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Time and Place: Tuesdays, 9:00 a.m. – 11:50 a.m., Room. 41-268 CHS
Required readings: Course syllabus (Reader at Quinx Copies, 888-824-1441)
References (useful texts) On Reserve in the Biomedical Library:

Bowling, A. Measuring Health: a review of quality of life instrument scales. 1997 Milton Keynes: Open University press.

Kane RL. Understanding Health Care Outcomes Research. 1997, Aspen Publishers, Inc.

McDowell I, Newell C. Measuring Health, 2nd Edition, 1996, New York: Oxford University Press

Patrick DL, Erickson P. Health Status and Health Policy: Quality Life in Health Care Evaluation and Resource Allocation, 1993, New York: Oxford University Press.

Spilker B (ed). Quality of Life and Pharmacoeconomics in Clinical Trials. 2nd edition, 1996, Lippincott-Raven Publishers, Philadelphia, PA.

Staquet M, Hays R, & Fayers P. (eds.), Quality of Life Assessment in Clinical Trials: Methods and Practice, 1998, Oxford: Oxford University Press.

Stewart AL, Ware JE Jr. Measuring Functioning and Well-being, The Medical Outcomes Study Approach, 1992, Durham and London: Duke University Press

Wilkin D, Hallam L, Doggett MA. Measures of Need and Outcome for Primary Health Care, 1992, New York: Oxford University Press.

Additional readings listed in syllabus:

Because of the expense of publication, the additional readings (references) for each session are not included in the course reader; however, the full citations are provided.

Course objectives:

This course will provide a broad perspective on the conceptualization and development of health-related quality of life and their application to the assessment of outcomes and effectiveness in medical care. The focus is on the links between theory, methods, and practical applications. Representative state-of-the-art methods will be reviewed and placed in the context of current health service research practice. By the end of the course students will be familiar with a variety of approaches to health status assessment and should have a framework and specific skills for determining how and when health status assessment should be incorporated into health services research programs.

Evaluation of Student Performance: Class participation 30%, Term Paper 70%

READING ASSIGNMENTS ARE TO BE DONE BEFORE CLASS

Lecture Schedule

Tuesdays 9:00 - 11:50 am 41-268 CHS

Week	Date	Topic	Lecturer
1	January 8	Importance of Health-related Quality of Life and Introduction to Measures	Litwin
2	January 15	Generic and Targeted Measures of HRQOL	Hays
3	January 22	Meaningful (Minimally Important) Differences and Responsiveness to Change	Hays
4	January 29	Data Quality Assessment: Reliability, Validity, and Acceptability	Litwin
5	February 5	Cross-Cultural Equivalence of Health Measures Applications in Health Services	Kagawa-Singer Hays
6	February 12	Applicability of Generic Measures to Persons with Disabilities: Response Shift and Other Issues	Hays
7	February 19	Breast Cancer; Prostate Cancer	Ganz ; Litwin
8	February 26	Profile and Preference Measures of HRQOL (Utilities)	Hays
9	March 5	Neurological Disease; Eye Disease	Vickrey; Mangione
10	March 12	HIV and AIDS	Cunningham
	March 19	Papers Due	

READING ASSIGNMENTS ARE TO BE DONE BEFORE CLASS

January 8, 2002 (Week 1)**A: Importance of health-related quality of life****B: Introduction to measures**Required Readings

Wilkin, pp. 1-16.

Reiser S. The era of the patient: Using the experience of illness in shaping the missions of health care. JAMA 1993; 269:1012-1017.

Guyatt GH, Feeny DH, Patrick DL. Measuring Health-related Quality of Life. Ann Int Med. 1993;118:622-29.

References:

Bergner M, Bobbitt RA, Kressel S, et al. The Sickness Impact Profile: conceptual formulation and methodology for the development of a health status measure. International Journal of Health Services 1976;6:393-415.

Breslow L. A quantitative approach to the World Health Organization definition of health: Physical, Mental and Social Well-being. Int J Epid 1972; 1:347-355.

Guadagnoli E and McNeil BJ. Outcomes research: Hope for future or the latest rage? Inquiry 1994; 31:14-24.

Patrick DL, Bush JW, Chen MM. Toward an operational definition of health. Journal of health and social behavior 1973; 14:6-23.

Spilker B. Quality of Life and Pharmacoeconomics in Clinical Trials. 1996. 2nd Edition. Lippincott-Raven Publishers, Philadelphia, PA. Introduction pgs 1-10.

Supplement to Medical Care Journal (Special Issue). 2000;38(9).

Ware JE Jr., Brook RH, Davies AR, Lohr KN. Choosing measures of health status for individuals in general populations. Am J Public Health 1981; 620-635.

Ware JE. Conceptualizing disease impact and treatment outcomes. Cancer 1984;53S:2316-2323.

January 15, 2002 (Week 2)**Generic and Targeted Profile Measures of HRQOL**Required Readings

Kane 19-30; 53-65.

Coons SJ, Rao S, Keininger DL, Hays RD. A comparative review of generic quality of life instruments. *Pharmacoeconomics* 2000; 17: 13-35.

References

Patrick D, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Medical care* 1989; 27(3):S217-233.

Stewart AL, Hays RD, Ware JE. The MOS short-form General Health Survey (SF-20). Reliability and validity in a patient population. *Medical Care* 1988;26:724-735.

Stewart AL, Greenfield S, Hays RD, et al. Functional status and well-being of patients with chronic conditions. *JAMA* 1989;262:907-913.

Siu AL, Reuben DB, Hays RD. Hierarchical measures of function in ambulatory geriatrics. *JAGS* 1990; 38: 1113-1119.

Vickery BG, Hays RD, Genovese BJ, Myers LW and Ellison GW. Comparison of a generic to disease-targeted health-related quality-of-life measures for multiple sclerosis. *Journal of Clinical Epidemiology*. 1997; 50(5):557-569.

Ware JE and Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): conceptual framework and item selection. *Medical Care* 1992;30:473-483.

January 22, 2002 (Week 3)**Meaningful (Minimally Important) Differences and Responsiveness to Change**Required Readings

Hays RD, and Woolley JM. The Concept of Clinically Meaningful Difference in Health Related Quality of Life Research: How Meaningful Is It? *Pharmacoeconomics* 2000; 18(5): 419-423.

References

Bindman AB, Keane D, Lurie N. Measuring health changes among severely ill patients: the floor phenomenon. *Medical Care* 1990; 28(12):1142-1152.

Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. *J Chronic Disease* 1987;4(2):171-178.

Hays RD and Hadorn D. Responsiveness to change: An aspect of validity, not a separate dimension. (Editorial) *Quality of Life Research* 1992; 2:73-76.

Kazis LE, Anderson JJ, Meenam RF. Effect sizes for interpreting changes in health status. *Medical Care*. 1989;27:S178-189.

Sprangers M and Aaronson N. The role of health care providers and significant others in evaluating the quality of life of patients with chronic disease: a review. *Clin Epidemiol* 1992; 45 (7): 743-760.

Weinberger M, Oddone EZ, Samsa GP, Landsman PB. Are health-related quality of life measures affected by the mode of administration? *J Clin Epidemiol*. 1996;49:135-140.

January 29, 2002 (Week 4)

Data Quality Assessment: Reliability, Validity, and Acceptability

Required Readings

Dawes RM. Supposed we measured height with rating scales instead of rulers. *App Psy Meas*. 1977;2:267-273.

Kane, pp 219-233.

Hays RD, Anderson RT; Revicki D. Assessing reliability and validity of measurement in clinical trials. In M. Staquet, Hays R, and Fayers P, eds. Quality of Life Assessment in Clinical Trials: Methods and Practice Oxford: Oxford University Press. 1998. Chapter 10, pgs. 169-182.

References

Cunningham WE, Hays RD, Burton TM and Kington RS. Health status measurement and health status differences by age, ethnicity, and gender: Assessment in the Medical Outcomes Study. *Journal of Health Care for the Poor and Underserved*. 2000;11:58-76.

Hays RD, Hayashi T. Beyond internal consistency reliability: Rationale and user's guide for Multitait Analysis Program on the microcomputer. *Behavior Research Methods, In*. 1990; 22(2) 167-175.

Juniper EF, Guyatt GH, Jaeschke R. How to develop and validate a new health-related quality of life instrument. in *Quality of Life and Pharmacoeconomics in Clinical Trials*. 2nd Edition, B. Spilker ed. Lippincott-Raven Publishers, Philadelphia, PA. 1996., Chapter 6, pgs 49-56.

McHorney CA, Ware JE, Razcek AE. The MOS 36-Item Short-Form Health Survey (SF-36): Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical Care* 1993; 31(3): 247-263.

McHorney, C.A., Ware, Jr., J.E., Lu, J.F.R., and Sherbourne, C.D. (1994). The MOS 36-item short-form health survey (SF-36): III. Tests of data quality, scaling assumptions, and validity among diverse patient groups. *Medical Care*, 32(1), 40-66.

Sherbourne, C. D. and L. S. Meredith. 1992. Quality of self-report data: a comparison of older and younger chronically ill patients. *Journal of Gerontology* 47(4):S204-S211.

February 5, 2002 (Week 5)

A: Applications in Health Services

B: Cross-Cultural Equivalence of Health Measures

Required Readings

Part A:

Kane, pp 1-14, and pp 93-123.

Ware JE, Bayliss MS, Rogers WH, et al. Differences in 4-year health outcomes for elderly and poor, chronically ill patients treated in HMO and fee-for-service systems. *JAMA*. 1996;276:1039-1047.

Part B:

Hays RD, Morales LS and Reise SP. Item Response Theory and Health Outcomes Measurement in the 21st Century. *Medical Care* 2000; 38(Suppl):II-28-II-42.

References:

Part A:

Brook RH, Ware JE Jr., Rogers WH, et al. Does free care improve adults' health? Results from a randomized controlled trial. *NEJM* 1983;309:1429-34.

Stewart AL, Greenfield S, Hays RD, et al. Functional status and well-being of patients with chronic conditions. Results from the Medical Outcomes Study. *JAMA*. 1989;262:925-930.

Tarlov AR, Ware JE Jr., Greenfield S, et al. The Medical Outcomes Study. An application of methods for monitoring the results of medical care *JAMA* 1989; 262:925-930.

Wells KB, Stewart A, Hays RD, et al. The functioning and well-being of depressed patients. Results from the Medical Outcomes Study. *JAMA* 1989; 262:914-919.

Part B:

Angel R and Guranaccia PJ. Mind, body, and culture: somatization among Hispanics. *Social Science and Medicine* 1989; 28:1229-1238.

Bucquet D, Condon S, Ritchie K. The French version of the Nottingham Health Profile: A comparison of items weights with those of the source version. *Social Science Medicine* 1990; 7:829-835.

Campos SS and Johnson TM. Cultural Considerations. In Spilker B, (ed) Quality of Life Assessments in Clinical Trials. Raven Press, Ltd., New York, 1990.

Guarnaccia PJ. Anthropological Perspectives: The importance of culture in the assessment of quality of life. In Quality of Life and Pharmacoeconomics in Clinical Trials. 2nd Edition, B. Spilker ed. Lippincott-Raven Publishers, Philadelphia, PA. 1996.

Hendricson WD, Russell J, Prihoda TJ, et al. An approach to developing a valid Spanish language translation of a health-status questionnaire. *Medical Care* 1989; 27:959-966.

Kleinman A, Eisenberg L, Good B. Culture, illness, and care: Clinical lessons from anthropologic and cross-cultural research. *Annals of Internal Medicine* 1978; 88:251-258.

February 12, 2002 (Week 6)**Applicability of Generic Measures to Persons with Disabilities: Response Shift and Other Issues**Required readings:

Andresen EM, Meyers AR. "Health-related quality of life as a disability outcomes measure", *Arch Phys Med Rehabil*, 81(12 supplement 2):S30-S45, 2000.

Meyers AR, Andresen EM. "Enabling our instruments: accommodation, universal design, and assured access to participation in research", *Arch Phys Med Rehabil*, 81(12 supplement 2):S5-S9, 2000.

References:

Andresen EM, Gravitt GW, Aydelotte ME, Podgorski CA. "Limitations of the SF-36 in a sample of nursing home residents", *Age Aging*, 28:562-566, 1999.

Andresen EM, Fouts BS, Romeis JC, Brownson CA. "Performance of health-related quality-of-life instruments in a spinal cord injured population", *Arch Phys Med Rehabil*, 80:877-884, 1999.

February 19, 2002 (Week 8)**A: Breast Cancer****B: Prostate Cancer**Required Readings

Part A:

Ganz PA, Schag CAC, Lee JJ, et al. Breast conservation versus mastectomy. Is there a difference in psychological adjustment or quality of life in the year after surgery? *Cancer* 1992; 69:1729-1738.

Part B:

Litwin MS, Hays RD, Fink A, Ganz PA, Leake B, Leach GE, Brook RH. Quality of life outcomes in men treated for localized prostate cancer. *JAMA* 1995;273:129-135.

References

Part A:

Coates A, GebSKI V, Bishop JF, et al. Improving the quality of life during chemotherapy for advanced breast cancer. *NEJM* 1987; 317:1490-5.

Ganz PA, Hirji K, Sim M-S, et al. Predicting psychosocial risk in patients with breast cancer. *Med Care* 1993; 31:419-431.

Part B:

Litwin MS, Lubeck DP, Henning JM, Carroll PR. Differences in urologist and patient assessments of health-related quality of life in men with prostate cancer: results from the CaPSURE database. *J Urol* 1998; 159:1988-1992.

Litwin MS, Shpall AI, Dorey F, Nguyen TH. Quality of life in men treated for metastatic prostate cancer. *Am J Clin Oncol (CCT)* 1998; 21: 327-332.

February 26, 2002 (Week 7)**Profile and Preference Measures of HRQOL (Utilities)**Required Readings

Kane, pp. 35-48.

Bowling, pp.14-15

Revicki DA, and Kaplan RM. The relationship between psychometric and utility-based approaches to the measurement of HRQOL. 1993; *Quality of Life Research* 2:477-487.

Hays RD, Alonso J, Coons SJ. (1998) Possibilities for summarizing health-related quality of life when using a profile instrument. In M. Staquet, R. Hays & P. Fayers (eds.) Quality of Life Assessment in Clinical Trials: Methods and Practice. Oxford: Oxford University Press. pgs. 143-153.

References

Part A:

Feeny G, Torrance GW, Furlong WJ. 1996. Health Utilities Index. In *Quality of Life and Pharmacoeconomics in Clinical Trials*. Spilker B, ed. Philadelphia: Lippincott-Raven Publishers; Chapter 26, pgs 239-252

Hornberger JC, Redelmeier DA, Petersen J. Variability among methods to assess patients' well-being and consequent effect on a cost-effectiveness analysis. *J Clin Epidemiol* 1992; 45: 505-512.

Kaplan RM. Health Outcome Models for Policy Analysis. *Health Psychology* 1989; 8:723-735.

Kind P. 1996. The EuroQol Instrument: An Index of Health-Related Quality of Life. In *Quality of Life and Pharmacoeconomics in Clinical Trials*. Spilker B, ed. Philadelphia: Lippincott-Raven Publishers, Chapter 22, pgs. 191-202.

McNeil BJ, Weichselbaum R, Pauker SG. Speech and Survival: Tradeoffs between quality and quantity of life in laryngeal cancer. *NEJM* 1981; 305:982-87.

Translating functional health and well-being: International quality of life assessment (IQOLA) project studies of the SF-36 health survey. *Journal of Clinical Epidemiology*. Gandek B and Ware, eds. 1998.

Tsevat, J, Cook EF, Green ML, et al. Health values of the seriously ill. SUPPORT investigators. *Annals of Internal Medicine*, 1995;122(7):514-20.

March 5, 2002 (Week 9)**A: Neurological Disease****B: Eye Disease**Required Readings

Part A:

Vickrey BG, Hays RD, Engel J, Spritzer K, Rogers WH, Rausch R, Graber J, Brook RH. Outcome assessment for epilepsy surgery: The impact of measuring health-related quality of life. *Ann Neurol* 1995;37:158-166.

Part B:

Mangione CM, Lee PP, Gutierrez PR, Spritzer K, Berry S, Hays RD. Development, reliability, and validity of the 25-item National Eye Institute Visual Function Questionnaire (VFQ-25). *Archives of Ophthalmology*. In press.

References:

Part A:

Deyo RA; Diehr P; Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. *Controlled Clinical Trials*, 1991 Aug, 12(4 Suppl):142S-158S.

Sneeuw KCA, Aaronson NK, de Haan RJ, Limburg M. Assessing quality of life after stroke: The value and limitations of proxy ratings. *Stroke* 1997;28:1541-1549.

Vickrey BG, Hays RD, Graber j, et al. A health-related quality of life instrument for patients evaluated for epilepsy surgery. *Medical Care*, 1992;30:299-319.

Part A:

Part B:

Mangione CM, et al. Improved visual function and attenuation of declines in health-related quality of life after cataract extraction. *Archives of ophthalmology* 1994 ;112:1419-1425.

Scott IU, Schein OD, West S, et. al. Functional status and quality of life measurement among ophthalmic patients. *Arch. Ophthalmol*, 1994 ; 112: 329-335.

March 12, 2002 (Week 10)**HIV and AIDS**Required Readings

Part A.

Cunningham WE, Hays RD, Ettl MK, Dixon WJ, Beck CK, Shapiro MF. The prospective effect of access to medical care on health-related quality of life outcomes in patients with symptomatic HIV disease. *Medical Care*. 1998;36(3):295-306.

Hays RD, Cunningham WE, Sherbourne CD, et al. Health-related quality of life in patients with Human Immunodeficiency virus Infection in the United States: Results from the HIV Costs and Services Utilization Study. *American Journal of Medicine* 2000;108:714-722.

References

Part A:

Cleary PD, Fowler FJ, Weissman J, et al. Health-related quality of life in persons with acquired immune deficiency syndrome. *Med. Care* 1993; 31:569-580.

Cunningham WE, Bozzette SA, Hays RD, Kanouse DE, Shapiro MF. Comparison of health-related quality of life in clinical trial and non-clinical trial HIV infected cohorts. *Medical Care*, April 1987.

Schag, Ganz, Kahn, and Petersen. Assessing the needs and quality of life of patients with HIV infection: development of the HIV overview of Problems-Evaluation System (HOPES). *Qual Life Res*. 1992 ; 1:397-413

Wu AW, Hays RD Kelly S Malitz KF Bozzette SA. Applications of the medical outcomes study health-related quality of life measures in HIV/AIDS. *Quality of Life Research*. 1997; 6:531-554.

March 19, 2002 Papers due

Proposal abstract

Due February 15 by 4:00pm

(by email attachment to mlitwin@ucla.edu)

one page maximum

The purpose of this assignment is to begin planning your final proposal. The essential elements are as follows:

1. Objectives or Purpose, including a brief rationale (1-2 sentences)
2. Methods (can be broken down in different ways, here's one useful suggestion)
 - a. Design (1-2 sentences)
 - b. Setting (1 sentence)
 - c. Sample or patients (1 sentence)
 - d. Measures (be as specific as you can, especially regarding dimensions of HRQOL, even though you may change later); be sure to mention other dependent and independent variables (a few short lists)
 - e. Analysis plan for evaluating the performance (i.e., reliability and validity) of your measures in this particular application. The most important thing is to describe how your analysis will address your original objectives. What comparisons will be made, and how will you make them (the general statistical approach). What will you do to minimize bias in your comparisons? (2-5 sentences)
3. Significance
What will your study contribute to the field, and how might it influence health care providers, managers in health care organizations, policy-makers, and/or researchers? This should relate to your objectives, and especially your analysis.

Proposal

Due March by 4:00pm

(by email attachment to mlitwin@ucla.edu)

Email acknowledgement of receipt will be sent to you; if you don't receive acknowledgement, assume that your submission was not received.

Purpose:

To identify a health services or clinical research problem whose evaluation would be enhanced by the use of HRQOL outcome measures. You should address the following questions:

- a. How will HRQOL measurements contribute to the evaluation of effectiveness or outcomes in your chosen application?
- b. How is HRQOL conceptualized?
- c. How is HRQOL operationalized?
- d. How is HRQOL analyzed in your study?
- e. What other measures of health are relevant to your proposed study?
- f. What would (or could) your proposed evaluation contribute to the field of effectiveness or outcomes research?

Requirements:

- a. Paper should be 12-20 pages (excluding references) and double spaced, with 1" margins, 12-point Times Roman.
- b. Content should include:
 - 1) Purpose: research question(s) or objective(s) to be addressed
 - 2) Rationale: why is addressing the question important; background on what is known in the literature
 - 3) Design: (i.e., prospective cohort, quasi-experiment, randomized intervention etc.)
 - 4) A brief description of the setting for the study
 - 5) A description (list) of the main independent variable, other independent variables (control variables), the HRQOL variables, and other outcome variables, including some rationale for the selection of these variables (consideration of what is practical is also important)
- c. A description of the study subjects or sample (including approximate sample sizes)
- d. The specific proposed HRQOL instrument(s) including a description of existing evidence of reliability and validity, and a description of normative or comparative data available in the literature
- e. The methods for collecting the data or implementing the study and evaluating the reliability and validity of the HRQOL measures in your study sample
- f. The specific approach that will be used to analyze the HRQOL data in order to address the research question(s)
- g. Discussion of potential implications and limitations of the study.

In your proposal, include the name and source (reference) of the instrument(s), a table summarizing the characteristics of the instruments considered, as well as the one selected. The text should describe the rationale for the final instrument(s) selected in terms of the purpose and study population characteristics. The feedback provided on your proposal abstracts is intended to jump start your final paper proposal. You may obtain additional optional email feedback or make appointments by email with either instructor to discuss your proposed topics.