are still being lost on account of unacceptably high rates of morbidity and mortality, both resulting from inadequate medical care or even total lack of it in certain areas. India accounts for 16.6% of the world’s population but sadly harbors one fifth of the world’s diseases. Still worse, India is home to one-third of all the diarrheal diseases, tuberculosis, chest and respiratory infections besides parasitic diseases and prenatal complications, one-fourth of maternal problems and one-fifth of diabetes and nutritional deficiencies. More alarmingly, India has a large number of HIV / AIDS cases, second only to South Africa.

The budget allocation for health in India is among the lowest in the world, just 0.9% of the total Gross Domestic Product (GDP).

But private spending on health is three times the public spending which is a healthy sign, given the returns in this sector being considerably low. However, the last two general budgets have seen higher allocations being made to the health sector with a determined resolve by the states of the nation to match their funding with the central assistance. The robustly expanding economy will ensure that total health spending by the government is 2% to 3% of the GDP by the year 2012.

India: Diabetes capital of the world

Background
The scenario above reflects both the progress made in the health sector in alleviating human suffering as well as the shortcomings because of deficiencies and gaps in the execution of various policies. But what has taken the country by storm is the spread of Type 2 diabetes; it is so rapidly that it can be equated to an epidemic. Some analysts have gone even further and termed the scenario as pandemic, a stage much worse than an epidemic. In fact, the Indian subcontinent (which also includes South Asian countries such as Bangladesh, Pakistan and Sri Lanka) have witnessed an alarming increase in persons having diabetes – with more than half of them not even aware of their ailment. India has 40 million diabetics and this figure is going to double, astoundingly by 195%, by the year 2025. On a more dismal note, a World Health Organization (WHO) report says that the trend is growing in geometric proportions and by the end of year 2025, there will be 299 million in India alone suffering from diabetes, ‘the sweet killer’.

India survived through centuries of natural calamities like floods, famines, earthquakes and epidemics which resulted in starvation or malnourishment. The people living here cultivated a thrifty genome because of prolonged bouts of starvation. But all that has changed with the overall development witnessed across the country resulting in the transformation of “frugal eaters” to “food devourers.” Indian masses have been consuming more and more fat-rich food and have developed big bellies. Most of the people have “pear-shaped” bodies with pounds of fat stored around the waist that reflects the deteriorating food habits which are increasingly being aped from the West. It is estimated that 53% of all deaths taking place in India are accounted by non-communicable diseases such as cardio-vascular diseases, diabetes mellitus, cancer, chronic lung diseases and stroke. Until recently communicable diseases had been the bane of health-related miseries in India and the government was proactive in providing succour to the masses with the focus on these diseases only, but now this category is being overtaken by the burden of non-communicable diseases. Not surprisingly, the need to formulate the National Program on Prevention and Control of Diabetes, Cardiovascular Diseases and Stroke was felt by the health ministry and it did so. The prime objective behind initiating this program is to devise and implement the strategies for promotion, prevention, and control of these chronic diseases, diabetes being one of them.

Basic components of the program

Broadly, there are three components of this program:

1. Health Promotion for the Population
The prime objective of this component is to harness the vast reach of an effective communication network like media for propagating community mobilization and participation and focus on modifying the individual and community behavior. The priority is to reach up to the tiniest village, penetrating through the community, school and work place. Community-based interventions mean imparting better health education concerning physical activities, changing dietary habits through lectures, health talk
shows, distributing health education material, etc. NGOs, village health committees, self-help groups and other faith-based groups will be part of these health promotion measures. **Workplace interventions** include sessions of health talks, health check-up camps, advocating lifestyle changes screenings of those who are in the high-risk category. **School based interventions** will reassess the existing health program initiatives in schools such as physical education, nutrition and midday meals, and health fitness for school personnel; all this and making health promotion a well-defined agenda of the curriculum.

2. **Disease prevention for the risk prone**
   These interventions encompass early diagnosis followed by effective treatment in order to reduce the ratio of morbidity and mortality by identifying those people who run the risk of being easy victims because of high blood pressure, lipid and glucose levels, obesity, and sufferers of any previous cerebral or heart ailment. There will be a thorough **revamping of the public health delivery mechanism** at all levels of operation, viz. primary, secondary, and tertiary. Healthcare professionals will be retrained for detection of risk and screening and their skills will be bolstered so that they get involved with blood pressure checks, recommending lifestyle changes, impart knowledge and information and make referrals. **Special clinics** will be set up at all district hospitals for diabetes, cardiovascular diseases and strokes. Wherever medics are unavailable, private practitioners will be asked to act as visiting consultants. **Participation by the private sector** will be encouraged in order to bridge the gap and correct the cost imbalance due to the paying capacity of the poor. This can be achieved through harnessing the cost-effective interventions by the private sector players. Furthermore, referral systems at the tertiary level will be strengthened by attaching them to the nearest referral centers so that prompt intervention in the event of a cardiac problem is ensured.

3. **Evaluation of prevailing risk factors**
   **Data collection and analysis of risk factors** can go a long way in determining and predicting many non-communicable diseases. This component will also see research taking place in the field of casual association and cost effectiveness of the systems and procedures besides strengthening and upgrading the of data collection mechanism. These data pertain to the records and reports that are compiled and maintained by public health systems spread all over the districts of the country. The activity will be carried out under the supervision of a state-level institution like a medical college and will be supervised by a district level nodal officer besides the high-ranking officers of the district administration. The role of private practitioners and the private sector will be encouraged. The example has been set by a pharmaceutical company that has launched a diabetes patient support program wherein it will guide and counsel the patients over the phone.

### Conclusion
It is quite evident that diabetes is a leading factor of health problems for the Indian community residing in India and in other parts of the world. It is spreading at an alarmingly fast pace and has to be tackled by a firm resolve to increase budget allocations significantly and strengthen the public health system with an equal participation by the private sector, sooner than later.

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### Quality of Life Measurement in Neurodegenerative and Related Conditions

Crispin Jenkinson, Michele Peters and Mark B. Bromberg

Patient-reported outcome measures are central to the evaluation of medical care and treatment regimes. Such measures depart from traditional clinical assessments as they are based on issues known to be of importance to patients.

This book outlines the development and application of a variety of such measures in a wide range of neurological conditions. Introductory chapters outline issues in the application and validation of quality-of-life measures in neurology. Subsequent chapters survey the most widely used quality-of-life instruments in Parkinson’s disease, motor neurone disease, multiple sclerosis, multiple system atrophy, progressive supranuclear palsy, and Alzheimer’s/dementia. A chapter on cerebral palsy deals with the particular challenges to developing outcome measures for children.

The book also addresses issues relating to the translation of measures for use in cross-cultural studies, handling missing data, carer experiences of long-term conditions, and methodological challenges. Essential reading for clinicians and researchers working in the field of neurology, this book is the first to outline the development and application of a variety of such measures in a wide range of neurological conditions.

More information at:
http://ebooks.cambridge.org/ebook.jsf?bid=CBO9780511975363
The primary goal of MAPI Research Trust’s Patient Reported Outcomes 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 Trust.

Health-Related Quality of Life and Well-Being

Health-related quality of life (HRQL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death, and focuses on the impact health status has on quality of life. A related concept of HRQL is well-being, which assesses the positive aspects of a person’s life, such as positive emotions and life satisfaction.

For more information:
www.iom.edu/Activities/Disease/Epilepsy.aspx

ANNOUNCEMENTS

Health-Related Quality of Life Curricular Materials for Schools of Public Health

The US Centers for Disease Control and Prevention Division of Adult and Community Health developed curricular materials for schools of public health to increase awareness of the use of the Health-Related Quality of Life (HRQL) Surveillance Program’s measures and resources among public-health practitioners.

Curricular materials are available in five public-health discipline areas: biostatistics, behavioral sciences, environmental health, epidemiology, and policy.

To access the curricular material, please see: www.cdc.gov/hrqol/curriculum/index.htm

Health-Related Quality of Life and Well-Being measures will be used to monitor progress in achieving goals.

For more information:
www.healthypeople.gov/2020/about/QoLWAbout.aspx

The Public Health Dimensions of the Epilepsies

Epilepsy is one of the most common neurologic conditions in the United States, affecting at least 1 in 100 adults and 1 in 20 children. There are more than 40 types of epilepsy—referred to collectively as the epilepsies—that cause recurrent seizures and that can be responsible for brain damage; neurological, cognitive, or psychiatric impairment; and death. Advances in research are improving our understanding of the scope of epilepsy and its public health impact. However, current approaches do not fully take into account either the broad range of epilepsy disorders and their comorbidities or their consequences for health and quality of life.

The Institute of Medicine is undertaking a new study that will consider the public-health dimensions of the epilepsies in the United States—including healthcare and human services, health literacy, and education. The IOM will recommend priorities in these areas in order to better understand the public-health impact of the epilepsies and to meet the needs of people with epilepsy and their caregivers.

For more information:
www.iom.edu/Activities/Disease/Epilepsy.aspx

Call for Papers and Articles

PRO Newsletter 46
Special Edition for the 20th anniversary of the PRONL. Any contribution to celebrate this milestone with us is welcome!

PRO Newsletter 47
Any news and information on Patient-Reported Outcomes are welcome (e.g., short articles on ongoing Quality of Life research, announcements of publications, meetings, websites, etc.)
Please refer to PRO Newsletter Online website at www.pro-newsletter.com for submission information.

Deadline for the PRONL Special Edition 46:
August 15th, 2011

Deadline for the PRONL 47:
March 1st, 2012
Please send your paper by post, fax or e-mail to Barbara Wolf, MAPI RESEARCH TRUST, 27, rue de la Villette, 69003 Lyon, France. Fax: +33 (0)4 72 13 55 73 - E-mail: bwolf@mapigroup.com

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CALENDAR

May 21-25, 2011
ISPOR 16th Annual International Meeting
Baltimore, Maryland, USA
Hilton Baltimore
www.ispor.org

May 31 - June 1, 2011
Patient Adherence, Communication & Engagement Europe
Berlin, Germany
Hotel Concorde
www.eyeforpharma.com/patient

June 13-14, 2011
CBI: 8th Forum on Patient Reported Outcomes (PRO)
Philadelphia, Pennsylvania, USA
Loews Hotel
www.cbinet.com/show_conference.cfm?confCode=PC11141

June 19-23, 2011
DIA’s 47th Annual Meeting
Chicago, Illinois, USA
McCormick Place

July 18-22, 2011
ESRA: 4th conference of the European Survey Research Association
Lausanne, Switzerland
University of Lausanne
www.surveymethodology.eu

August 14-17, 2011
27th ICPE: International Conference on Pharmacoepidemiology & Therapeutic Risk Management
Chicago, Illinois, USA
Hyatt Regency Chicago
www.pharmacoepi.org/meetings

September 12-14, 2011
Université de Pharmaco-Epidemiologie: 8th Annual Conference of Pharmaco-Epidemiology
Paris, France
www.upe-avignon.org/uk

October 10-12, 2011
DIA 5th Annual Clinical Forum
Basel, Switzerland
Congress Center
www.diahome.org/DIAHome/FlagshipMeetings/Home.aspx?roi=echo4-12859669640-10222829-d56a689eb4fb31329ed04a7a487e164&meetingid=25232

October 26-29, 2011
ISOQOL 18th Annual Conference
Denver, Colorado, USA
Sheraton Denver Downtown
www.isoqol.org

November 5-8, 2011
ISPOR 14th Annual European Congress
Madrid, Spain
Hotel Auditorium Madrid
www.ispor.org

KEYWORDS

Adaptations
Adolescents
Arts and Health
Community-Based Interventions
Cultural Adaptation
Cumulative Distribution Function
Data Collection and Analysis
Diabetes
Diabetes Mellitus
Head and Neck Cancer
Health Services Research/Methods
Health Status
Irritable Bowel Syndrome (IBS)
Label Claim
Latin America
Linguistic Validation
Multicultural
Needs Assessment
Original Scores
Palliative Care
Patient Concerns Inventory
Patient-Reported Outcomes (PROs)
Patient-Reported Outcomes Measures (PROMs)
Percent Change
Preference-Based
Public Health
Public Health Delivery Mechanism
Quality Adjusted Life Years
Quality of Life
Questionnaires
School-Based Interventions
Spain
Spanish
Transformed Scores
Translation
Venous Ulceration
Workplace Interventions