

**10th International Cochrane Colloquium
Stavanger , Norway**



Pre-Colloquium Workshop:

**An Introductory Programme on Health-Related
Quality of Life for Reviewers of Clinical Trials**

Wednesday 31st July, 2002

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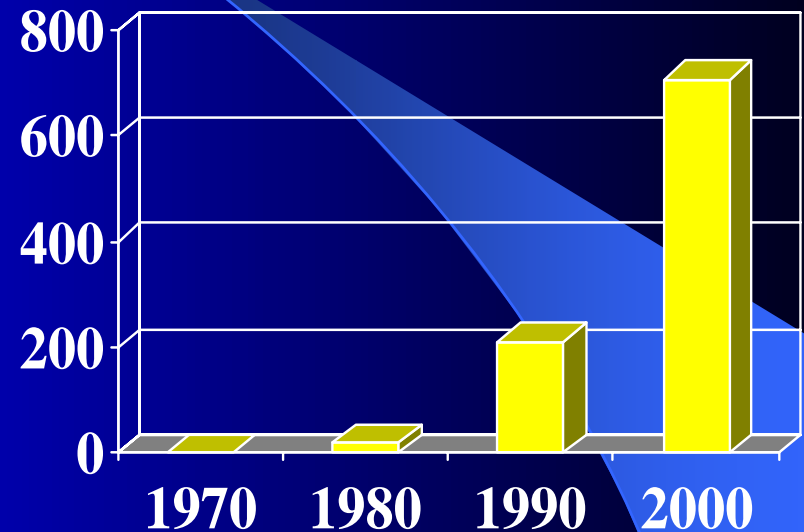
Evolution of HRQL assessment in Clinical Trials since 1966

★ Literature search (Medline)

“Quality of Life” Matched with
“Clinical Trials”:

Results: number of references

- ★ 1966 to 1970: 0
- ★ 1966 to 1980: 20
- ★ 1966 to 1990: 210
- ★ 1966 to 2000: 708



**Considerable increase
of HRQL assessment
in Clinical Trials**

Cochrane Health-Related Quality of Life Methods Group

Objective:

- To advise Cochrane reviewers about when and how to incorporate HRQL data into systematic reviews of health care interventions

- **Convenors: Catherine Acquadro, MD**

 - Prof. Dick Joyce, PhD, FBPoS**

 - Prof. Donald L. Patrick, MSPH, PhD**

- **Coordinator: Lucile Lapalus (llapalus@mapi.fr)**

- **Active members : 37 from 12 countries**

Objectives

- To help reviewers of clinical trials to acquire the skills needed to assess HRQL outcomes included in regulatory files and publications
- To facilitate decisions made by Health Authorities and health care providers

Historical Background of the Workmats Method

- 1st version developed by Donald L. Patrick in 1996
- Adaptation and development for a Programme on Health-Related Quality of Life for Reviewers of Clinical Trials in 2002, collaboration between
 - **Mapi Research Institute**, Lyon, France:
Juliette Longin, PhD, Project Manager, Research and Education Department
 - **Cochrane HRQL Methods Group**: Olivier Chassany, MD, PhD and Donald L. Patrick, MSPH, PhD

Presentation of the Workmats (1/2)

- **Workmats :**

- large worksheets
- contain concise information: background
- present various assignments

- **Workbook :**

- reference source
- additional information on HRQL

Presentation of the Workmats (2/2)

- **Interactive learning method**
- **Participants**
 - Small group discussions and interactions
 - To understand the new information
 - To complete the assignments through group discussions (writing material)
 - Group answers have to be discussed by all the groups to reach a consensus

Content

Workmats	Content
1	How do disease and treatment affect Health-Related Quality of Life (HRQL)?
2	Deciding which domains to include in a HRQL instrument
3	How is a new HRQL questionnaire developed? 1 st Steps
4	Choosing an appropriate existing HRQL measure
5	Analysis of HRQL data
6	Presentation and interpretation of HRQL outcomes included in clinical trials?

WORKMAT 1

**How do disease and treatment affect
HRQL?**

WORKMAT 1 : 11:00-11:30

- **Learning objectives**

- **To identify the impact of health conditions and treatment on HRQL**
- **To distinguish the different ways diseases and treatment can affect HRQL**
- **To create an awareness that treatments can affect HRQL**

WORKMAT 1

- Learning points

- Diseases and treatments can affect a person's quality of life in different ways
- HRQL is multi-dimensional and subjective

WORKMAT 2

**Deciding which domains to include
in HRQL instrument**

WORKMAT 2 : (12:00-12:30)

- Learning objective

- To define the relevant HRQL domains depending on the conditions studied

WORKMAT 2

- Learning points

- The relative burden of disease and treatment on population can be measured through HRQL domains
- At a minimum, HRQL consists of physical, psychological, and social domains
- The patient plays an important part in the questionnaire development

Lunch

13:00 – 13:30

WORKMAT 3

**How is a new HRQL questionnaire
developed? 1st steps**

WORKMAT 3 : (13:30-14:30)

- Learning objective

- To describe the process of HRQL instrument development

WORKMAT 3

- Learning points

- Instrument development is a scientific rigorous process
- No single *right* way to develop an instrument although best practices available for steps in the process
- The instrument should have empirical evidence of validity

WORKMAT 4

**Choosing an appropriate existing
HRQL measure**

WORKMAT 4 : (14:30-15:00)

- **Learning objectives**

- To explore the process for selecting appropriate health status instrument for use in specific clinical trial scenario
- To examine the trade-offs in the selection process
- To review the criteria necessary for appropriately evaluating an HRQL instrument
- To identify and evaluate established questionnaires for use in specific patient group

WORKMAT 4

- Learning points

- The first step is to ask yourself Key Questions
- The choice of domains and the selection of an HRQL instrument is influenced by severity and nature of the disease and the expected benefits and side effects of treatment