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COMMENTARY

Editorial comment on "Disregarding clinical trial-based patient-reported outcomes is unwarranted: Five advances to substantiate the scientific stringency of quality-of-life measurement"

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Professor Miriam Sprangers from Amsterdam, The Netherlands, highlights the important value of Patient Reported Outcomes (PRO) and their use in clinical trials and practice during the disease trajectory [1]. Professor Sprangers uses the definition of PRO as suggested by The United States Food and Drug Administration (U.S. Department of Health Human Services, FDA, Research, Evaluation, & Health, 2006); "A PRO is a measure of any aspect of a patient's health status that comes directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)", including disease symptoms, patient functioning, and HRQoL [2].

Initially PRO assessment was added to medical outcomes solely to describe patients' wellbeing followed by assessment of changes in patients' health status during the cancer disease trajectory and in the evaluation of effects of cancer care and treatment. However, professor Sprangers clearly demonstrates how PROs nowadays are acknowledged as being as reliable as commonly used clinical measures such as tumour response. She emphasizes that the use of PROs must be as well-reasoned as the use of traditional clinical measures and thereby need to be incorporated into the methodology of clinical trials in the design phase. The workshop discussions took the standpoint that the need of using PROs as outcome in clinical trials and clinical practice is obvious, but also emphasized that the kind of aspects to measure is not yet entirely clear. It is of importance to underline that a measure of PRO might be reliable and valid on a group level but not automatically on an individual level or appropriate for specific populations such as different diagnostic groups and treatment modalities. In addition, aspects important for the individual patient must be considered as well as differences due to diverse cultures. Furthermore, the issue of when and how to collect PROs is also a future challenge. Professor Sprangers pointed out the importance of the application of computer adaptive testing to develop computerized item banks. The item bank serves as a resource to select the most appropriate PROs on an individual level leading to higher precision and reduction of each patient's burden. However, this requires large sample sizes and highlights the importance to perform multicenter studies in Sweden.

The topic of incorporation of PROs in clinical practice was vividly discussed in the workshop and identified as a prioritized challenge for the future. The use of PROs in clinical settings requires relevant and easy-to-use measures (certainly also relevant for collecting data in clinical trials). Such technological facilities exist in the form of web-based measures and handheld devices. However, experimental studies to investigate the effects of such methods are rare and the workshop discussion concluded this as being highly required. This also goes along with the importance of conducting research on the implementation process (i.e., translational research).

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In professor Spranger's presentation she raises the importance of interpreting changes in PROs. She conferred to the concept response shift which reflects the process of accommodating to illness. She pointed out that her current research interest in the area was to deepen and expand the concept by, for instance investigating its relationship to individual aspects.

The fourth key-note speaker at the State of Science conference, professor Langius-Eklöf, gave a presentation about the concept of Sense of Coherence (SOC) as one individual factor affecting PROs. The SOC concept contains three components which all together contribute to the unity of sense of coherence. The more comprehensive, manageable and meaningful a person views his/her life the higher the feeling of sense of coherence and the more successfully stressful life events are managed, followed by better health and well-being. The SOC Scale, developed to measure the concept of sense of coherence, has attracted a lot of attention within health care research during the past 20 years. A systematic review concludes that the SOC scale is available in 33 languages in 32 countries [3]. The review also concludes that the SOC Scale is reliable, valid and applicable cross-culturally. Furthermore, the SOC Scale relates to health by showing main, moderating or mediating role in the explanation of health and quality of life especially in psychosocial dimensions and for those rating higher SOC [4,5]. Concerning the stability the review concludes that the degree of SOC tends to increase with age but that variations over time (from 1 w-10 years) are small [3]. A clinical significant change is suggested to be reflected by a 10% change of a scale as also discussed by professor Sprangers. When penetrating studies in detail the mean changes in percent in almost all longitudinal studies are small (very few studies show changes over 8%). Two intervention studies indicate reinforcement in the degree of SOC in cancer populations [6,7]. Still the long-term effect is unknown. Thus as concluded in the workshop individual factors are important to consider in relation to PROs and disease process for explanation and interpretation of results.

Professor Sprangers invited us to the new research field regarding the impact of genetic disposition on quality of life. She presented data from some recent studies suggesting heritability for emotional states such as anxiety and depression and for subjective well-being and life satisfaction. She introduced the GENEQOL Consortium, an international, interdisciplinary consortium which has been established to plan and conduct clinically relevant research within this exciting field. The possible impact of this novel research field is hard to grasp but it has the potential to lead to extended possibilities to individualize and improve patient care.

The fact that Sweden has a long tradition of collecting and compiling data in National Healthcare Quality Registries was highly recognized in the workshop discussions. Thus, we have a strong infrastructure which should be used to facilitate systematic collection of PRO data. The addition of appropriate PROs to existing registries would be of the greatest importance for a successful development of cancer care research. A combination of medical data with PROs and genetic parameters may result in new promising strategies to improve cancer care by even more individualized medical treatments and support interventions, as pointed out by professor Sprangers.

As raised in an editorial in this issue [8] there is a need for increased collaboration in Swedish cancer care research. Multicenter studies are an imperative to conduct research projects with sufficient study samples due to the small Swedish population. The Swedish cancer care research is relatively strong and the knowledge base has increased during the past decades. Thus, there is a need for special initiatives to facilitate the development of research in Swedish cancer care by financial and infrastructural support for multicenter studies.

To conclude, the workshop based on professor Sprangers' presentation has identified a number of important front line research directions regarding 1) defining the most important PROs in clinical trials and practice, 2) interpretation of PRO data in relation to individual characteristics including cultural aspects, 3) the effects of the use of PRO in clinical routine and 4) translational research. Finally, the authors of this commentary address the consensus achieved in the workshop of the importance to incorporate PROs in the National Healthcare Quality Registries which will lead Swedish cancer research to a level of international excellence.

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