

Appendix 1

The questionnaire and PRO-algorithm development process

A research consensus team that included clinical experts in epilepsy and experts in patient-reported outcome (PRO) measures was established in September 2011. The group provided inputs to the content and construct of the epilepsy questionnaire and the PRO-algorithm used to support clinical decision-making in outpatient follow-up.

PREPERATION

Rationale

Clinicians working with epilepsy experienced an increased volume of patients in the outpatient clinic and the majority of these patients were well treated. However, the need of monitoring treatment effect and screen for functional and mental health issues were still necessary. Therefore, self-reported data collected from the patients' home was assumed to have a great potential in this patient group.

Purpose

The purpose was to develop an instrument which could screen for epilepsy patients' health problems to support clinical decision-making in outpatient follow-up.

Patient group

The target group was patients with epilepsy ≥ 15 years with no cognitive impairments.

DEVELOPMENT

Conceptual framework of what do we want to be measured

Based on the Wilson and Cleary (1995) model, definition and levels of constructs were discussed. Symptom status, functional status, overall quality of life, and characteristics of the individual and the environment were identified as being clinically relevant aspects to measure in the population.

Development and selecting items

Literature

A systematic research strategy was conducted to identify establish generic and epilepsy-specific PRO instruments. Several instruments were identified; however, no established disease-specific instruments covering the purpose of identifying patients who need clinical attention were found. Several generic established instruments were identified covering some of the constructs that had been selected to be measured. These instruments included the World Health Organisation Well-Being Index (WHO-5), items from the Short Form 36 (SF-36), and items from the Symptom Checklist 92 (SCL-92).

Experts

Clinical experts in epilepsy, including both physicians and nurses, provided inputs to content development of new items. The severity of each symptom separately was considered important.

Only one aspect of the symptom was selected if the symptom has different aspects, e.g. fatigue. Experts in PRO provided inputs to formulating and scoring of the items.

TESTING AND EVALUATION

First draft: pilot testing

The first version of the questionnaire was pre-tested by using semi-structural interviewing techniques in 20 representative epilepsy patients from two outpatient clinics in Central Denmark Region. The aim of the pilot test was to identify potential problems such as low relevance of items, ambiguity of items, and lack of important topics.

Evaluation

The majority of the patients found the questionnaire content relevant, and no critical comprehension difficulties were identified. Some patients pointed out recall problems regarding some of the seizure items. They did not report lack of any essential topics nor did the time used to fill in the questionnaire raise any criticism.

THE PRO-ALGORITHM

Based on the first draft of the questionnaire, a clinical expert group in epilepsy assigned the response options for each item in three colours: green, yellow, or red. The allocation was based on what the doctors considered clinically important to react on to identify patients with need of attention. The overall aim of the algorithm is a 'red flag' approach. Specific answers result in a red colour indicating need of clinical attention, e.g. pregnancy, suicidal thoughts, seizure impairment.

A red colour indicates that the patient needs or wishes contact with the outpatient clinic. A yellow colour indicates that the patient may need contact with the clinic. In yellow cases, a clinician assesses the patient's PRO response, and based on the PRO data and other information in the patient's record it is decided whether further contact is needed. A green colour indicates that the patient does not need or wish contact with the clinic, and a subsequent questionnaire is sent to the patient at a pre-defined interval (e.g. after 3, 6, or 12 months).

Subsequently, the PRO questionnaire and the PRO-algorithm were implemented and used in clinical practice, and experiences have been evaluated yearly since 2011 at consensus meetings.

Overview of items and the algorithm of the response categories in the epilepsy questionnaire

Item	Response categories					
Number of seizures during the last year	> 0					
Number of absence seizures during the last 3 months	> 0					
Number of generalised seizures during the last 3 months	> 0					
Seizure impairment	Yes	No				
Seizure injury	No	Yes, but not serious	Serious damage			
Emergency room visit due to epilepsy	Yes	No				
Relatives' worried	Never	Rarely	Occasionally	Frequently	Don't know	Not applicable
Headaches	Never	Occasionally	Sometimes	Often	Very often	
Dizziness	Never	Occasionally	Sometimes	Often	Very often	
Tremor/ shaking	Never	Occasionally	Sometimes	Often	Very often	
Double vision	Never	Occasionally	Sometimes	Often	Very often	
Loss of appetite	Never	Occasionally	Sometimes	Often	Very often	
Eating too much	Never	Occasionally	Sometimes	Often	Very often	
Difficulty remembering	Never	Occasionally	Sometimes	Often	Very often	
Difficulty concentrating	Never	Occasionally	Sometimes	Often	Very often	
Aggression	Never	Occasionally	Sometimes	Often	Very often	
Fatigue	Never	Occasionally	Sometimes	Often	Very often	
Sadness	Never	Occasionally	Sometimes	Often	Very often	
Fear of having seizures	Never	Occasionally	Sometimes	Often	Very often	
Problems with sexuality	Never	Occasionally	Sometimes	Often	Very often	
Being suicidal	Never	Occasionally	Sometimes	Often	Very often	
Well-being WHO-5 Index	Score < 50 or one extreme answer (at no time)					
General health	Excellent	Very good	Good	Fair	Poor	
General health compared to last year	Much better	Somewhat better	About the same	Somewhat worse	Much worse	
Medication adherence	Daily	Weekly	Monthly	Never / very rarely		
Side- effects	No	Yes, a few	Yes, some	Yes, many		
Work less because of epilepsy	Yes	Partly	No			
Social limitations	No	Yes				
Alcohol consumption	> consume 14/21 units a day					
Use of recreational drugs	Never	Monthly	Weekly	Daily		
Pregnant	Yes	No				
Planning pregnancy	Yes	No				
Car driving last month	Yes (+ seizures)	No				

Green: No need of contact with the outpatient clinic

Yellow: May need of contact (a clinician has to assess the PRO response)

Red: Need of contact with the clinic