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Session 2– Invited paper

DOMAIN DEFINITIONS FOR PROMIS
(Draft)

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Domain Hierarchy

1. Currently, there are two proposed hierarchies of patient-reported outcomes, which are similar in many respects (see figures 1 and 2, attached separately as document "PROMIS Domain Hierarchy"). Both start with three overall dimensions, as described by the World Health Organization (WHO): Physical, Mental and Social.

2. It may be useful to also review the International Classification of Functioning, Disability and Health (ICF), which is part of the "family" of international classifications developed by the WHO. The ICF is also a companion to the International Classification of Disease (ICD), which is used by all U.S. health care providers for billing, etc. There has been some movement toward requiring providers to code patients using ICF in addition to ICD. The overall aim of the ICF classification system is to provide a unified and standard language and framework for the description of health and health-related status. There are two overall ICF domains: *health domains* and *health-related domains* (e.g., education, work). These domains are described from the perspective of the body, the individual and society in two basic lists: 1) Body Functions and Structures, and 2) Activities and Participation. Environmental factors (e.g., natural environment, support and relationships) that interact with these constructs may also be evaluated. The ICF is provider-rated (see Figures 3 and 4, attached separately as document "WHO attachments").

* Paper prepared by Dagmar Amtmann.

3. Below is a draft set of definitions for selected domains, including the five domains that will be the initial focus of PROMIS.

Physical

4. Physical Function[1]. Physical Function is defined as one's ability to carry out various activities, ranging from self-care (activities of daily living) to more challenging and vigorous activities that require increasing degrees of mobility, strength or endurance (Stewart & Kamberg, 1992; Haley, Coster & Binda-Sundberg, 1994; Haley, McHorney & Ware, 1994; Wilson & Cleary, 1995).

5. Fatigue[1]. Fatigue is defined as an overwhelming, debilitating and sustained sense of exhaustion that decreases one's ability to carry out daily activities, including the ability to work effectively and to function at one's usual level in family or social roles (Stewart, Hays & Ware, 1992; North American Nursing Diagnosis Association, 1996; Glaus, 1998). It can be caused by disease and/or treatment.

6. Pain[1]. Pain is a sensation that hurts. It is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (Sherbourne, 1992; Merskey & Bogduk, 1994; Chang, 1999; Meuser, et al, 2001). Pain is always subjective. It is unquestionably a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience. Experiences, which resemble pain but are not unpleasant, e.g., pricking, should not be called pain (Merskey & Bogduk, 1994). Unpleasant abnormal experiences (dysesthesias) may also be pain but are not necessarily so because, subjectively, they may not have the usual sensory qualities of pain (Merskey & Bogduk, 1994)

7. The measurement of pain has been a challenge. A multidimensional, multi-source, and possibly multi-modality approach to pain measurement has been recommended (Snow, xxxx). A latent variable structural equation model is posited, where a stimulus leads to pain sensation, which leads to pain expression, a latent variable measured by cognitive, behavioral, emotional and sensory indicators. Another conceptual framework includes possible pain stimulus (touch) that leads to pain expression and to physical assault. How do we know that the latent construct that we are measuring is pain and not something else, e.g, hypersensitivity to tactile stimulation, invasion of space, etc.? For example, is touch really a pain stimulus and are the resulting verbal and non-verbal displays (e.g., weeping, flinching) really pain indicators? Similarly, are the cognitive, sensory, behavioral and emotional second order factors truly indicators of pain?

Mental

8. Negative Affect (Emotional Distress)[1]. Negative Affect is a term used to describe unpleasant feelings or emotions that may interfere with the ability to cope with a disease, its physical symptoms, and its treatment. This includes emotional distress and covers a wide range of feelings, including worry, powerlessness, sadness, fear, depression, anxiety and panic (Schag et al, 1994; Lawton, Parmellee, Katz & Nesselroade, 1996; van't Spijker, et al, 1997; Bottomley, 1998a; 1998b; Stark, et al, 2002). Negative Affect is correlated with, but distinct from, major depression.

9. An important issue is whether affect is a state or trait, or both. The concept of negative affectivity (Watson & Clark, 1984) has been defined as a propensity to report dissatisfaction and distress, regardless of external reality. The concept has been measured by scales, which relate to

self-reported pessimism, self-blame, worry, lack of self-confidence and dissatisfaction. Recent findings by Lawton and colleagues (1996) show that indicators of negative affect can vary among depressed individuals on a daily basis. Thus, negative affective symptoms (which may be caused by depression or by negative events) are considered to be more state-like in that different indicators may change in response to external stimuli.

10. It may also be useful to measure externalizing problems, e.g., substance abuse, anger, aggression, and other expressions of behavioral dyscontrol.

11. Positive Affect. Positive affect has been characterized as happiness, contentment, high energy and interest (Watson & Tellegen, 1985). Positive affect may be a more stable or trait-like construct, although evidence suggests that certain aspects are amenable to change based on environmental interventions (Lawton, VanHaitsma, Klapper, Kleban, Katz & Corn, 1998).

12. Illness Impact: Negative and Positive. Negative Illness Impact can be conceptualized as the direct negative psychosocial effect of an illness, distinct from general emotional distress such as anxiety and depression. Unlike general Negative Affect, *negative* illness impact refers to distress and other concerns specifically about the illness/condition or its sequelae (e.g., fear that cancer will recur or worsen). In contrast, *positive* illness impact refers to positive psychosocial outcomes of illness that can occur as a result of confrontation with one's mortality, such as greater life appreciation, interpersonal relationships and personal resources. This has been conceptualized as post-traumatic growth (Tedeschi & Calhoun, 1995; 1996), benefit-finding (Antoni, Lehman, Kilbourn, et al, 2001; Stanton, Danoff-Burg, Sworowski, et al, 2002; Tennen & Affleck, 2002), and meaning making (Davis, Nolen-Hoeksema, & Larson, 1998; Ersek & Gerrell, 1994; Taylor, 1995).

13. Cognitive Complaints. Cognitive impairments may be experienced as deficits in attention, memory, concentration, or language (Ahles & Saykin, 2001; Brezden, Phillips, Abdolell, et al, 2000; Schagen, van Dam, Muller, et al, 1999). Cognitive complaints or distress might be considered a sub-domain of Cognitive Health or Cognitive Function. In general, cognitive functioning is often better measured by other methods, rather than self-report.

14. Spiritual Well-being. Spiritual well-being is distinguished from religiosity (religious behavior), and targets sense of meaning and purpose in life, harmony, and comfort derived from faith (Peterman, Fitchett, Brady, et al, 2002). Daily spiritual experience is also considered a component of spirituality, and is a measure of the individual's perception of the transcendent (God, the divine) in daily life and the perception of interaction with, or involvement of, the transcendent in life (John E. Fetzer Institute, 1999).

15. There is some disagreement about whether Spiritual Well-being is a sub-domain of Mental Health, or whether it is a fourth domain at the same level as Physical, Mental and Social Health.

Social

16. Social Role Participation (Social Function)[1]. Role participation refers to involvement in, and satisfaction with, one's usual social roles, including marital relationships, parental responsibilities, work abilities and social activities (Sherbourne, 1992; McDowell & Newell, 1996; Dijkers, Whiteneck & El-Jaroudi, 2000). This has also been referred to as social adjustment (McDowell & Newell, 1996).

17. The term "Social Function" may refer to a higher-order domain, with measurable sub-domains. For example, the WHO incorporated Social Function into its Disability Assessment Schedule (WHO DAS II), in an effort to develop an assessment tool to operationalize the ICF. A major focus of the ICF classification system and the WHO DAS instrument is the individual's level of participation in society, and three of the six domains assessed by the instrument include components of social functioning (understanding and communication, getting along with people, and participation in society). Henderson and colleagues (Henderson, et al, 1981) outlined six attributes of social relationships: attachment, social integration, opportunity for nurturing, reassurance of personal worth, reliable alliance, and obtaining help and guidance. Other conceptualizations of social functioning are based on interpersonal attributes independent of particular roles, e.g., intimacy, assertiveness, sociability, submissiveness, interpersonal control, etc. (Horowitz, Rosenberg, Baer, et al, 1988).

18. Another conceptualization of social functioning focuses on assessing the quality, reciprocity, and size of an individual's social network (Beels, et al, 1984; Brekke, Long & Kay, 2002). This includes the existence of, and interconnections between, social ties, e.g., marital status, number of relationships, frequency of contacts with friends and relatives, church membership, volunteer participation (Wills, 1985). However, quantitative measures are often not related to well-being.

19. Social Support. Social support refers to feeling cared for and valued as a person, communication with others, and feelings of belonging and trust (McDowell & Newell, 1996; Larson, 1993). In this context, perceived social support is a sub-domain of Social Well-being/Social Health. However, some researchers consider social support to be an extraneous factor that influences health-related quality of life, similar to other factors such as quality of the environment, socioeconomic status, etc.

Note

[1] These five domains have been selected for the initial focus in PROMIS.

References

Ahles, T. A. & Saykin, A. J. (2001). Cognitive effects of standard-dose chemotherapy in patients with cancer. Cancer Investigation, 19 (8), 812-820.

Antoni, M. H., Lehman, J. M., Kilbourn, K. M., Boyers, A. E., Culver, J. L., Alferi, S. M., Yount, S. E., McGregor, B. A., Arena, P. L., Harris, S. D., Price, A. A., & Carver, C. S. (2001). Cognitive-behavioral stress management intervention decreases the prevalence of depression and enhances benefit finding among women under treatment for early-stage breast cancer. Health Psychology, 20 (1), 20-32.

Beels, C. C., Gutwirth, L., Berkely, J., Struening, E. (1984). Measurement of social support in schizophrenia. Schizophr Bull 10:399-411.

Bottomley, A. (1998a). Depression in cancer patients: A literature review. European Journal of Cancer, 7 (3), 181-191.

Bottomley, A. (1998b). Anxiety and the adult cancer patient. European Journal of Cancer Care, 7 (4), 217-224.

Brekke JS, Long JD, Kay DD: The structure and invariance of a model of social functioning in schizophrenia. J Nerv Ment Dis 190:63-72, 2002.

Brezden, C. B., Phillips, K. A., Abdolell, M., Bunston, T., & Tannock, I. F. (2000). Cognitive function in breast cancer patients receiving adjuvant chemotherapy. Journal of Clinical Oncology, 18 (14), 2695-2701.

Chang, H. (1999). Cancer pain management. Medical Clinics of North America, 83 (3), 711-736.

Davis, C. G., Nolen-Hoeksema, S., & Larson, J. (1998). Making sense of loss and benefiting from the experience: Two construals of meaning. Journal of Personality and Social Psychology, 75 (2), 561-574.

Dijkers, M. P., Whiteneck, G., El-Jaroudi, R. (2000). Measures of social outcomes in disability research. Arch Phys Med Rehabil 81:S63-S80.

Ersek, M. & Gerrell, B. R. (1994). Providing relief from cancer pain by assisting in the search for meaning. Journal of Palliative Care, 10 (4), 15-22.

Glaus, A. (1998). Fatigue in patients with cancer: Analysis and assessment. Heidelberg, Germany: Springer-Verlag Berlin.

Haley, S. M., Coster, W. J., & Binda-Sundberg, K. (1994). Measuring physical disablement: The contextual challenge. Physical Therapy, 74 (5), 443-451.

Haley, S. M., McHorney, C. A., & Ware, J. E., Jr. (1994). Evaluation of the MOS SF-36 physical functioning scale (PF-10): I. Unidimensionality and reproducibility of the Rasch item scale. Journal of Clinical Epidemiology, 47 (6), 671-684.

Henderson, S., Byrne, D. G., Duncan-Jones, P. (1981). Neurosis and the Social Environment. Academic Press, San Diego, CA.

Horowitz, L. M., Rosenberg, S. E., Baer, B. A., Ureno, G., Villasenor, V. S. (1988). Inventory of interpersonal problems: Psychometric properties and clinical applications. J Consult Clin Psychol 56:885-892.

John E. Fetzer Institute. (1999). Multidimensional Measurement of Religiousness /Spirituality for Use in Health Research. *A report of a national working group supported by the Fetzer Institute in collaboration with The National Institute on Aging.* Kalamazoo, MI: John E. Fetzer Institute.

Larson, J. S. (1993). The measurement of social well-being. Social Indicators Research, 28, 285-296.

Lawton, M.P., Parmelee, P.A., Katz, I. & Nesselroade, J. (1996). Affective states in normal and depressed older people. *Journal of Gerontology: Psychological Sciences, 51B*, 309-316.

Lawton, VanHaitsma, Klapper, Kleban, Katz & Corn. (1998). *[need ref]*

McDowell, I. and Newell, C. (1996). Measuring Health: A Guide to Rating Scales and Questionnaires. 2 ed. New York, NY: Oxford University Press.

Merskey H, Bogduk N. (eds.) (1994). Classification of Chronic Pain: Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms, *Second Edition*.

Meuser, T., Pietruck, C., Radbruch, L., Stute, P., Lehmann, K., & Grond, S. (2001). Symptoms during cancer pain treatment following WHO-guidelines: A longitudinal follow-up study of symptom prevalence, severity, and etiology. Pain, 93 (3), 247-257.

North American Nursing Diagnosis Association (1996). Nursing diagnoses: Definition and Classification, 1997-1998. Philadelphia, PA: McGraw-Hill.

Peterman, A. H., Fitchett, G., Brady, M. J., Hernandez, L., & Cella, D. (2002). Measuring spiritual well-being in people with cancer: The Functional Assessment of Chronic Illness Therapy--Spiritual Well-being Scale (FACIT-Sp). Annals of Behavioral Medicine, 24 (1), 49-58.

Schag, C. A., Ganz, P. A., Wing, D. S., Sim, M. S., & Lee, J. J. (1994). Quality of life in adult survivors of lung, colon and prostate cancer. Quality of Life Research, 3 (2), 127-141.

Schagen, S. B., van Dam, F. S., Muller, M. J., Boogerd, W., Lindeboom, J., & Bruning, P. F. (1999). Cognitive deficits after postoperative adjuvant chemotherapy for breast carcinoma. Cancer, 85 (3), 640-650.

Sherbourne, C. D. (1992). Social functioning: Social activity limitations measures. In A. L. Stewart & J. E. Ware (eds.), Measuring functional status and well-being: The Medical Outcomes Study Approach (pp. 173-181). Durham, NC: Duke University Press.

Sherbourne, C. D. (1992). Pain measures. In A. L. Stewart & J. E. Ware (eds.), Measuring functional status and well-being: The Medical Outcomes Study Approach (pp. 230-234). Durham, NC: Duke University Press.

Snow…*[need ref]*

Stanton, A. L., Danoff-Burg, S., Sworowski, L. A., Collins, C. A., Branstetter, A. D., Rodriguez-Hanley, A., Kirk, S. B., & Austenfeld, J. L. (2002). Randomized, controlled trial of written emotional expression and benefit finding in breast cancer patients. Journal of Clinical Oncology, 20 (20), 4160-4168.

Stark, D., Kiely, M., Smith, A., Velikova, G., House, A., & Selby, P. (2002). Anxiety disorders in cancer patients: Their nature, associations, and relation to quality of life. Journal of Clinical Oncology, 20 (14), 3137-3148.

Stewart, A. L., & Kamberg, C. (1992). Physical functioning. n A. L. Stewart & J. E. Ware (eds.), Measuring functional status and well-being: The Medical Outcomes Study Approach (pp. 86-142). Durham, NC: Duke University Press.

Stewart, A. L., Hays, R. D., & Ware, J. E. (1992). Health perceptions, energy/fatigue, and health distress measures. In A. L. Stewart & J. E. Ware (eds.), Measuring functional status and well-being: The Medical Outcomes Study Approach (pp. 143-172). Durham, NC: Duke University Press

Taylor, E. J. (1995). Whys and wherefores: Adult patient perspectives of the meaning of cancer. Seminars in Oncology Nursing, 11 (1), 32-40.

Tedeschi, R. G. and Calhoun, L. G (1995). Trauma and Transformation: Growing in the Aftermath of Suffering. Thousand Oaks, CA: Sage.

Tedeschi, R. G. & Calhoun, L. G. (1996). The Post-traumatic Growth Inventory: Measuring the positive legacy of trauma. Journal of Traumatic Stress, 9 (3), 455-471.

Tennen, H. & Affleck, G. (2002). Benefit-finding and benefit-reminding. In C.R.Snyder & S. J. Lopez (Eds.). Handbook of positive psychology (pp. 584-597). London: Oxford University Press.

van't Spijker, A., Trijsburg, R. W., & Duivenvoorden, H. J. (1997). Psychological sequelae of cancer diagnosis: A meta-analytical review of 58 studies after 1980. Psychosomatic Medicine, 59 (3), 280-293.

Watson, D. & Clark, L.A. (1984). Negative affectivity: The disposition to experience aversive emotional states. *Psychological Bulletin,* 96, 465-490.

Watson, D. & Tellegen, A. (1985). Toward a consensual structure of mood. *Psychological Bulletin,* 98, 219-235.

Wills TA. Supportive functions of interpersonal relationships. In: Cohen S, Syme SL (eds). *Social Support and Health*. Orlando, FL: Academic Press, Inc., 1985: 61-82.

Wilson, I. B. & Cleary, P. D. (1995). Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. The Journal of the American Medical Association, 273 (1), 59-65.
