

Perceptorship of Rehabilitation in MS
Valens CH, September 2013

**PATIENT-REPORTED OUTCOMES
AND SHARED DECISIONS
IN REHABILITATION**
Alessandra Solari
Neuroepidemiology Unit



1. A paradigm shift: PROs

A PRO is the measurement of any aspect of a patient's health status **that comes directly from the patient** (i.e., without the interpretation of patient's responses by a physician or anyone else) *Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims*

PROs include assessment of the following:

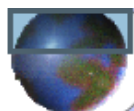
- Symptoms** (impairments)
- Functioning** (activity limitation/disability)
- Participation restriction**
- HRQOL**

1. A paradigm shift: PROs

APPLICATIONS OF PRO MEASURES:

- Individual patient care monitoring
- Population surveys
- RCTs
- Development of clinical and public policy guidelines
- Economic analyses

1. A paradigm shift: PROs



Why Use Patient-Reported Outcome Instruments in Medical Product Development?

FDA Guidance

PRO instruments are included in clinical trials for new medical products because :

1 Some Treatment Effects Are Known Only to the Patient

For example, **pain** intensity and pain relief are the fundamental measures used in the development of analgesic products. There are no observable or physical measures for these concepts.

2 Patients Provide a Unique Perspective on Treatment Effectiveness

... improvements in clinical measures of a condition may not necessarily correspond to improvements in how the patient functions or feels.

3 Formal Assessment May Be More Reliable Than Informal Interview

Self-completed questionnaires capture directly the patient's perceived response to treatment, without a third party's interpretation...

FDA Guidance, P3-4, L103-120

1. A paradigm shift: PROs

Rothwell PM, et al. BMJ 1997; 314:1580-3

Physician's
perspective:
DISEASE

Patient's
perspective:
ILLNESS

agreement?

1. A paradigm shift: PROs

Review

MULTIPLE
SCLEROSIS
JOURNAL | MSJ

The effects of clinical interventions on health-related quality of life in multiple sclerosis: a meta-analysis

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Ayse Kuspinar¹, Ana Maria Rodriguez¹ and Nancy E Mayo^{1,2}

39 RCTs (DMD excluded) up to 2011
13 (33%) HRQOL as primary or co-primary endpoint
6 intervention categories

Recommended domain-based method. Effect size (ES) was used to measure the effect of each intervention on HRQL. The studies were combined using a random-effects model to account for inter-study variation. Heterogeneity was tested for using the *I*-test and publication bias was assessed using funnel plots and the Egger weighted regression statistic. Thirty-nine RCTs met the criteria, all with acceptable methodological quality. Six major types of interventions were identified through the search. The smallest effect was observed for self-management and complementary and alternative medicine (ES=0.2), followed by medication (ES=0.3) then cognitive training and exercise (ES=0.4), and psychological interventions to improve mood (ES=0.7). The magnitude of positive effect on HRQL varied between the different types of interventions. The extent to which interventions are able to improve HRQL depends on delivering a potent intervention to those persons who have the potential to benefit.



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Ayse Kuspinar¹, Ana Maria Rodriguez¹ and Nancy E Mayo^{1,2}

Abstract

The objective is to estimate the extent to which existing health care interventions designed specifically to target health-related quality of life (HRQL) in persons with multiple sclerosis (MS) achieve this aim. The structured literature search was conducted using multiple electronic databases including Ovid MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature and the Cochrane Central Register of Controlled Trial, for the years 1960 to 2011. The methodological quality of selected randomized controlled trials (RCTs) was assessed using the Cochrane Collaboration's recommended domain-based method. Effect size (ES) was used to measure the effect of each intervention on HRQL. The studies were combined using a random-effects model to account for inter-study variation. Heterogeneity was tested for using the *I*-test and publication bias was assessed using funnel plots and the Egger weighted regression statistic. Thirty-nine RCTs met the criteria, all with acceptable methodological quality. Six major types of interventions were

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1. A paradigm shift: PROs

Editorial

MULTIPLE
SCLEROSIS
JOURNAL | MSJ

Quality of life reporting in multiple sclerosis clinical trials: enough quality?

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Selecting a PRO/HRQOL instrument...

- Content** (e.g. generic vs. condition-specific, pertinent domains covered)
- Properties** (chiefly reliability, responsiveness)
- Practical issues** (e.g. mode of administration, timing, instrument length, availability in the target language/culture)

Reporting data (pre-specified hypothesis if primary outcome, analysis)

2. A paradigm shift: SDM

Preference-sensitive decisions:

Uncertain/no obvious evidence supporting one testing, screening or treatment **option over another**

Options have **different inherent benefits/risks**

Patient values important in optimizing decision

The Patient

- Experience of illness
- Social circumstances
- Attitude to risk
- Values
- Preferences



The Health Professional

- Diagnosis
- Disease aetiology
- Prognosis
- Treatment options
- Outcome probabilities

Embracing
patient
partnership

**INFORMED
CHOICE**

2. A paradigm shift: SDM

INFORMED CONSENT: decision consistent with **best available evidence**

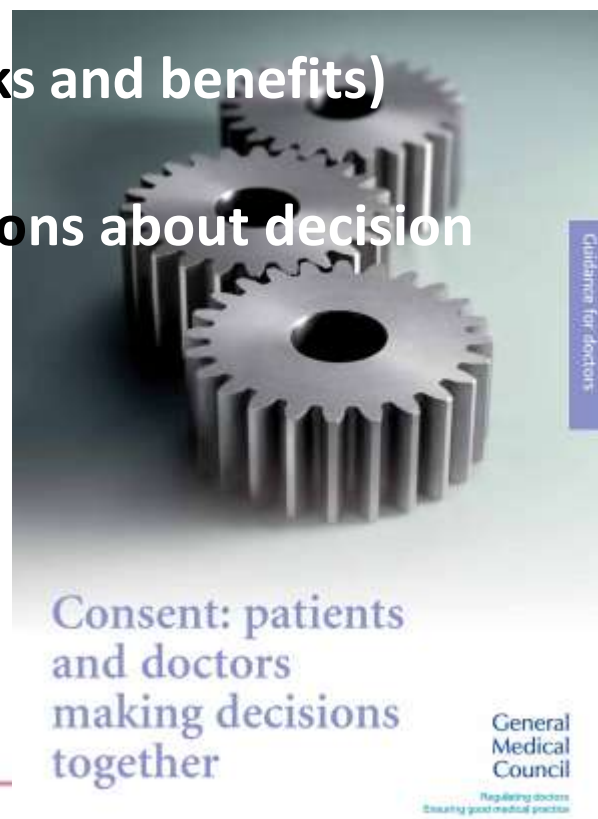
INFORMED CHOICE (SDM): decision consistent with **best available evidence**, and **values and preferences** of the (informed) patient

Different people have different attitudes to their health leading them to **place different values** on health-related behaviours. Thus, for some people an informed choice may be a choice not to engage in a behaviour or treatment, even if recommended by their physician

2. A paradigm shift: SDM

Steps in the SDM process

1. Define/explain the problem
2. Equipose statement
3. Portray options
4. Provide information (each option's risks and benefits)
5. Check understanding
6. Explore ideas, concerns, and expectations about decision
7. Identify preferences
8. Make or explicitly defer decision
9. Follow-up arrangement



3. SDM in MS rehabilitation



OPTION Observing patient involvement © March 2009

Date of Rating: DD MM YY

Practitioner: Age Sex

Rater Name:

Patient: Age Sex

Clinician Code:

Consultation Type: New
 Review
 Composite

Consultation Number:

Consultation Duration:
(minutes, seconds)

Another Person In The Room? Yes No
Who?

Description of Index Problem:

1. The clinician draws attention to an identified problem as one that requires a decision making process.

0 = No attempt to draw attention to a need for a decision making process (*there is no clarity about problems, or at least no clarity about the decisions to be taken about the problem or problems identified*).

1 = Very brief or perfunctory attempts to draw attention to the need to embark on a decision making process.

2 = Baseline skill level: Clinician draws attention to a problem that requires a decision making process.

3 = Clinician puts emphasis on the decision making process required.

4 = The skill is exhibited to a high standard (*e.g. supplementary explanations and evidence of patient recognizing the need to engage in the process of decision making*).

in MS ...

Patients' and Observers' Perceptions of Involvement Differ. Validation Study on Inter-Relating Measures for Shared Decision Making

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Abstract

Objective: Patient involvement into medical decisions as conceived in the shared decision making method (SDM) is essential in evidence based medicine. However, it is not conclusively evident how best to define, realize and evaluate involvement to enable patients making informed choices. We aimed at investigating the ability of four measures to indicate patient involvement. While use and reporting of these instruments might imply wide overlap regarding the addressed constructs this assumption seems questionable with respect to the diversity of the perspectives from which the assessments are administered.

Methods: The study investigated a nested cohort (N=79) of a randomized trial evaluating a patient decision aid on immunotherapy for multiple sclerosis. Convergent validities were calculated between observer ratings of videotaped physician-patient consultations (OPTION) and patients' perceptions of the communication (Shared Decision Making Questionnaire, Control Preference Scale & Decisional Conflict Scale).

Results: OPTION reliability was high to excellent. Communication performance was low according to OPTION and high according to the other rating and administered measures. No correlations were found between observer and patient ratings, neither for the shared decision making instruments. Patient report measures showed some inter-rater correlations.

Conclusion: Existing SDM measures do not refer to a single construct. A gold standard is missing to decide whether any of these measures has the potential to indicate patient involvement.

Practice Implications: Pronounced heterogeneity of the underpinning constructs implies difficulties regarding the interpretation of existing evidence on the efficacy of SDM. Consideration of communication theory and basic definitions of SDM would recommend an inter-subjective focus of measurement.

Mean OPTION score = 30

Making in Physical Therapy: Observed Level of Involvement and Patient Preference

Katrine Dierckx, Myriam Deveugele, Philip Roosen, Ignaas Devisch

in rehab...

Background. Shared decision making (SDM) reduces the asymmetrical power between the therapist and the patient. Patient involvement improves patient satisfaction, adherence, and health outcomes and is a prerequisite for good clinical practice. The opportunities for using SDM in physical therapy have been previously considered.

Objective. The objective of this study was to examine the status of SDM in physical therapy, patients' preferred levels of involvement, and the agreement between therapist perception and patient preferred level of involvement.

Design. This was an observational study of real consultations in physical therapy.

Methods. In total, 237 consultations, undertaken by 13 physical therapists, were audiorecorded, and 210 records were analyzed using the Observing Patient Involvement (OPTION) instrument. Before the consultation, the patient and therapist completed the Control Preference Scale (CPS). Multilevel analysis was used to study the association between individual variables and the level of SDM. Agreement on preferences was calculated using kappa coefficients.

Results. The mean OPTION score was 5.2 (SD=6.8), out of a total score of 100. Female therapists achieved a higher OPTION score ($D=-0.86$, $P=0.01$). In total, 36.7% of the patients wanted to share decisions, and 36.2% preferred to give their opinion before delegating the decisions. In the majority of cases, therapists believed that they had to decide. The kappa coefficient for agreement was poor at .062 (95% confidence interval = -.018 to .144).

Limitations. Only 13 out of 125 therapists who were personally contacted agreed to participate.

Conclusion. Shared decision making was not applied; although patients preferred to share decisions or at least provide their opinion about the treatment, physical therapists did not often recognize this factor. The participating physical therapists were more likely to make decisions in the best interest of their patients; that is, these therapists tended to apply a paternalistic approach rather than involving the patient.

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[Dierckx K, Deveugele M, Roosen P, Devisch I. Implementation of shared decision making in physical therapy: observed level of involvement and patient preference. *Phys Ther.* 2013;93:xxx-xxx.]

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3. SDM in MS rehabilitation

in MS rehab...

MULTIPLE
SCLEROSIS
JOURNAL | MSJ

Neuropsychological rehabilitation does not improve cognitive performance but reduces perceived cognitive deficits in patients with multiple sclerosis: a randomised, controlled, multi-centre trial

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Heini Huhtala⁵ and Päivi Hämäläinen⁴

Abstract

Background: There is preliminary evidence on the positive effects of neuropsychological rehabilitation on cognition in multiple sclerosis (MS), but the generalisability of the findings is limited by methodological problems.

Objective: The aim of the present study was to determine the effects of strategy-oriented neuropsychological

Primary outcomes: Processing speed SDMT,
perceived cognitive problems PDQ
GAS (only intervention arm)



Secondary outcomes: cognition BRBNT, MSQ-P, MSQ-I, fatigue FSMC,
QOL WHOQOL-BBREF, mood BDI-II, MSIS-29



3. SDM in MS rehabilitation

in MS rehab...

Disability
and
Rehabilitation

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RESEARCH PAPER

A cluster randomised controlled trial on the efficacy of client-centred occupational therapy in multiple sclerosis: good process, poor outcome

Isaline C. J. M. Eyssen¹, Martijn P. M. Steultjens², Vincent de Groot^{1,3}, Esther M. J. Steultjens^{4,5}, Dirk L. Knol⁶, Chris H. Polman⁷, and Joost Dekker^{1,3,8}

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3. SDM in MS rehabilitation

in MS rehab...

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More time spent on consultation than on treatment?

⁴Dutch Association of Occupational Therapy (EN). Utrecht, the Netherlands. ⁵Expertise centre Neurorehabilitation. HAN University of applied

Primary outcomes: *Disability* DIP, *Participation & Autonomy* IPA



Secondary outcomes: *Functional* arm 9-HPT, fatigue MFIS, pain



PES, cognitive PDQ, occup prerformance COPM

Process ECGP (HP and Pt), QuoteEEE



KEY POINTS

- **PROs increasingly used**, but need: (a) to **improve quality** in planning, gathering, analyzing, and reporting (particularly in RCTs); (b) for **easier to use** instruments (admin/scoring/retrieval)
- **SDM** endorsed by HPs but **insufficiently implemented** in the MS field and in rehabilitation (few studies found on SDM in MS rehab)
- PROs and SDM both expression of a **shift from disease-centeredness to patient-centeredness**
- **Contamination & common strategies** needed in MS care & research to **inform decision-making at the micro, meso** (e.g. guideline development) and **macro level** (health policy)