

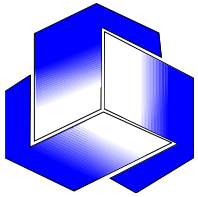
Development of the Fatigue Module (EORTC FA25; FAR15)

J. Weis & Y. Gao

EORTC Quality of Life Group Meeting

4th May, 2006

Paris

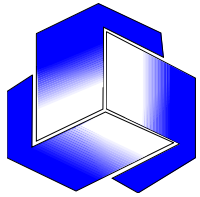


Retrospect

- Phase I/II based on n=36 expert interviews (physicians, nurses, psychologists) from 8 different European countries.
- From phase II: fatigue module available in two versions:
 - FA-R15 to be used in combination with EORTC QLQ C30
 - FA25 (with 25 items) to be used without EORTC QLQ C30. FA25 includes items of the EORTC QLQ C30

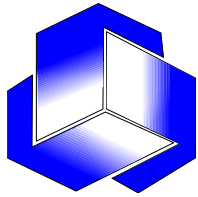
update

- FA-R15 is now available in English, French, German, Italian, Spanish, Norwegian and Swedish



Phase III: Module development

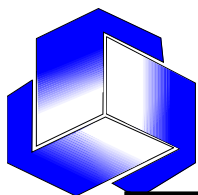
- Pre-testing of the provisional module (FA-R15)
- Patients will be interviewed: relevance and adequacy of coverage of the items:
 - 1) to identify and solve potential problems in its administration (e.g. phrasing of items, sequence of questions);
 - 2) to determine the need for additional questions;
 - 3) to shorten the module as well as avoiding overlapping
 - 4) to ask for patients priority rating



Current Phase III Collaborators

- Data Centre: Andrew Bottomley
- Translation Centre: Karen West
- UK: University Hospital Aintree
 - Andrea Griffin, Clare Byrne, Louise Jones, Liverpool
- Germany:
 - Claudia Fleissner, Berlin
 - Susanne Singer, Leipzig
 - Henning Flechtner, Cologne
 - Fabian Fehlauer, Hamburg
- Sweden: Eva Hammerlid, Goteburg
- France: Thierry Conroy
- Austria: Bernhard Holzner, Innsbruck
- Italy Fabio Efficace?
- Spain ???

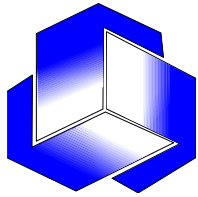




Distribution of Patient Sample

Country	Acute treatment	Rehabilitation/ Recovery	Hospice/ paliative care
Germany	ca 15	ca 15	ca 15
UK	ca 15	ca 15	ca 15
France	ca 15	ca 15	ca 15
Sweden	ca 15	ca 15	ca 15
Austria (inactive)	ca 15	ca 15	ca 15
Pending	ca 15	ca 15	ca 15
Pending	ca 15	ca 15	ca 15
Total	100	100	100 Σ 300

update

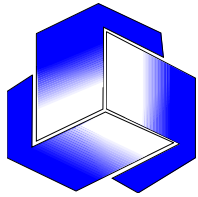


Phase III Patients interviews

- EORTC QLQ Module development guidelines:
 - patients complete the core questionnaire and the provisional module (FA-R15)
 - structured interview asking for any questions that were difficult, upsetting etc., irrelevant items, important items which are not included
 - Basic medical and socio-demographic data

update

- Complete study protocol is now available
 - The Clinical and Socio-demographic Form is now available
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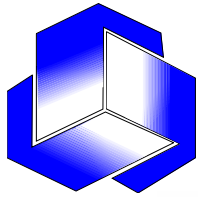


Informed consent and ethical issues

- The QL protocol must be approved by local ethical committees according to the national requirements. Each patient's informed consent must be obtained prior to administration of the provisional module and interviews. The interviewer may take notes during the interview, but the discussion will not be tape-recorded. All patient data will be kept anonymous using only study number or initials.

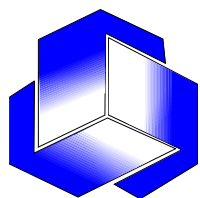
News

- Two collaborators each from Germany and France have obtained the Ethical Approval from their centres



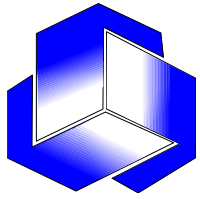
Clinical Data and Socio-demographic I

Name of Centre:		Date of Interview (DD/MM/YY):	
Patient's ID Number:		Country of Origin:	
Gender:	Age:	Marital Status:	
Male <input type="checkbox"/>		Single <input type="checkbox"/>	
Female <input type="checkbox"/>		Married/Living with partner <input type="checkbox"/>	
Employment Status:		Divorced/Separated <input type="checkbox"/>	
Employed full-time*	<input type="checkbox"/>	Widow/Widower <input type="checkbox"/>	
Employed part-time	<input type="checkbox"/>	Highest Level of Education:	
Self employed	<input type="checkbox"/>	Less than compulsory school education	<input type="checkbox"/>
Unemployed	<input type="checkbox"/>	Compulsory school education	<input type="checkbox"/>
Home-maker	<input type="checkbox"/>	Post compulsory education	
Retired	<input type="checkbox"/>	-Below university	<input type="checkbox"/>
Student	<input type="checkbox"/>	-University level	<input type="checkbox"/>



Clinical Data and Socio-demographic Form II

Patient's Medical Information						
Position of	Primary Tumour	Secondary Tumour	Recurrent Tumour	Type of Treatment:	Completed	Ongoing
Breast	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surgery	<input type="checkbox"/>	<input type="checkbox"/>
Colorectal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Chemotherapy	<input type="checkbox"/>	<input type="checkbox"/>
Lung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
Head/Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Hormone therapy	<input type="checkbox"/>	<input type="checkbox"/>
Prostate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Others _____	<input type="checkbox"/>	<input type="checkbox"/>
Testicular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Time since completion of treatment:		
Pancreatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tumour Status:		
Haematological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Complete remission	<input type="checkbox"/>	
Others _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Incomplete remission	<input type="checkbox"/>	
				Progressive disease	<input type="checkbox"/>	
Secondary Tumour:				Type of Care:		
Metastases Yes <input type="checkbox"/> No <input type="checkbox"/>				Acute care (inpatient) <input type="checkbox"/>		
Time since diagnosis:				Acute care (outpatient) <input type="checkbox"/>		
Primary Tumour: _____				Rehabilitation <input type="checkbox"/>		
Secondary Tumour: _____				Hospice <input type="checkbox"/>		
Recurrent Tumour: _____				Others _____ <input type="checkbox"/>		



Thank you for your attention!!

