

Why do we need new quality of life assessment tools?

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Outline

- Cancer and Quality of life
- Brief history of QOL measurement
- Why we need a new QOL tool
- Development of the content of EUonQOL

Cancer plan for Europe

- In 2020 - **2.7 million people in the European Union** were diagnosed with cancer
 - 1.3 million people lost their lives due to cancer
 - Survival rates vary between countries (20% for breast cancer)
- **Improving quality of life for cancer patients and survivors**
 - advances in early detection, effective therapies and supportive care
 - estimated over 12 (or 20) million cancer survivors in Europe
 - appropriate **follow-up care**, access to **social protection** and access to financial services (insurance)

European Code of Cancer Practice: 10 rights



1. EQUAL ACCESS

Equal access to affordable and optimal cancer care, including the right to a second opinion.

[READ MORE](#)



2. INFORMATION

Information about your disease and treatment from your medical team and other reliable sources, including patient and professional organisations.

[READ MORE](#)



3. QUALITY, EXPERTISE & OUTCOMES

Information about the quality and safety of care, the level of expertise and the outcomes achieved for your type of cancer in the centre where you are being treated.

[READ MORE](#)



4. SPECIALISED MULTIDISCIPLINARY CARE

Receive care from a specialised multidisciplinary team, ideally as part of a cancer care network.

[READ MORE](#)



5. SHARED DECISION-MAKING

Participate in shared decision-making with your healthcare team about all aspects of your treatment and care.

[READ MORE](#)



6. RESEARCH & INNOVATION

Be informed about ongoing research relevant to you, and your ability and eligibility to participate in research.



7. QUALITY OF LIFE

Discuss with your healthcare team your priorities and preferences to achieve the best possible quality of life.



8. INTEGRATED SUPPORTIVE & PALLIATIVE CARE

Receive optimal supportive and palliative care, as relevant, during any part of your cancer journey.



9. SURVIVORSHIP & REHABILITATION

Receive and discuss with your care team a clear, managed and achievable plan for your survivorship and rehabilitation.



10. REINTEGRATION

Be fully reintegrated into society and protected from cancer-related stigma and discrimination, so that, in so far as is possible, you can return to a normal life.



1950ies-70ies Health status

- 1950-ies - Increased interest in measurement of health, functioning and well-being
- Changing pattern of diseases
 - Predominance of chronic diseases
 - Maintaining functioning and well-being
 - Cancer as a chronic disease
- 1952 - WHO definition of health-Fundamental shift in health-related thinking
 - Presence of positive physical, mental and social well-being, not merely the absence of disease or infirmity
- 1977 Engel - Bio-psychosocial model of health replacing biomedical model

1980-90ies- Health-Related Quality of Life

- Subjective perception of the impact of health (including disease and treatment) on:
 - physical
 - psychological and
 - social functioning and
 - well-being

1990-2000ies Patient-Reported Outcomes(PROs)

- FDA - Umbrella term: Any reports provided by the patient without interpretation or adjustment from clinician or anybody else (PROMs-measures)
- *HRQOL is a PRO*
- FDA and NIH BeST glossary
- <https://www.ncbi.nlm.nih.gov/books/NBK338448/>
- *HRQOL is a Clinical outcome*

We have quite a few QOL measures: EORTC

List of questionnaires



Code	Name	Core	Phases
QLQ-C30	Quality of Life of Cancer Patients	Core	validated
PR-SURV19	Survivorship	Core	IV - in development
CR-SURV33	Survivorship	Core	IV - in development
BR-SURV40	Survivorship	Core	IV - in development
AYA	Adolescents and Young Adults	Core	III b - in development
QLQ-C15-PAL	Quality of Life in palliative cancer care patients	Core	validated
SURV100	Survivorship	Core	IV - in development

We have quite a few QOL measures: EORTC item library

 EORTC Item Library

Create a new questionnaire

Galina Velikova ▾

157 questionnaires, 1028 questions

Include custom questionnaires from the community

Official questionnaires

Custom questionnaires

Item classification

We have quite a few QOL measures: FACT-G (FACIT)

FACIT.org

FACIT
Measures & Languages

OVER 100 MEASURES IN AS MANY AS 80 LANGUAGES

We have quite a few QOL measures: FACT-G (FACIT)



Intro to PROMIS®

PROMIS includes over 300 measures of physical, mental, and social health for use with the general population and with individuals living with chronic conditions.

- PROMIS

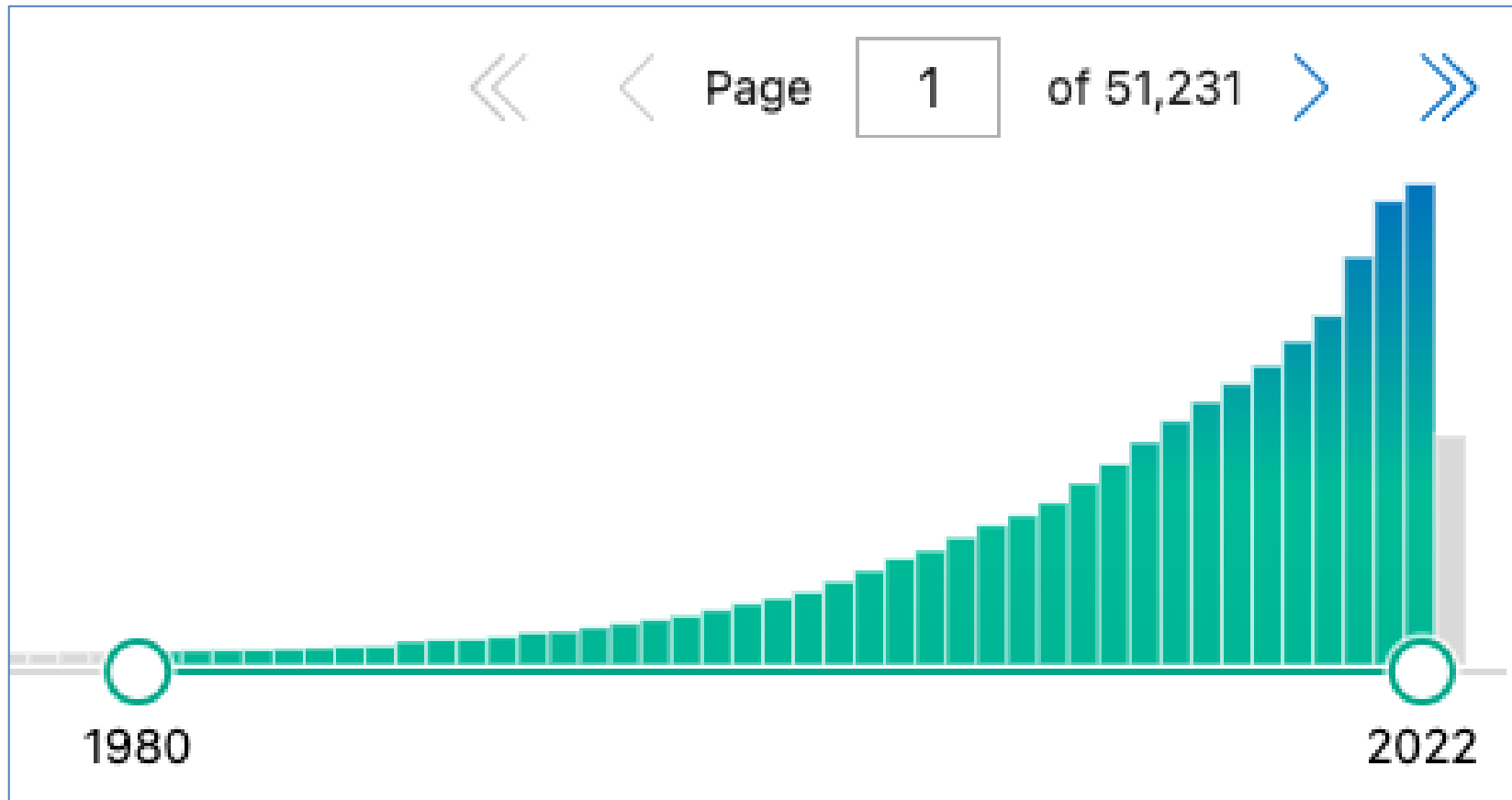
- ➕ Intro to PROMIS

- List of Adult Measures
 - List of Pediatric

- Adult Assessment

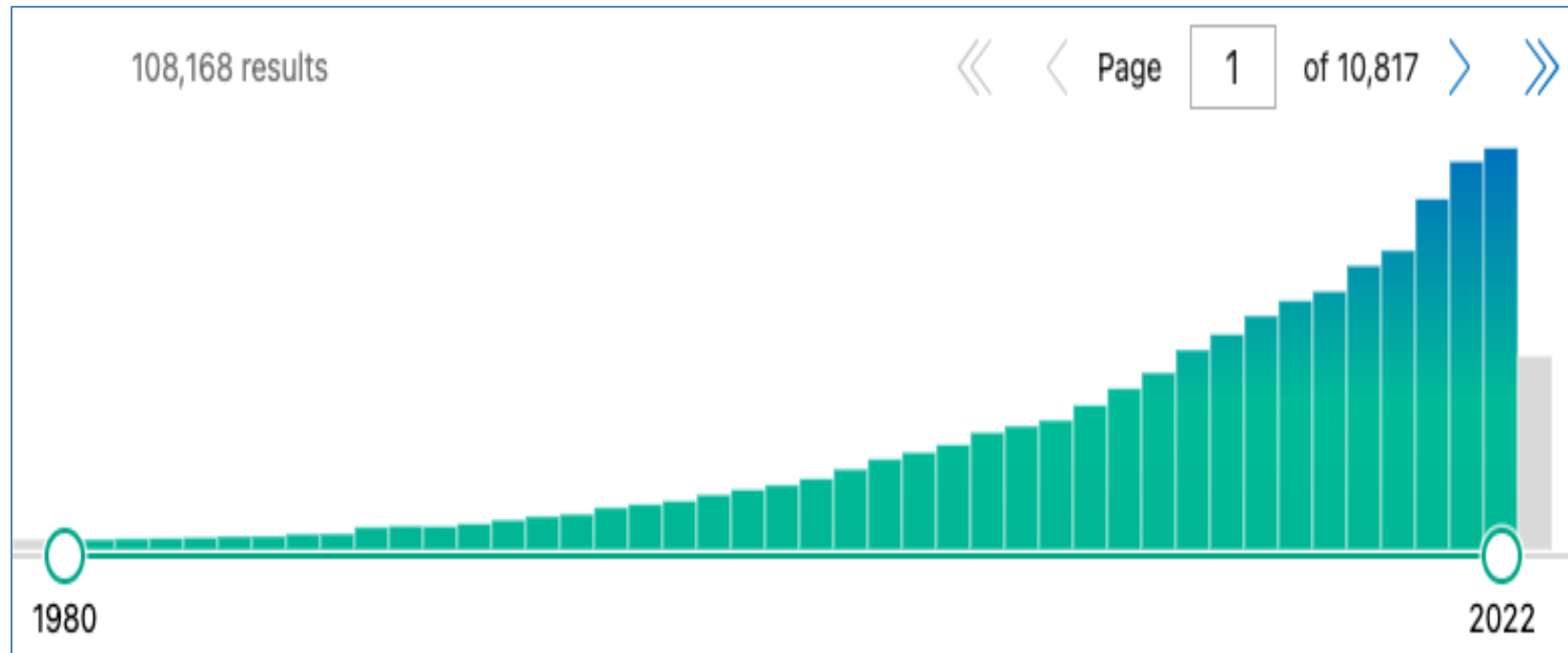
- PROMIS developed self-report measures for adults for functions, symptoms, behaviors, and feelings. See the [List of Adult Measures>>](#)
 - Measures are available in Spanish and many other languages. See the [List of Available Translations>>](#)

Application of QOL measures in clinical research



Pubmed
publications
containing **QOL** in
title/abstract
1980 n=400
2022 n= 55,000

Application of QOL measures in clinical research



Pubmed
publications
containing “**QOL
AND Cancer**” in
title/abstract
1980 n=80
2022 n= 11,000

Taking stock of achievements and moving forward

Micro level
Individual care/benefits
Clinical practice

Meso level
Group benefit
Institutions

Macro level
Government policy
Population benefit

- **We have learned a lot**
- Measures were widely used in clinical trials and research studies
- Increasing use in clinical practice for patient care
- Some application to populations (EQ5D as utility measure)

Quality of Life Research, 2, pp. 297–303

Commentary

Quality of life assessments and levels of decision making: differentiating objectives

H. J. Sutherland,* and J. E. Till



Example of QOL on a population level

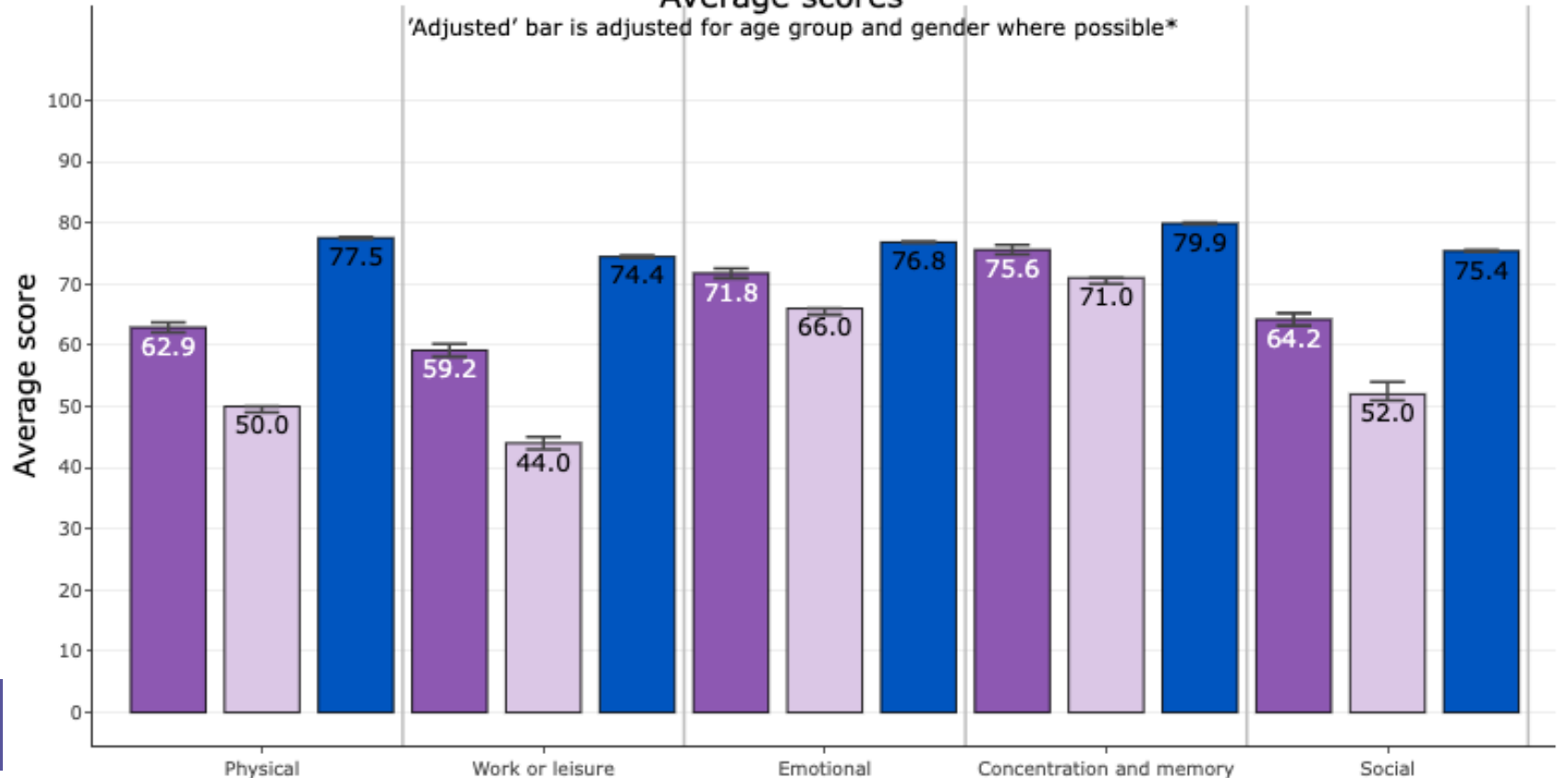
<https://www.cancerdata.nhs.uk/cancerqol>



111,470 responses (47%)

Quality of life functional categories (EORTC QLQ-C30)-
Average scores

'Adjusted' bar is adjusted for age group and gender where possible*



Lung cancer
England vs all
cancers



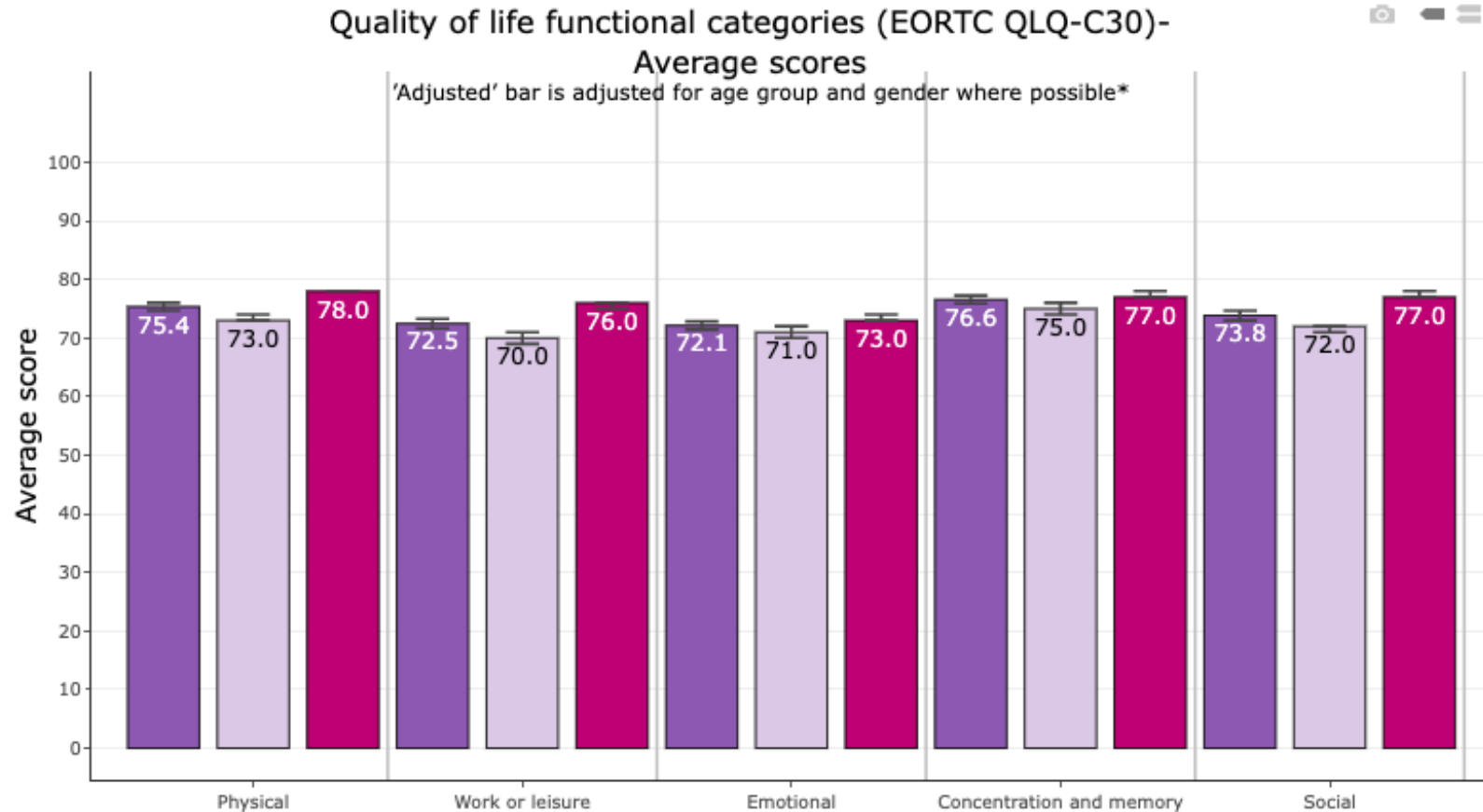


Example of QOL on a population level

<https://www.cancerdata.nhs.uk/cancerqol>



**Breast cancer
Region vs
England**



Taking stock of achievements and moving forward

Challenges

- The main tools were designed in the 1990ies
- Static tools not covering new treatment aspects
 - Proliferation of large number of disease- and treatment-specific tools
- Patients comments
 - Heavy medical focus
 - Not always relevant to them
- Cultural validation
- Challenges with administration and patient burden



Why do we need a new quality of life assessment tool?



Changing cancer care. Complex new treatments

- Increasing number of survivors/ those living with cancer
- Flexible tools to cover the full spectrum



Patient engagement in decision-making

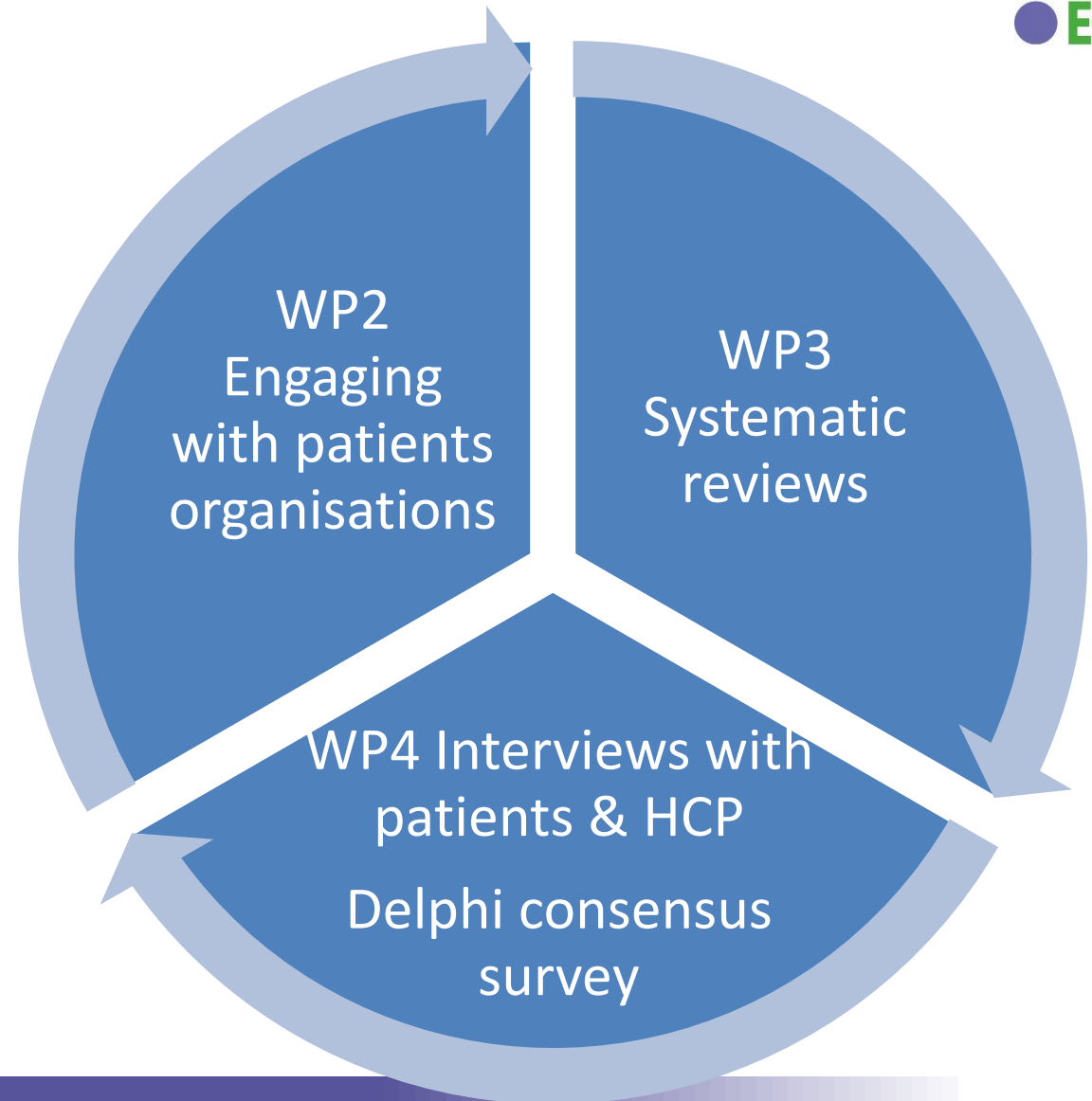
- Co-design and relevance to both patients and clinicians
- Patient burden



Technology and new measurement methodology

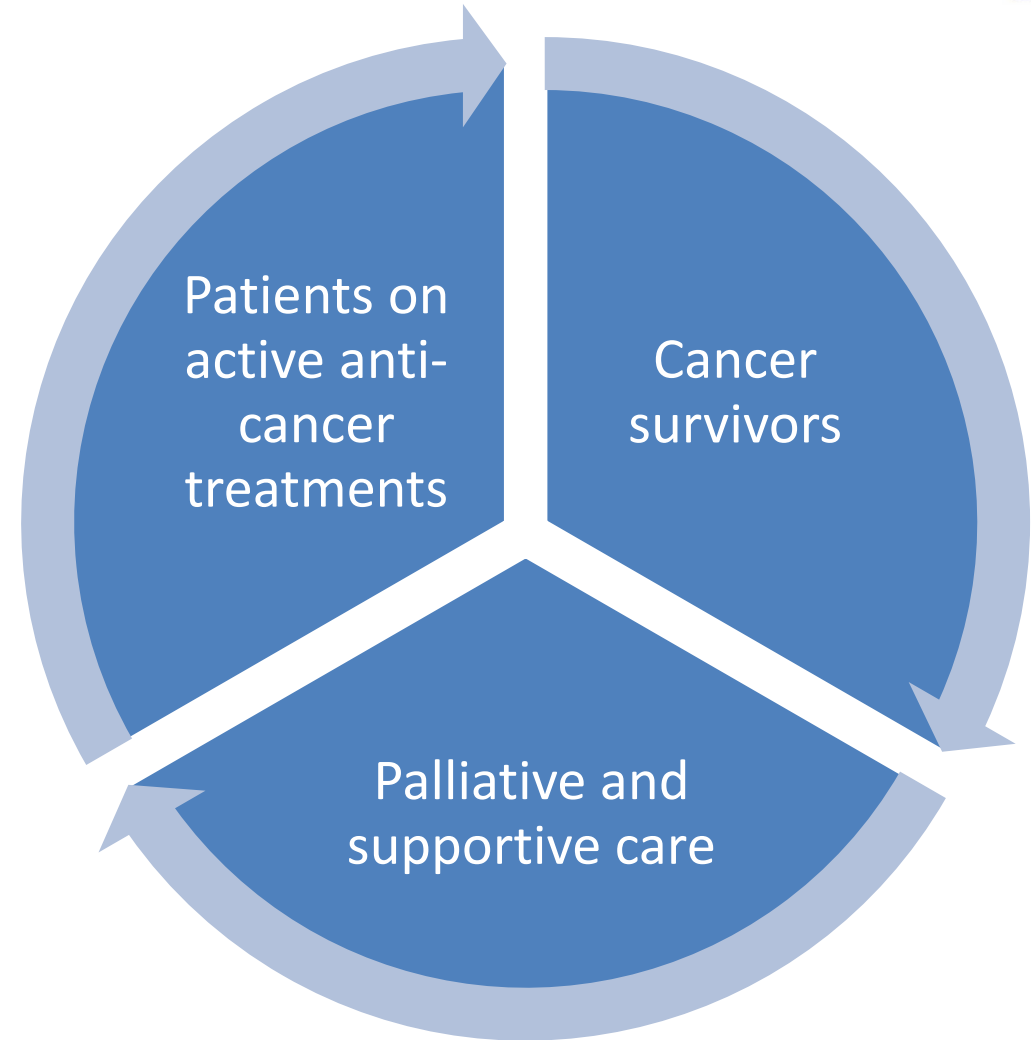
- Digital and mobile technology
- Computer Adaptive Testing

**Addressing the
challenge:
Developing the
content of the
EUonQOL toolkit**



**Patients and survivors
groups**

**Common cancers
(breast, prostate, lung,
GI) and others**



WP3 Systematic reviews-Current state of the art

Tools

- Systematic review
- Identify and analyse existing QOL measures

Domains

- Systematic review
- Identify needs and relevant QOL domains

CAT

- Scoping review
- Implementation of Computer Adaptive Testing
- Feasibility in European cancer patients and survivors

WP4 Develop the Content of EUonQOL

Interviews

- Interviews with patients and HCP
- Selection of relevant QOL domains

Delphi survey

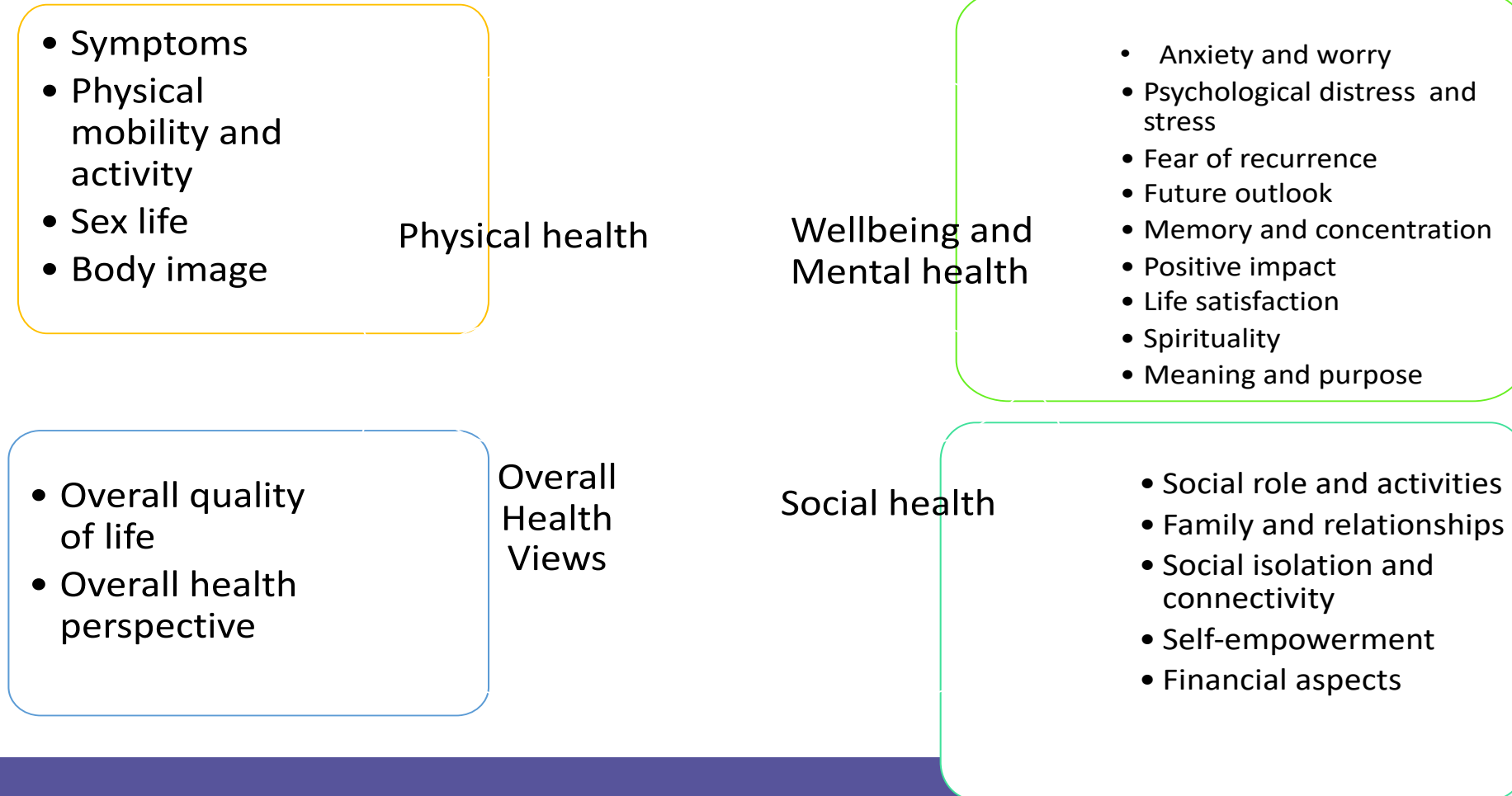
- 3 rounds: Patients, patient advocates, HCP
- Rating and consensus on QOL domains

First version of EUonQOL

- Combine results from systematic reviews, interviews and Delphi
- Consensus meeting WP2, WP3 and WP4

Health related quality of life domains

Diagram to use as a prompt during the interviews



Example of participants interviews: Physical health

Health domains	Examples of questions	Examples of importance	Response
Physical health			1-4
Physical symptoms			
Pain/pain interference	Have you had pain? Not at all, A little, Quite a bit, Very much	1) essential; (2) desirable; (3) optional; (4) to be excluded as irrelevant	
Energy	Have you lacked energy?	1) essential; (2) desirable; (3) optional; (4) to be excluded as irrelevant	
Sleeping problems	Have you had trouble sleeping?	1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant	
Mobility and activity			
Mobility	Do you need to stay in bed or a chair during the day?	1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant	
Physical exercise	Do you have any trouble taking a short walk outside of the house?	1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant	
	Do you have any trouble taking a long walk?		

Example of participants interviews: Mental health

Wellbeing and Mental Health		
Anxiety	Did you worry? Have you felt panic?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>
Depression/ Sadness	Did you feel depressed? Have you felt sad? Have you felt motivated to continue with your normal hobbies and activities?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>
Positive impact	Has the experience of cancer helped you to distinguish between important and unimportant things in life?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>
Fear of recurrence	Have you worried about recurrence of your disease?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>

Example of participants interviews: Social health



Social Health			
Social roles & activities			
Leisure activities - Hobbies	Were you limited in pursuing your hobbies or other leisure time activities?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>	
Leisure travel	Have you been limited in your ability to travel?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>	
Social activity limitations	Has your physical condition or medical treatment interfered with your social activities?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>	
Family and Relationships			
Impact on children/family	Has your physical condition or medical treatment interfered with your family life?	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>	
Partner relationship	Is your relationship with your partner stronger? N/A for some	<i>1) essential; (2) desirable; (3) optional; and (4) to be excluded as irrelevant</i>	

WP4 Develop the Content of EUonQOL

Interviews

- Interviews with patients and HCP
- Selection of relevant QOL domains

Delphi survey

- 3 rounds: Patients, patient advocates, HCP
- Rating and consensus on QOL domains

First version of EUonQOL

- Combine results from systematic reviews, interviews and Delphi
- Consensus meeting WP2, WP3 and WP4

Small pilot of provisional EUonQOL

Digital platform

- Digital version of EUonQOL
- Develop CAT for core domains

Small pilot

- In-house translations
- Administer to 5-10 patients per country

Ready for larger pilot

- Make improvements
- Formal translations, cultural adaptations
- Ready for larger scale pilot testing and validation

Contributors- multi-national

- Italy – A Ceraceni (WP4 co-lead)
- UK – A Gilbert & Velikova (WP4 co-lead)
- The Netherlands-L van dePoll-Franse (Delphi lead)
- Belgium – H Vachon (WP3 lead)
- France
- Denmark
- Austria
- Spain
- Germany



Reserve slides





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Measurement of Outcomes

[CanCORS](#)

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[Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events \(PRO-CTCAE™\)](#)

Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)

This site was designed to provide you with information about the PRO-CTCAE, a patient-reported outcome measurement system developed by the National Cancer Institute to capture symptomatic adverse events in patients on cancer clinical trials.

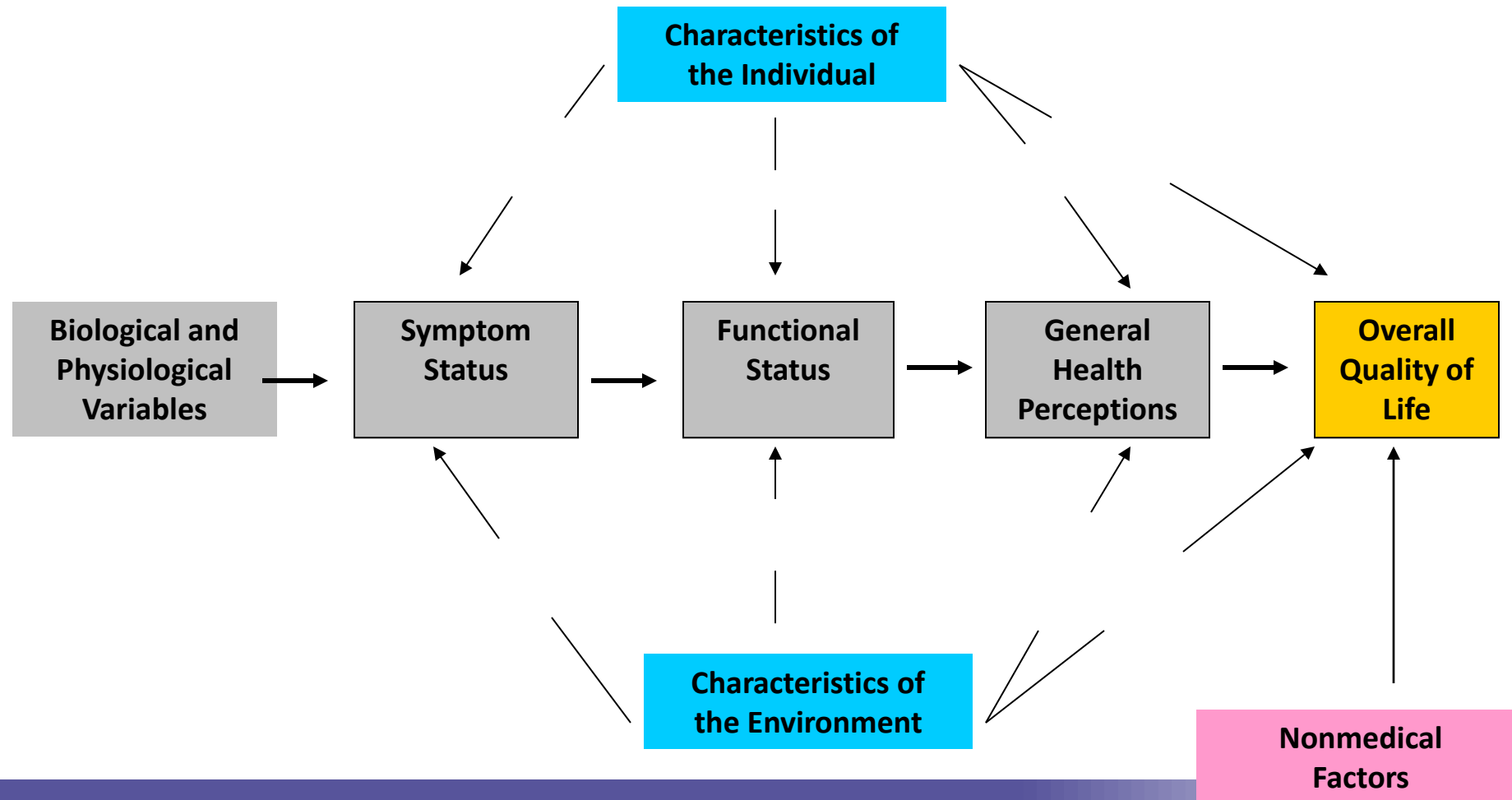
The site includes an overview of the methods used to develop this measurement system, and resources and references for further information.

- [▶ What Is PRO-CTCAE?](#)
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HRQOL conceptual model

Wilson and Cleary model, modified by Ferrans

(Wilson and Cleary, JAMA 1995; 273(1): 59-65)



Conceptual framework of health cancer survivors

van Leeuwen et al. *Health and Quality of Life Outcomes* (2018) 16:114
<https://doi.org/10.1186/s12955-018-0920-0>

Health and Quality of Life Outcomes

RESEARCH

Open Access



Understanding the quality of life (QOL) issues in survivors of cancer: towards the development of an EORTC QOL cancer survivorship questionnaire

Marieke van Leeuwen^{1*}, Olga Husson², Paola Alberti^{3,4}, Juan Ignacio Arraras⁵, Olivier L. Chinot⁶, Anna Costantini⁷, Anne-Sophie Darlington⁸, Linda Dirven^{9,10}, Martin Eichler¹¹, Eva B. Hammerlid¹², Bernhard Holzner¹³, Colin D. Johnson¹⁴, Meropi Kontogianni¹⁵, Trille Kristina Kjær¹⁶, Ofir Morag¹⁷, Sandra Nolte¹⁸, Andrew Nordin¹⁹, Andrea Pace²⁰, Monica Pinto²¹, Katja Polz²², John Ramage²³, Jaap C. Reijneveld²⁴, Samantha Serpentine²⁵, Krzysztof A. Tomaszewski²⁶, Vassilios Vassiliou²⁷, Irma M. Verdonck-de Leeuw²⁸, Ingvild Vistad²⁹, Teresa E. Young³⁰, Neil K. Aaronson¹, Lonneke V. van de Poll-Franse^{1,31,32} and on behalf of the EORTC QLQ

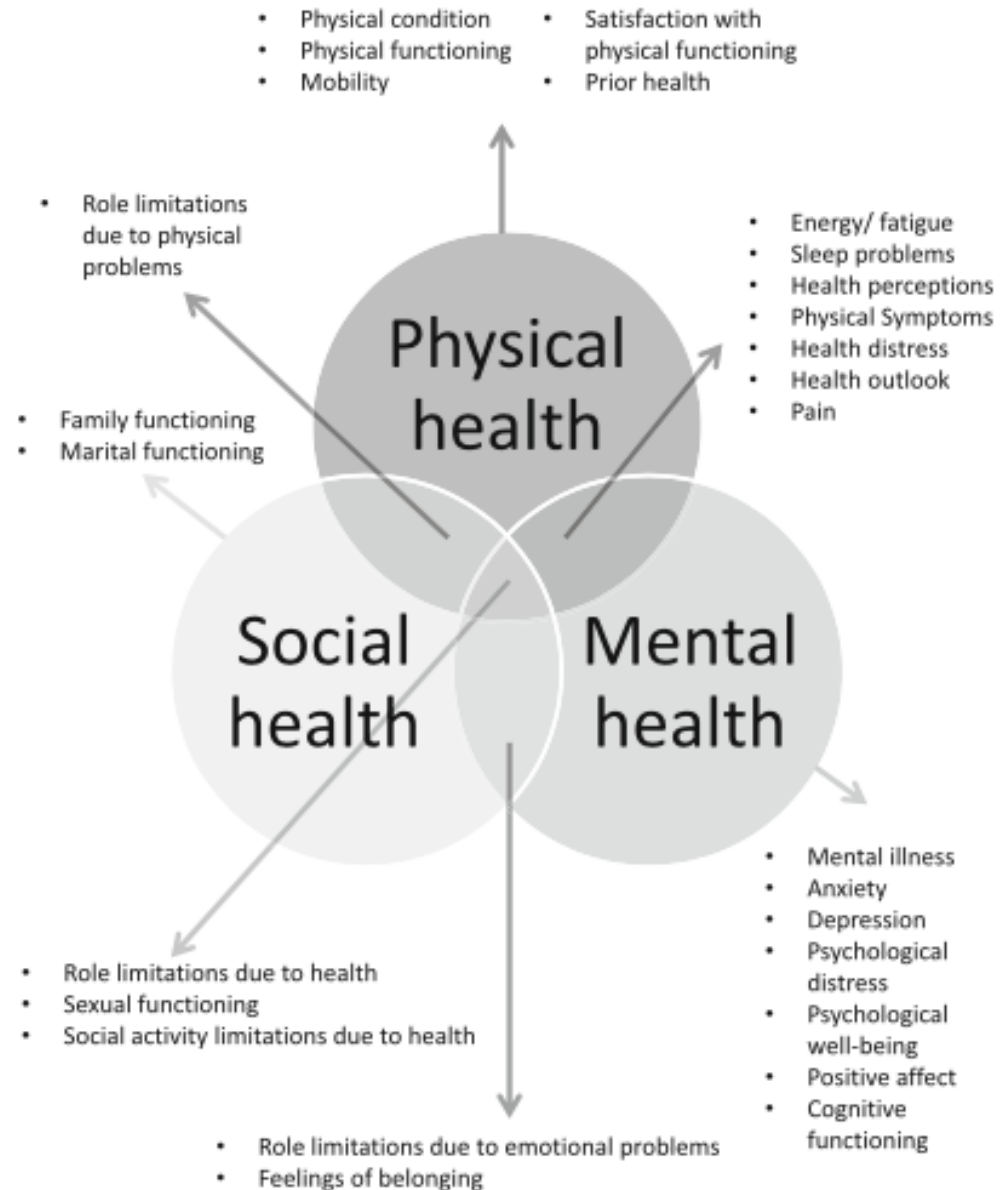


Fig. 1 Three-dimensional theoretical framework of health. In this framework health is assessed by multiple health indicators