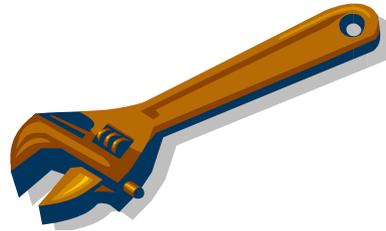


Another Perspective on PRO Content in Clinical Practice



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Disclaimer and Recommendation

- When all else fails, lower your standards
- I have no connection or interest in any deodorant producers or in Pfizer.

PEST - BUDA

Albert Wu







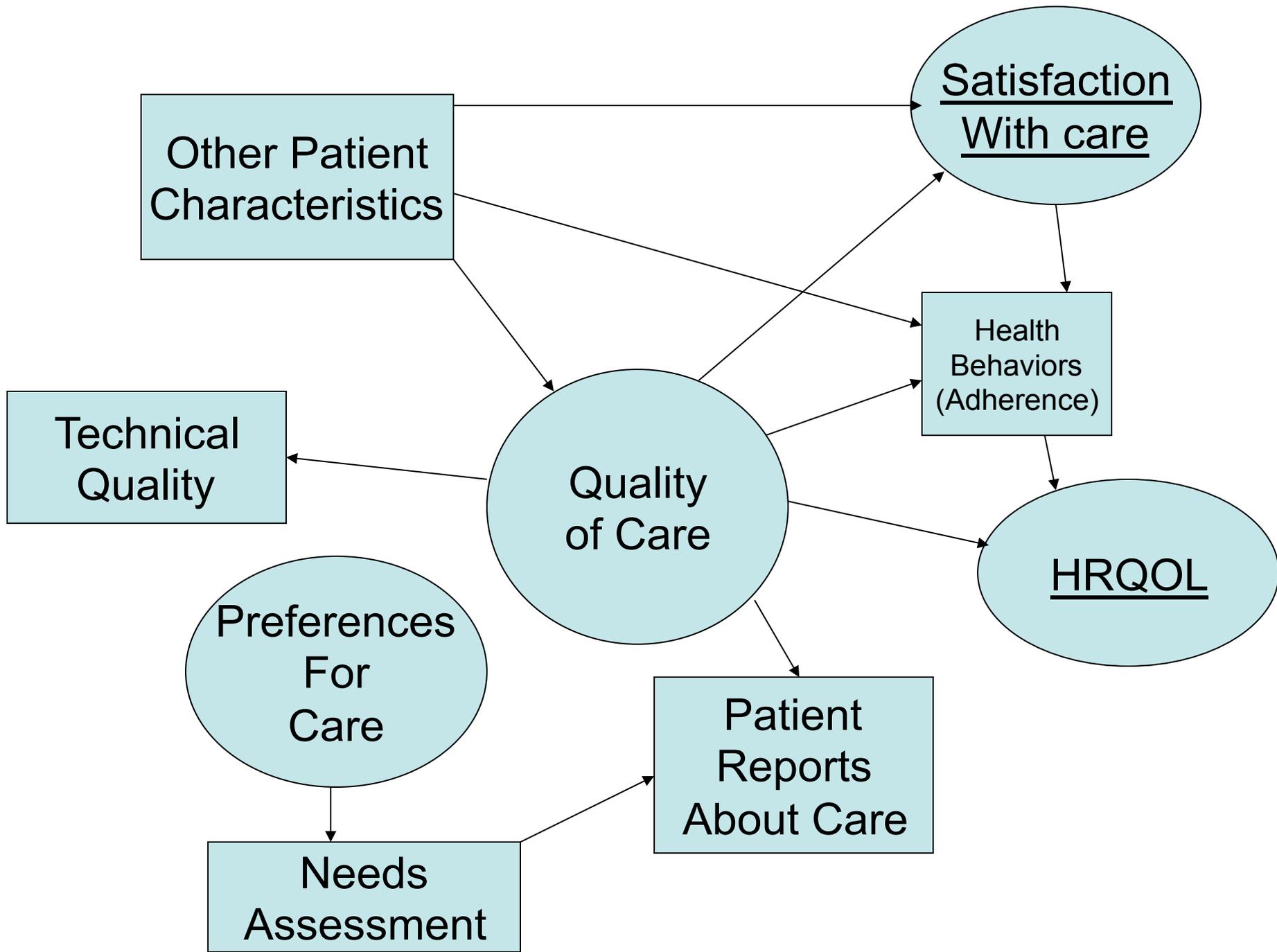
Patient-Reported Outcomes

“Any report coming from patients about a health condition and its treatment”

(U.S. FDA, 2006)

Including

- Health-related quality of life (HRQOL)
- Satisfaction with treatment
- Adherence to treatment
- *Patient reports about care*
- *Needs assessment*



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Does Ambulatory Process of Care Predict Health-Related Quality of Life Outcomes for Patients with Chronic Disease?

Katherine L. Kahn, Diana M. Tisnado, John L. Adams, Honghu Liu, Wen-Pin Chen, Fang Ashlee Hu, Carol M. Mangione, Ronald D. Hays, and Cheryl L. Damberg

Objective. The validity of quality of care measurement has important implications for practicing clinicians, their patients, and all involved with health care delivery. We used empirical data from managed care patients enrolled in west coast physician organizations to test the hypothesis that observed changes in health-related quality of life across a 2.5-year window reflecting process of care.

Data Sources/Study Setting. Patient self-report data as well as clinically detailed medical record review regarding 963 patients with chronic disease associated with managed care from three west coast states.

Study Design. Prospective cohort study of change in health-related quality of life scores across 30 months as measured by change in SF-12 physical component scores.

Data Collection/Extraction Methods. Patient self-report and medical record abstraction.

Principal Findings. We found a positive relationship between better process scores and higher burden of illness ($p < .05$). After adjustment for burden of illness, using an instrumental variables approach revealed better process is associated with smaller declines in SF-12 scores across a 30-month observation window ($p = .014$). The application of the best quartile of process of care to patients currently receiving poor process

6.00 x 9.00 in

63 (1 of 21)

Patient Reported Measures

- Outcomes
 - HRQOL
 - Satisfaction
- Mediators
 - *Health behaviors (adherence)*
- *Health Care*
 - Reports about care (e.g., communication)
 - Needs assessment (preferences for care)

Patient-Centered Care

In order to be “respectful and responsive to individual patient preferences, needs, and values” (IOM, 2001, p. 6) health care providers need to know what is important to patients (needs assessment)

The extent to which providers meet the needs of their patients is revealed by patient reports and satisfaction with care

Core PRO Domains

- HRQOL
 - Functioning
 - Physical functioning
 - Social/role participation
 - Symptoms
 - Pain, fatigue, etc.
 - Energy/fatigue
 - Well-being
 - Emotional distress
 - General health perceptions
- Global Satisfaction with Care

Other Important PRMs

- Patient health behaviors
 - Taking medicines, exercising, not smoking
- Patient evaluations of care
 - Communication, coordination of care, getting needed care
- Patient preferences for care
 - Needs assessment
- Other patient characteristics
 - Values and Beliefs (e.g., desire to participate in care)
 - Social support

IDEAL model of patient care

- Identify problem
- Decide on appropriate action
- Explain it to patient
- Action
- Learn about the effects (outcomes)

Potential PRMs at each step

- Identify problem
 - Baseline HRQOL
- Decide on appropriate action
 - Needs assessment
 - Knowledge, skills, resource guides, etc.)
- Explain it to patient
 - Patient report about communication
- Action
 - Patient adherence
- Learn about the effects
 - Satisfaction and change in HRQOL

Content Flexibility

- Need to have a comprehensive arsenal of items tapping the array of PRMs
 - Combination of Generic and Condition-Targeted HRQOL
 - Variety of health Behaviors (medication taking, exercise, not smoking, etc.)
 - Multiple domains of health care assessed by patient
- Tailored to the patient

65 year old woman with arthritis

- * Generic HRQOL measure indicates that compared to similar patients this woman
 - has been anxious and worried during last 7 days
- Targeted emotional distress measure reveals the woman
 - has well controlled arthritis pain
- * Targeted symptom measure shows she has had
 - GI symptoms (abdominal pain) during the last 7 days

Office visit continued

- Needs assessment shows
 - She is most interested in relief of her GI symptoms and knowing about alternative medicines for her pain
- The doctor reduces Celebrex from daily to every other day, telling the woman this should take care of her GI symptoms.
- The doctor tells the patient to call if her symptoms persist.
- A week later the lady is called at home by a survey interviewer hired by the lady's medical group to assess her perceptions of the doctor's care.
- The lady thought the caller was trying to sale her something so she hung up the phone.

Office Visit Continued

- The survey vendor calls back and reassures the lady and then assesses her perceptions of the doctor's communication during the last visit.
- The lady reports that the doctor explained things pretty well, but didn't address all of her concerns. When probed she says the doctor didn't say anything about alternative medicines.
- The lady reports being *somewhat satisfied* with the visit.

Office Visit

- Shortly after the call, the lady decides to stop taking Celebrex and her arthritis pain returns.
- She receives an SF-36 by mail and compared to the last time she completed it her:
 - pain, social functioning, role functioning and emotional well-being scores are worse.
- The SF-36 scores are transmitted to the doctor's office, prompting a staff member to call her and schedule a follow-up visit.
- She lives happily ever after.

PRMS (summary)

- Help to target care (needs assessment)
- Evaluate care (patient reports about care)
- Assess patient health behaviors such as adherence to provider recommendations
- Indicate whether care meets the needs of the patient (satisfaction with care)
- Tell if care improved the patient's functioning and well-being (health-related quality of life)



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Questions?

- When, where and how should PRMs be collected and how does that vary by health care setting?
- What approaches should be used to ensure that appropriate content is reflected in PRMs? How do we know that we have the right content?

- What norm or comparison values are most appropriate for monitoring PROs over time in clinical practice?