

# **Transferring patient-reported outcomes from clinical research to clinical practice: Possibilities and challenges**

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## **HRQL in clinical research vs. practice**

- HRQL outcomes are now widely accepted as relevant, if not essential to the clinical trial process
- In clinical practice, HRQL issues also play a role, albeit informally, in decision-making
- However.....

## Statement of the problem

- Functional and psychosocial health problems experienced by patients are often not discussed, and thus remain undetected and under- or untreated:

- Fatigue
- Depression
- Role functioning
- Sexuality
- Social isolation
- Cognitive decline

This holds true for both primary and specialty care

## Communication about specific HRQL topics

(N = 240 oncology consultations with patients receiving palliative chemo)

	yes	physician initiated	physician asked open question
daily activities	64%	73%	40%
pain	72%	52%	28%
fatigue	46%	32%	7%
emotional	35%	21%	17%

## Example of closed questions

Doctor: “So, at home you’re able to do everything you want?”

Patient: “Well, no, not really. I do what I can manage.”

Doctor: “Mmhhh. Did you have problems with a sore mouth this time as well?”

## Let’s change the subject

- Patient: “Well, I think it’s a side-effect of the chemotherapy; that’s probably why I’m physically and mentally exhausted?”
- Doctor: “Yes, probably, so, how is your pain?”

## Who cares?

### Patients' preferences for discussing HRQL issues (%)

	No	Yes, if the doctor initiates	Yes
Daily activities	10.4	25.4	62.1
Symptoms	1.3	9.2	87.9
Emotional issues	6.3	26.1	66.9

- No statistically significant differences in communication as a function of preferences

## Roots of the problem – The doc

- Lack of time (“opening a can of worms”)
- Lack of interest/low priority
- Lack of training and/or skills in eliciting problems
- Perceived paucity of effective interventions (e.g., fatigue). “Don’t diagnose what you can’t treat.”

## Roots of the problem – The patient

- Too many problems to discuss – comorbidity
- Belief that problems come with the territory (particularly if chronic)
- Reluctance to “burden” doc with problems
- Limited “vocabulary of distress” (e.g., children, poorly educated, ethnic minorities with language issues, cognitively challenged patients)
- Culturally-determined willingness to raise issues and express emotions

## Extremes of expressiveness

Southern Europe



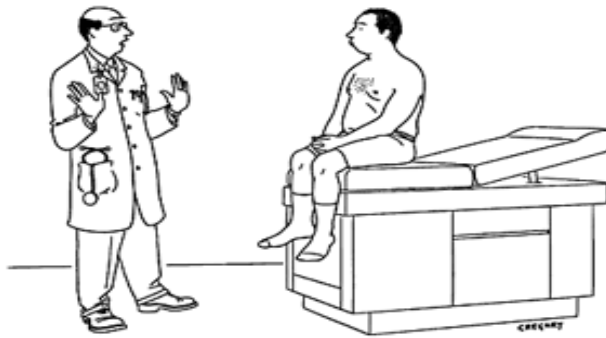
Northern Europe



## Roots of the problem – The system

- Concerns about reimbursement for staff time and effort
- Concerns with liability (responsibility to act on information)
- Absence of well-coordinated, multidisciplinary care
- Limited institutional mission statement (“center of excellence” = high cure rate)

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*"Whoa—way too much information!"*

## Conspiracy of silence + doorknob phenomenon



## Possible solutions

- Communication skills training
- Patient empowerment initiatives
- Development of effective medical and psychosocial interventions
- Introduction of standardized, routine assessment of patients' functional health and symptom experience

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- **Introduction of standardized, routine assessment of patients' functional health and symptom experience**

## Making the problem go away (a first step)

- Ensure that key physical, functional and psychosocial problems are assessed and reported to clinicians, nurses, and other caregivers on a regular basis

### How?

- By means of routine, standardized assessments using patient self-report questionnaires that are:
  - brief and simple to complete
  - summarized in a simple, easily digestible format
  - easy to interpret

## Patient-reported outcomes in clinical practice

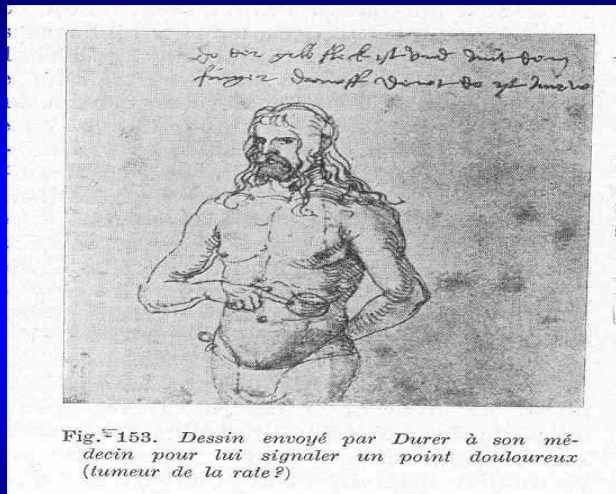


Fig. 153. Dessin envoyé par Durer à son médecin pour lui signaler un point douloureux (tumeur de la rate?)

Albrecht Durer, 1471-1528

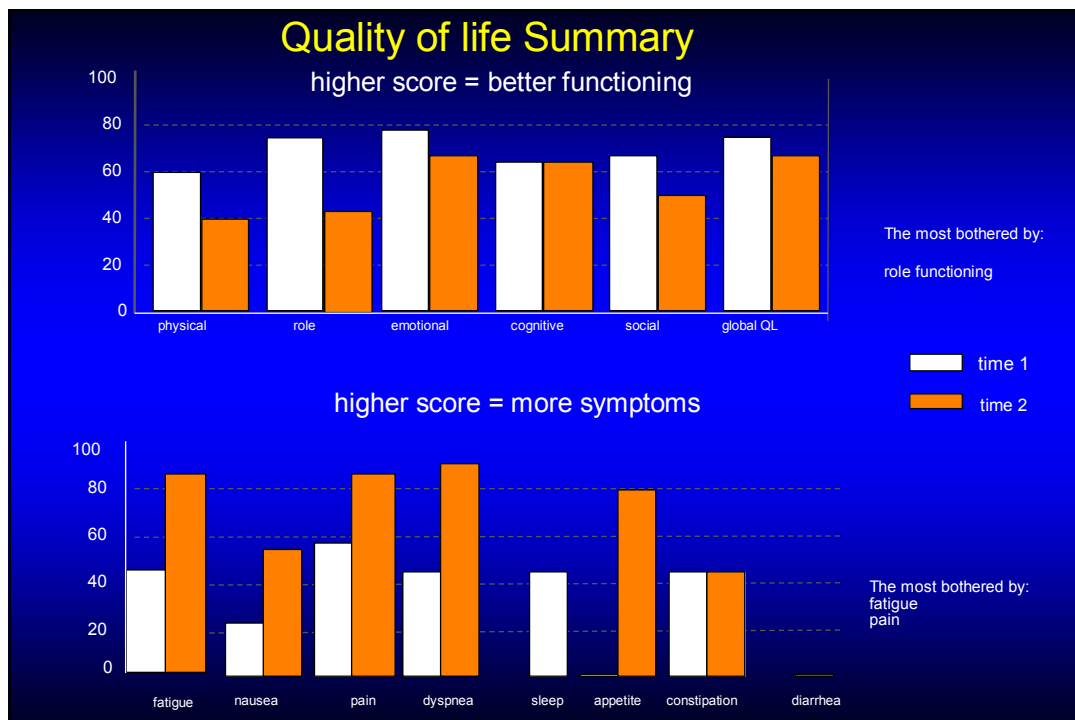
German renaissance artist and mathematician

Brodman K. et al. The Cornell Medical Index: An adjunct to medical interview JAMA 1949; 140:531-4

- 195 item self-administered questionnaire on physical and psychological symptoms and medical history
- completed prior to office visit in 10-30 minutes; high compliance rates
- Elicited information not found in medical records

## Clinic-based HRQL data capture

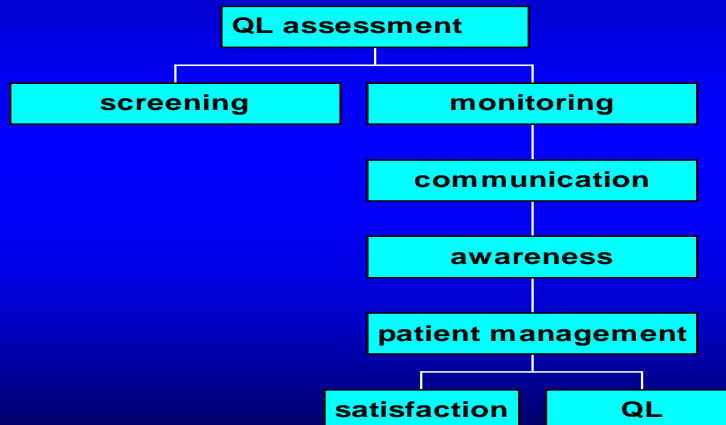




## HRQL assessment in daily clinical practice: Feasibility

- Self-administered questionnaires can be completed quickly in office-based practice
- Computer-assisted (e.g., touchscreen) administration is acceptable and efficient
- No evidence that collection of standardized QL data interferes with normal clinic routine or lengthens average visit time

## What can you expect to achieve? A cascade of effects



## HRQL assessment in clinical practice

### 16 controlled studies published 1987-2004

(Taenzer et al. 2000; McLachlan et al. 2001; Detmar et al. 2002; Velikova et al. 2003)

- communication +
- awareness +
- patient management +/-
- satisfaction +/-
- HRQL +/-

## HRQL assessment in daily clinical practice Systematic review of RCT's

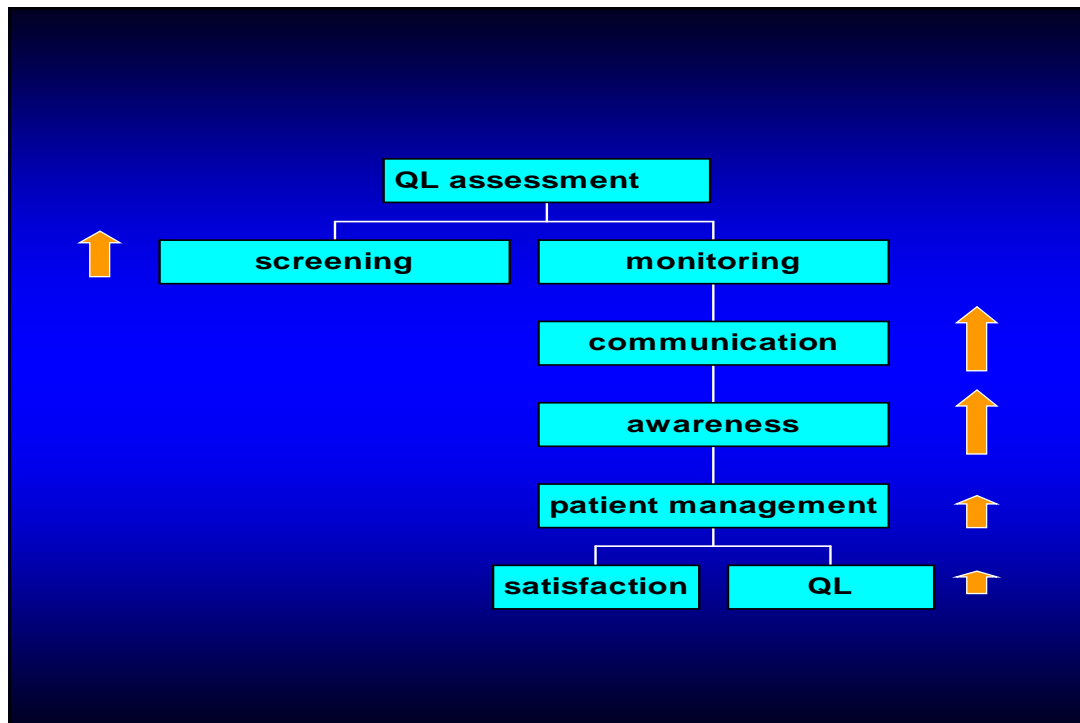
(Valderas JM et al. Qual Life Res 2008; 17:179-93)

- 28 RCT's published between 1978-2007
- 19 in primary care; 9 in specialist care
- 54% of interventions were single point-in-time PRO assessments only
- 50% assessed psychiatric problems only
- 70% provided feedback to clinicians in real time

## PRO assessment in daily clinical practice Systematic review of RCT's

(Valderas JM et al. Qual Life Res 2008; 17:179-93)

	Studies (n)	Significant results (%)
Process of care		
• Advice, education, counseling	7	43%
• Target diagnoses and notations	14	50%
• Referrals, consultations	11	18%
Outcomes of care		
• General functional status	6	50%
• Satisfaction with care	12	42%
• Physician-rated utility of intervention	6	66% (28-97%)



## Possible strategies to increase impact on patient management and health outcomes

- Get more concrete – Supplement or replace generic HRQL measures with condition-specific measures
- Combine quantitative, questionnaire-based HRQL data with qualitative, interview-based information
- Link HRQL information to treatment guidelines and clinical pathways

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## The use of HRQL assessments in daily clinical oncology nursing practice:

### A community hospital-based intervention study

Doranne L. Hilarius, Paul Kloeg, Chad M. Gundy, Neil K. Aaronson

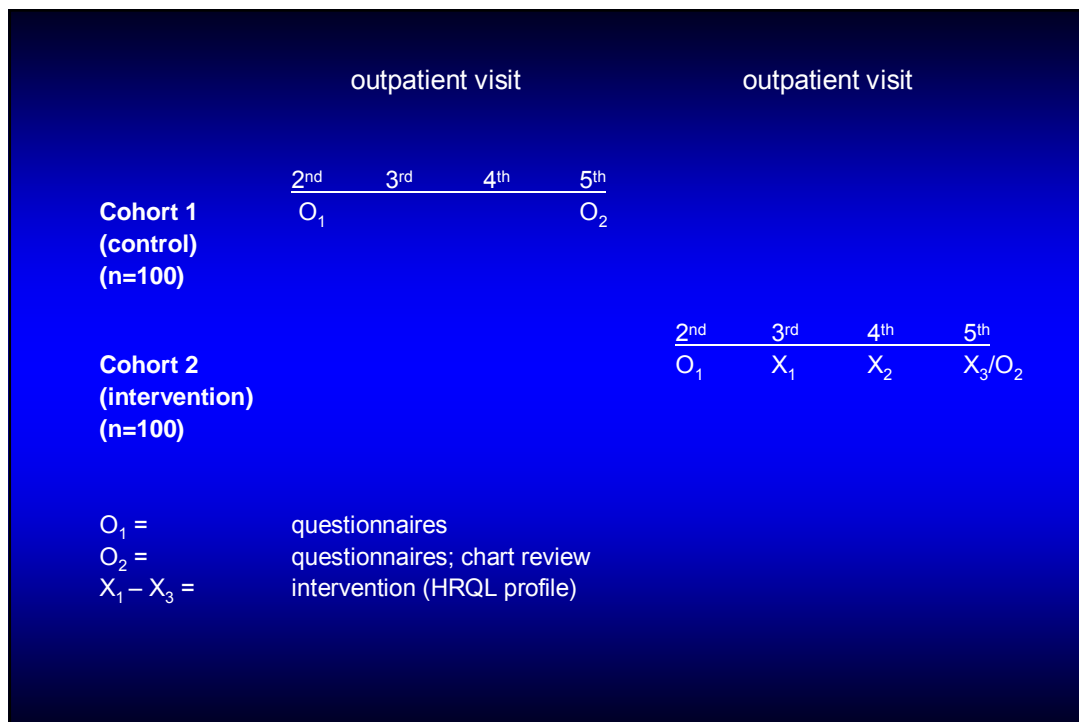
*Cancer* (in press)

## Study participants

- 219 cancer patients receiving adjuvant or palliative chemotherapy in the outpatient clinic of a large community hospital in North Holland.
- 11 oncology nurses responsible for the delivery of the chemotherapy

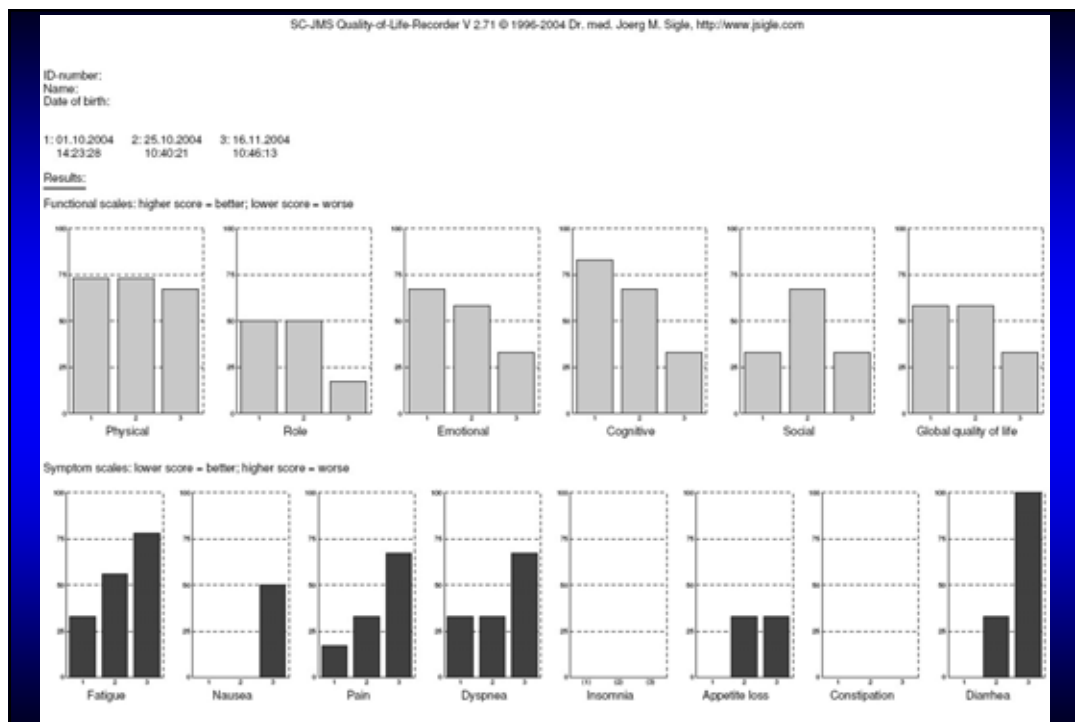
## Research design

- Classical randomized study was contra-indicated due to risk of contamination effect
- Chose for **sequential cohort design**
  - 1st cohort of 100 patients = usual care control group
  - 2nd cohort of 100 patients = intervention group



## Intervention

- Completion via computer touch screen of:
  - a “core” HRQL questionnaire (the EORTC QLQ-C30)
  - EORTC HRQL modules for breast, colon and lung cancer
- Graphic summary provided to both patient and nurse immediately before encounter
- Cumulative scores presented at each subsequent visit



## Key results

- Significant increase in:
  - frequency with which HRQL issues were discussed (both generic and condition-specific)
  - nurses' awareness of patients' HRQL
  - number of HRQL-related notations in the medical records
  - HRQL-related counseling behavior
- No significant effect on patients' satisfaction or HRQL over time

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Assessment is not enough: A randomized controlled trial of the effects of HRQL assessment on quality of life and satisfaction in oncology clinical practice

Rosenbloom SK, Victorson DE, Hahn E, Peterman AH, Cella D

*Psycho-oncology 2007; 16:1069-79*

## Study participants

- 213 cancer patients receiving palliative chemotherapy for breast, lung or colorectal cancer
- oncology nurses responsible for the delivery of the chemotherapy (*n* not reported)

## Study design and intervention

- 3-arm randomized clinical trial
  - Completion of FACT-G, with summary given to treating nurse prior to clinical encounter
  - Completion of FACT-G + personal interview, with summary given to treating nurse
  - Usual care control group

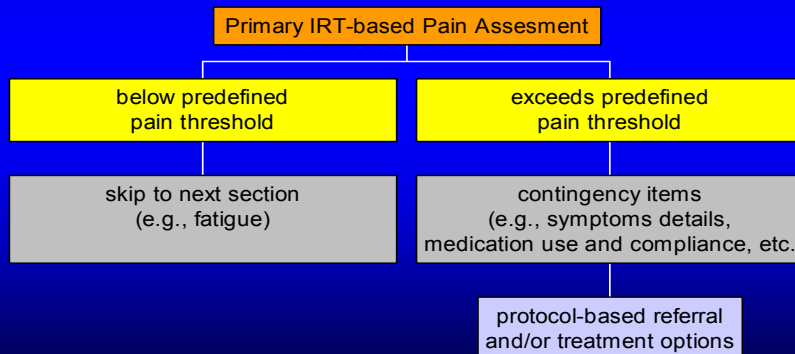
## Key results

- Nurse-patient communication and nurses' awareness not assessed
- No significant impact on:
  - Patient management
  - Patient satisfaction over time
  - Patient HRQL over time

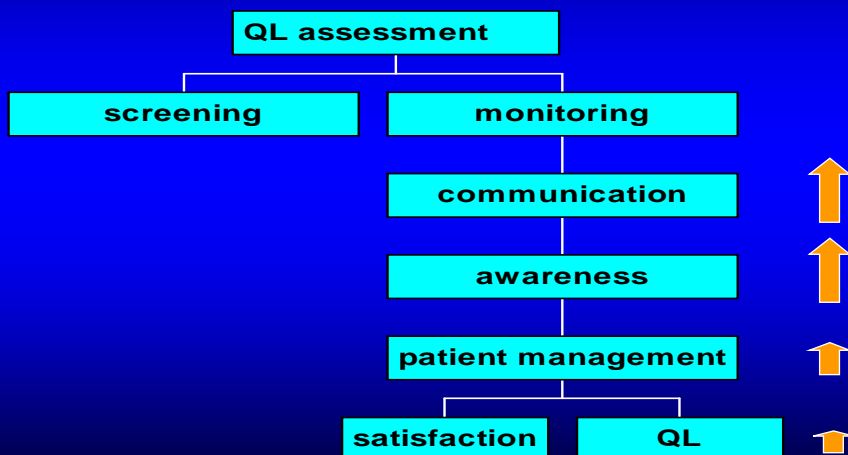
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# CAT + Contingency approach to HRQL assessment in daily clinical practice



## Conclusions: Results to date



## Future directions

- Develop more efficient questionnaires using computer adaptive (dynamic) testing
- Identify critical thresholds for symptoms and functional impairment that trigger more specific probes
- Link clinically relevant HRQL outcomes to treatment guidelines
- Develop tailored health education feedback to patients based on their HRQL responses (clinical pathways)

“It is likely that in the early years of the 21st century, the completion of a quality of life questionnaire at a patient visit will be as routine as the taking of vital signs.”

*Ganz PA *Oncology* 1995; 9:61-5*

“In theory there is no difference between theory and practice. In practice there is.”

Yogi Berra

“The future ain't what it used to be”

Casey Stengel

"The best way to predict the future is to invent it."

Alan Kay