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Validation of the European Oncology toolkit for the self-assessment of Quality of Life (EUonQoL-Kit) in cancer patients and survivors: study protocol of a pan European survey.

Apolone G, Costantini M, Caselli L, Bos N, Caraceni A, Couespel N, Ferrer M, Groenvold M, Kaasa S, Ciliberto G, Lombardo C, Pietrobon R, Pravettoni G, Sirven A, Vachon H, Velikova G, Garin O, Gilbert A, Machiavelli A, Marzorati C, Miceli R, Pe M, Petersen MA, Tanzilli A, van Schelven F, Dantas C, Minnée-van Braak I, Pinnavaia L, Brunelli C; for the EUonQoL WG.

Supplementary Information 1. List of dos and don'ts on patient interaction.

This appendix was drafted in collaboration with a group of patient co-researchers actively involved in this study, who contributed their perspectives and advice based on personal experience. The following tables, a significant outcome of this collaboration, contain recommendations for interacting with patients during the recruitment and questionnaire administration phases.

Interaction with patients: getting started

GENERAL DOS AND DON'TS			
DOS		**DON'TS**	
✓	Understand that every patient's situation is unique.	x	Don't make assumptions based on their diagnosis or treatment.
✓	Approach the potential participants with empathy, understanding, and sensitivity to their condition.	x	Don't be impersonal or dismissive about the patient's emotional state while discussing participation or during questionnaire administration.
✓	Ensure conversations are private and do not compromise patient privacy.	x	Don't approach patients if you think the setting conditions are not convenient for the patients.
✓	Make the recruitment process accessible and convenient for patients, considering their health condition and limitations (e.g., good accessibility, heating/cooling and parking conditions may ease their participation).		
✓	Be aware that informing the patient about the study is part of the study itself.	x	Don't consider that informing the patient about the study is just a formality.
✓	Use language that the patient can understand.	x	Don't use medical jargon (unless explicitly requested), nor speak in a childish manner.
✓	Take the time and space to clarify any doubts.	x	Don't take anything for granted.
✓	Work closely with the project team members to clear any doubts or solve emergent issues.		

Recruitment phase: Q&As

Q1	How can I make sure that I provide the patients with all relevant information about the study?		
DOS		**DON'TS**	
✓	Provide the patients with clear explanations of each relevant point included in the study information leaflet.	x	Don't simply hand out the study information material without verbal explanations.
✓	Clearly explain that the study is "observational", i.e., it will not impact in any way on the participant's routine medical care or treatment of disease.	x	Don't take for granted that the participant knows the meaning of "observational" study.
✓	Clearly explain that the study's aim is to validate the EUonQoL-kit: a new questionnaire to assess the quality of life of people who are at different stages of the cancer care continuum.	x	Don't be too general in explaining the aim of the study, but clearly state why the study is important.

✓	Clearly explain that validating a questionnaire means to test that it measures what it intends to measure, and that this measurement is reliable.		
✓	Clearly explain the study's benefits: having scientifically valid questionnaires for measuring QoL helps to ensure that healthcare practices provide good QoL to patients.	x	Don't forget to mention the positive implications of the study for individuals and the community.
✓	Clearly explain the study's risks: there are no medical risks associated with the participation, but a few people may find it upsetting to think about some of the issues addressed in the questionnaire.	x	Don't forget to mention any risks (even if minor) of the study.
✓	Provide detailed information about the study procedures (electronic completion of 1 or 2 questionnaires at the clinical centre + sociodemographic questions) and timing (15'-20' + additional 10' in case of completion of 2 questionnaires).	x	Don't just give a general description of the study procedures and timing but provide all the information necessary to understand what will happen if the person decides to participate in the study.
✓	Clearly explain that the person can withdraw from the study at any time without giving any explanation.	x	Don't forget to mention the possibility of withdrawing from the study.
Q2	**How can I make sure that I provide all relevant information on data processing?**		
	DOS		**DON'TS**
✓	Ensure the patient's privacy and explain how their data will be protected.	x	Don't be too general in explaining the terms and conditions of data processing, but clearly explain the rights and obligations of patients who decide to participate in the study
✓	Point out that personal data will be stored in a pseudonymized form for the time sufficient and necessary for clinical research purposes (i.e., 5 years).		
✓	Explain that the questionnaire contains questions about experience of care and answers to these questions will only be visible to researchers (not to the patients' clinicians).		
✓	Explain that, in case of consent withdrawal, data will be no longer used for future activities of the study. However, the use of data will be valid for everything done before the withdrawal (e.g. analyses, scientific publications).		
Q3	**How can I make sure that I provide the patient with all relevant information for choosing properly and giving truly informed consent?**		
	DOS		**DON'TS**
✓	Use the previous points as a checklist to ensure you provide all relevant information.	x	Don't ask for consent without going through all relevant points of the information material (this would not be "informed" consent).
✓	Ask patients whether they have understood all the information provided or need further clarifications.		
✓	Respect patients' decision if they decline.	x	Don't pressure patients into participating in any way.
		x	Don't make their participation feel a burden or an obligation.

Questionnaire administration phase: Q&As

Q1	**How can I make sure that the patient feels comfortable before starting to fill in the questionnaire?**		
	DOS		**DON'TS**
✓	Ensure the room is quiet and isolated and directly ask the patient whether he/she feels comfortable.	x	Don't administer the questionnaire before making sure that the patient is comfortable with the environment, the tablet, and the objective of the questionnaire (i.e., collect patient's feedback on QoL).
✓	Ensure the patients there is no need to have any experience using electronic devices.		
✓	Ensure the patients there are no right or wrong answers to the questionnaire.		
Q2	**How can I make sure that the patient has clearly understood the instructions on the questionnaire?**		

	DOS		DON'TS
✓	Explain clearly that the EUonQoL-Kit is to be filled out by the patients themselves and provide simple instructions on how to self-complete the questionnaire.		
Q3	**What should I do if the patient needs assistance in filling in the questionnaire?**		
	DOS		**DON'TS**
✓	Provide any necessary assistance and take notes of the type of support provided (e.g., use of tablet, interpretation of question).	x	When helping the patient, don't interpret the questions beyond what is explicitly stated to avoid them producing biased answers.
Q4	**What should I do if the patient gets slow or tired while filling in the questionnaire?**		
	DOS		**DON'TS**
✓	Be flexible in the administration process, allowing breaks or adjustments based on the patient's comfort.	x	Don't rush patients through the questionnaire.
✓	Provide them with the necessary time to comprehend and respond.		
✓	Respect the patient's time and energy.		
Q5	**What should I do if the patient finds certain questions emotionally challenging?**		
	DOS		**DON'TS**
✓	Be available to offer support but respect boundaries and reassure they can take their time and breaks.	x	Don't push patients to discuss aspects of their life that make them uncomfortable.
		x	Don't dismiss or trivialize any concerns raised by patients

Supplementary Information 2. E-tools and procedures for patient registration and data collection

Patient registration, random allocation to the subsamples shown in Table 4, and eCRF data collection will be centralised through a CRF.net platform (Istituto Nazionale Tumori, IRCCS - Fondazione G. Pascale, Napoli (INT-NA), GPL v3 license), accessible to investigators and data managers of each clinical centre. Questionnaires and patient-reported sociodemographic forms will be filled out on tablet devices through a dedicated mobile app (Clinical Research Technology - CRT, Salerno (Italy)). For each registered patient, the CRF.net platform will generate a QR code that will be scanned with the tablet to allow each patient to complete the assigned questionnaires and forms. A paper version of the questionnaire will be downloadable via the platform in the event that the electronic version cannot be used due to force majeure. The dynamic administration of the EUQoL-Kit will be performed through the integration of a CAT-engine provided by the European Organization for Research and Treatment of Cancer (EORTC, Bruxelles, Belgium). For each enrolled patient, participation in the study will be considered concluded after completion of the expected questionnaires and forms.

Each centre will be provided with SOPs, specifically prepared for both Local Survey Coordinators, responsible for supervising the survey process, and Data Collectors, responsible for patient enrolment and questionnaire administration. In addition, professionals involved in the conduction of the study will be specifically trained about the procedures through ad hoc organized webinars.

Supplementary Information 3. Ethical, legal, and regulatory aspects

This study was designed and shall be implemented and reported in accordance with national and European legal and ethical requirements. Eligible subjects may only be included in the study after providing written Ethics Committee (EC)-approved informed consent, to be obtained before conducting any study-specific procedures (i.e., all the procedures described in the present protocol).

To guarantee a high level of scientific and ethical conduct, each centre has received specific support for the application of the study protocol to the local Ethics Committee. In addition, the following regulatory actions are implemented: i) a formal remote site initiation visit to all participating centres to discuss the study protocol and procedures; ii) centralised remote and on-site data monitoring visits to verify data completeness, consistency, and accuracy.

Supplementary Information 4. Data management and confidentiality

Data will be managed and curated in accordance with the EU regulation 2016/679. A data sharing agreement has been signed to allocate tailored roles and responsibilities emerged from the data protection impact assessment. Data will be captured in pseudonymized form and stored via cloud services at INT-NA, appointed as data processor under article 28 GDPR. The key to the identification code list will only be available to the local clinical centre. Confidentiality will be ensured by the local principal investigator according to research guidelines. Pseudo-anonymized data will be stored until the end of the project. In any case, after 5 years from data collection, all personal information related to the study, including informed consents, will be anonymized/destroyed according to the Ethics Code on data processing for statistics or scientific research purposes issued by the Italian Data Protection Authority under article 20, par. 4, LD 101/2018. Anonymized data will be made available as open as possible.