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Phase III study of the European Organisation for Research and Treatment of Cancer Quality of Life cancer survivorship core questionnaire

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Abstract

Purpose The purpose of this study is to develop a European Organisation for Research and Treatment of Cancer Quality of Life Group (EORTC QLG) questionnaire that captures the full range of physical, mental, and social health-related quality of life (HRQOL) issues relevant to disease-free cancer survivors. In this phase III study, we pretested the provisional core questionnaire (QLQ-SURV111) and aimed to identify essential and optional scales.

Methods We pretested the QLQ-SURV111 in 492 cancer survivors from 17 countries with one of 11 cancer diagnoses. We applied the EORTC QLG decision rules and employed factor analysis and item response theory (IRT) analysis to assess and, where necessary, modify the hypothesized questionnaire scales. We calculated correlations between the survivorship scales and the QLQ-C30 summary score and carried out a Delphi survey among healthcare professionals, patient representatives, and cancer researchers to distinguish between essential and optional scales.

Results Fifty-four percent of the sample was male, mean age was 60 years, and, on average, time since completion of treatment was 3.8 years. Eleven items were excluded, resulting in the QLQ-SURV100, with 12 functional and 9 symptom scales, a symptom checklist, 4 single items, and 10 conditional items. The essential survivorship scales consist of 73 items.

Conclusions The QLQ-SURV100 has been developed to assess comprehensively the HRQOL of disease-free cancer survivors. It includes essential and optional scales and will be validated further in an international phase IV study.

Implications for Cancer Survivors The availability of this questionnaire will facilitate a standardized and robust assessment of the HRQOL of disease-free cancer survivors.

Keywords Patient reported outcomes · Health-related quality of life · Cancer survivor · Survivorship questionnaire · Disease-free · Oncology

Introduction

Given the steady increase in the number of people who are living beyond cancer (cancer survivors), attributed to early detection, improved treatments, and the ageing of the population [1], there is a growing interest in evaluating their health-related quality of life (HRQOL) [2]. Increasingly,

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clinical trials and comparative effectiveness studies are being designed to include long-term follow-up to assess, in addition to survival, HRQOL, and late effects of treatment. In order to integrate HRQOL in such studies, the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group (QLG) has embarked on a project with the primary objective to develop an HRQOL assessment strategy that captures the full range of issues relevant to disease-free cancer survivors, both in general and for specific cancer sites [3].

The conceptual framework we employed for the development of our assessment strategy follows the World Health Organization (WHO) definition of health, dating from 1948, combined with the Medical Outcomes study (MOS) framework [4]. In this framework, we recognize three key dimensions of health: physical, mental, and social. Our survivorship measurement strategy is intended to be used among cancer survivors, treated with curative intent, who are at least 1 year post-treatment (with the exception of maintenance treatment), and believed to be disease-free (i.e. have no evidence of active disease). It includes a cancer survivorship core questionnaire that is intended for a wide range of cancer survivor populations, which can be used as a standalone questionnaire or can be supplemented with a cancer site-specific (survivorship) module [3] and/or selected items from the EORTC QLG item library [5].

Our questionnaires are targeted at disease-free survivors who are 1 year or more post-treatment, as we previously found evidence that both physical and psychosocial health issues tend to stabilize after this period [3]. This also marks the end of the early survivorship period in which patients often have dealt with the initial emotions surrounding their diagnosis and acute treatment-related symptoms, are confronted with the more chronic problems associated with their disease and its treatment, and might be for many of them the beginning of finding meaning in their experience of having had cancer.

We have previously reported on the identification of the issues relevant for disease-free cancer survivors [3], which is the first phase in the development of the EORTC QLG's four-phase process of questionnaire development [6]. In the second phase, these issues were converted into questionnaire items. In this paper, we present the results of phase III of the EORTC questionnaire development in which we pre-tested and further developed the preliminary EORTC QOL cancer survivorship core questionnaire, the QLQ-SURV111. To meet the needs for a shorter version of the survivorship questionnaire that is suitable for evaluating long-term HRQOL outcomes in clinical trials and routine clinical assessments, we also identified essential scales which always need to be included when assessing HRQOL in cancer survivors and optional scales which can be added to provide a more complete picture of the HRQOL of cancer survivors.

Methods

Preliminary development of the QLQ-SURV111

Phase I of *The development of an EORTC QOL cancer survivorship questionnaire* consisted of two sub-phases: phases 1a and 1b. In phase 1a, we generated an exhaustive list of all HRQOL issues relevant to disease-free cancer survivors irrespective of their cancer diagnosis and irrespective of whether they were generic issues or specific to particular cancer diagnoses. In the process of compiling the list, two sources were consulted: the literature (134 studies) and cancer survivors ($N = 117$). In phase 1b, the resulting list of 267 issues was rated for relevance by 458 cancer survivors and 89 healthcare providers. This resulted in a list of 116 generic survivorship issues, of which 2 were sex-specific [3].

In phase II, we deleted or rephrased issues of the generic survivorship issue list that were rated as redundant, unclear, or upsetting or did not fit in our conceptual framework. We also carried out preliminary factor analyses to identify redundant issues. The remaining issues were operationalized into questionnaire items using the four-point Likert-type response scale and 1-week or 4-week time frame as typically used for EORTC HRQOL questionnaires. The 1-week recall period is for symptoms that, if present, typically will have occurred in the past week, like feeling tired or having swelling in legs, ankles, or feet. This 1-week time frame is more sensitive to change than longer recall periods [7]. However, it is less suitable for sexual issues, as many people do not engage in sexual activities on a weekly basis. Therefore, the EORTC QLG has chosen during the development of its questionnaire to apply a 4-week time frame for all issues related to sexual functioning or problems [8, 9]. Two additional reference points were added to accommodate certain questions: "Since the diagnosis and treatment of your cancer" and "Because of your experience with cancer".

Rather than developing new items, if available, relevant items with appropriate content were selected from the EORTC QLG item library [5] or were based on items from existing patient-reported outcome measures. This resulted in a provisional survivorship core questionnaire, the QLQ-SURV111 (see Table 1). The QLQ-SURV111 consists of 111 items and retained 25 of the original items from the QLQ-C30 (excluding only those items that assessed acute symptoms), 9 additional items from the EORTC Computer Adaptive Test (CAT) item bank [10], and a range of generic survivorship issues (i.e. issues not specific to a given cancer diagnosis). The QLQ-SURV111 was translated into Bengali, Portuguese (Brazil), Danish, Dutch, French, German, Greek, Hebrew, Icelandic, Italian, Norwegian, Polish, Spanish, and Swedish according to standard EORTC procedures

Table 1 Items and hypothesized scales of the QLQ-SURV111 and confirmatory factor analyses fitting results of the hypothesized scales

Hypothesized scale	Item	C30/CAT
Physical functioning *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.983, CFI: 0.987*	
S1	Do you have any trouble hiking 3 km on uneven surfaces?	CAT
S2	Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	CAT
S3	Do you have any trouble running a short distance, such as to catch the bus?	CAT
S4	Do you have any trouble running fast?	CAT
S5	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	C30
S6	Do you have any trouble taking a long walk?	C30
S7	Do you have any trouble taking a short walk outside of the house?	C30
S8	Do you need to stay in bed or a chair during the day?	C30
S9	Do you need help with eating, dressing, washing yourself or using the toilet?	C30
Fatigue *(symptom scale)*	***CFA: 1 factor model*** *TLI: 0.996, CFI: 0.998*	
S10	Have you felt exhausted?	CAT
S11	Were you tired?	C30
S12	Have you felt weak?	C30
S13	Did you need to rest?	C30
S14	Have there been moments when you suddenly felt very tired?	
Sleep problems *(symptom scale)*	***CFA: 1 factor model*** *TLI: 0.961, CFI: 0.987*	
S15	Have you had difficulty falling asleep?	
S16	Have you had trouble sleeping?	C30
S17	Have you woken up during the night?	CAT
S18	Have you woken up too early?	CAT
Pain *(symptom scale)*		
S19	Have you had aches or pains in your joints?	
S20	Have you had aches or pains in your muscles?	
S21	Have you had pain?	C30
S68	Did pain interfere with your daily activities?	C30
Raynaud *(symptom scale)*		
S22	Have your hands and/or feet been sensitive to hot and cold?	
S23	Have you had pale/cold fingers or toes?	
Neuropathy *(symptom scale)*		
S24	Have you had tingling or numbness in your fingers or hands?	
S25	Have you had tingling or numbness in your toes or feet?	
Skin problems *(symptom scale)*		
S26	Have you had nail problems (change of colour, splitting nails, inflammation, losing the whole nail)?	
S27	Have you had skin problems (e.g. itchy, dry, flaky)	
S28	Has your skin been thin?	
Leg problems *(symptom scale)*		
S29	Have you experienced restless legs?	
S30	Have you had trouble standing for a long time?	
S31	Have you had swelling in your legs, ankles or feet?	
Muscle problems *(symptom scale)*		
S32	Have you had muscle cramps?	
S33	Have you had muscle weakness?	
Various physical symptoms *(single item symptom scales)*		
S34	Have you felt cold?	
S35	Have you had acid indigestion or heartburn?	
S36	Have you felt ill or unwell?	
S37	Were you short of breath?	C30
S71	Have you had difficulty controlling your weight?	
Body image *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.994, CFI: 0.997*	
S38	Have you felt unattractive?	
S39	Have you felt older than your age?	

Table 1 (continued)

Hypothesized scale	Item	C30/CAT
S40	Have you been dissatisfied with your physical appearance?	
S41	Have you felt that you could not trust your body?	
S42	Have you felt embarrassed about your body?	
Cognitive functioning *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.995, CFI: 0.998*	
S43	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	C30
S44	Have you had difficulty remembering things?	C30
S45	Have you had difficulty performing two tasks simultaneously, e.g. having a conversation while cooking?	CAT
S46	Have you had problems thinking clearly?	
S47	Have you felt that your ability to think (to process information) has slowed down?	
Emotional functioning *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.940, CFI: 0.957*	
S48	Did you worry?	C30
S49	Did you feel tense?	C30
S50	Did you feel depressed?	C30
S51	Have you felt frustrated?	
S52	Have you felt angry?	
S53	Did you feel irritable?	C30
S54	Have you had mood swings?	
S55	Have you felt the need for professional psychological help?	
Health distress *(symptom scale)*	***CFA: 1 factor model*** *TLI: 0.982, CFI: 0.989*	
S56	Have you worried about your treatment causing (future) health problems?	
S57	Have you worried that your family members are at risk of getting cancer?	
S58	Have you worried about dying?	
S59	Have you worried about getting another type of cancer?	
S60	Have you worried about your cancer coming back or that it may spread to other parts of your body?	
S61	Have you worried about your health?	
Fertility *(symptom scale)*		
S62	Have you been concerned about your ability to have children?	
Health awareness *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.689, CFI: 0.896*	
Symptom awareness (functional scale)		
S72	Have you been alert for symptoms that may signal a return of your cancer?	
S73	Have you been more likely to contact your GP when you experience symptoms?	
Positive health behaviour change (functional scale)		
S74	Have you taken better care of yourself?	
S75	Have you made positive life style changes (e.g. more exercise, healthy food, cutting down smoking)?	
Negative health outlook *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.957, CFI: 0.974*	
S63	Have you felt you were still a cancer patient?	
S76	Have cancer-related physical problems interfered with your life?	
S77	Have you felt uncertain about the future?	
S78	Have you worried about your health in the future?	
S95	Have you had to limit your life plans or goals?	
S96	Do you feel that your life has been on hold?	
Posttraumatic growth *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.899, CFI: 0.928*	
	CFA: 3 factor model *TLI: 0.961, CFI: 0.976*	
Positive life outlook (functional scale)		
S79	Have you appreciated life more?	
S80	Has the experience of cancer helped you to distinguish between important and unimportant things in life?	
S81	Have you been better able to cope with problems?	
S94	Do you feel that your life has more purpose?	
Positive impact on behaviour towards others (functional scale)		
S82	Have you been more willing to help others?	
S83	Have you been more understanding of other people's feelings?	
Positive social functioning (functional scale)		
S97	Are your relationships with family and friends stronger?	

Table 1 (continued)

Hypothesized scale	Item	C30/CAT
S98	Is your relationship with your partner stronger?	
S99	Are your relationships with family and friends more important to you?	
Meaning of cancer *(functional scale)*		
S84	Have you given a deeper meaning to your having (had) cancer?	
Role functioning		
Work (functional scale)	***CFA: 1 factor model*** *TLI: 0.969, CFI: 0.990*	
S89	Have your career/job opportunities been limited?	
S90	Do you work fewer hours than you would like?	
S91	Do you perform your work less well?	
S93	Do you lack support and understanding from colleagues and or/management?	
Role functioning (functional scale)		
S65	Have you been limited in doing physically demanding recreational activities (e.g. swimming or cycling)?	CAT
S66	Were you limited in doing either your work or other daily activities?	C30
S67	Were you limited in pursuing your hobbies or other leisure time activities?	C30
Social functioning-negative *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.868, CFI: 0.934*	
Social interference (symptom scale)		
S69	Has your physical condition or medical treatment interfered with your family life?	C30
S70	Has your physical condition or medical treatment interfered with your social activities?	C30
Social isolation (symptom scale)		
S85	Have you felt that the impact of having (had) cancer is **not** understood by family and friends?	
S86	Have you felt that that the impact of having (had) cancer is **not** understood by acquaintances?	
S100	Do you feel that people treat you differently?	
	conditional item	
S87	Have you worried about the impact of your cancer on your children?	
Financial issues		
S70	Has your physical condition or medical treatment caused you financial difficulties?	C30
	Conditional items	
S88	Have you had problems with (obtaining) insurance, loans, and/or a mortgage?	
S92	Have you lost income?	
Sexual problems and functioning *(functional scale)*	***CFA: 1 factor model*** *TLI: 0.748, CFI: 0.874*	
Sexual problems (symptom scale)		
S103	Have you had problems being sexually intimate?	
S104	Have you felt uncomfortable about being sexually intimate?	
S107	Have you avoided having sex?	
Sexual functioning (functional scale)		
S108	Have you been interested in sex?	
S109	Have you been sexually active?	
	Conditional items	
S101	Have you had problems becoming sexually aroused?	
S102	Has sexual activity been enjoyable for you?	
S105	Females only: Have you experienced a dry vagina during sexual activity?	
S106	Males only: Have you had problems getting or maintaining an erection?	
Global health status		
S110	How would you rate your overall quality of life during the past week?	C30
S111	How would you rate your overall health during the past week?	C30

In the table, the items and hypothesized scales of the QLQ-SURV111 are presented. In case items were existing items from the EORTC QLQ-C30 or the EORTC CAT core, this is indicated with C30 or CAT. Further, the table presents the fitting results of the confirmatory factor analyses. *CFA* confirmatory factor analyses, *TLI* Tucker-Lewis Index, *CFI* comparative fit index, *C30* EORTC QLQ-C30, *CAT* EORTC CAT core

[11]. The phase I and II development process reports and paper [3] were peer-reviewed and formally approved by the EORTC QLG Protocol and Module Development Committee (PMDC) before the start of phase III.

Study sample

We recruited cancer survivors from hospitals and cancer registries from four geographic regions: English-speaking countries

(UK, Australia), Northern Europe (Belgium, Denmark, Germany, Iceland, the Netherlands, Norway, Sweden), Southern Europe (Cyprus, France, Greece, Israel, Italy, Spain), and outside Europe (Brazil, India). Eligible patients were those aged 18 years or older at the time of diagnosis who had sufficient command of their native language and did not have serious psychological or cognitive problems that would interfere with their ability to take part in the study. We recruited survivors with a range of cancer diagnoses, selected on the basis of their prevalence and/or survival rates. These included 11 diagnoses: breast, colorectal, prostate, bladder, gynaecological (ovarian, cervical, and endometrial), head and neck, lung, and testicular cancer, lymphoma, melanoma, and glioma. Eligible patients had completed their treatment with curative intent (both primary treatment and treatment of recurrent disease) 1 to 10 years earlier and were disease-free (i.e. no evidence of disease). They could be receiving maintenance therapies (e.g. hormonal treatment for primary breast cancer). Although low-grade glioma patients were not treated with curative intent and were not disease-free, they were included since they can have a very long period of survival (up to 16 years), and in the relatively long period between primary treatment and recurrence, they often do not receive any treatment [12, 13].

We employed purposive sampling to ensure an approximately equal distribution of survivors across diagnoses and time since treatment categories [6]. We distinguished four different time periods since end of last treatment (1 to < 2 years/2 to < 3 years/3 to < 5 years/5 to 10 years) and included all 11 diagnostic groups mentioned above. Based on the cancer diagnosis and time since of end of treatment, a recruitment matrix was created consisting of 11 by 4 cells. We aimed to include five participants per cell. In addition, the sample was stratified by geographical region. For breast, colorectal, and prostate cancer, our goal was to include 20 survivors per cell (80, in total, per tumour type), as we were simultaneously developing cancer site-specific survivorship modules for these survivor populations. We will report on the development of these modules in subsequent papers. In total, our goal was to recruit 400 survivors into the study.

Procedures

Eligible survivors were given written information about the objectives and procedures of the study and were invited to participate in accordance with ethical and governance requirements of each participating centre. Ethical approval was gained at each site. Basic sociodemographic data collected at study entry included age, sex, education, employment status, and living arrangement. Clinical data collected included primary diagnosis, stage of disease, type of treatment, date of diagnosis, date of start and completion of primary treatment, previous disease recurrence(s), date of completion of treatment for last recurrence, and comorbidity as assessed by the Charlson Index [14].

All participants completed the QLQ-SURV111 and were asked to indicate for each item whether they would include it in a survivorship questionnaire (response options yes/no). If participants commented on any items while they completed the questionnaire or had problems understanding any items, this was noted by the interviewer for further analyses. After completing the questionnaire, the participants were asked to answer a series of "debriefing" questions to determine if any of the candidate items of the QLQ-SURV111 were too difficult, confusing, upsetting, or redundant, or if important issues were missing.

Paper versions of the questionnaires were completed: (1) in a face-to-face interview setting; (2) in a telephone interview setting whereby the respondent had the questionnaire at his or her disposal; or (3) by mail, without a subsequent interview. Following the translation procedures of the EORTC [11], our goal was to have at least 10 questionnaires per translation completed in an interview setting in order to inquire in detail about the comprehensibility of each of the translations. The telephone setting was an option for survivors who preferred not to travel to the hospital. We included the subsample of survivors who completed the questionnaire by mail without an interview to ensure that we had sufficient cases for the requisite psychometric analyses.

Criteria for item selection based on descriptive statistics

The questionnaire data were analysed using descriptive statistics according to the EORTC guidelines [6]: items were retained when (1) at least 60% of the sample had indicated that the item should be included in the next version of the QLQ-SURV111 and (2) the observed scale range of the item should be greater than 2 points. The remaining EORTC criteria were applied per subgroup: (3) mean item score > 1.5 (on a four-point scale ranging from 1 to 4, with 1 being "not at all" and 4 "very much"); (4) prevalence of the item (score of 2 or greater) > 30%; and (5) item completed by at least 95% of the respondents. Subgroups were as follows: time since last treatment (1 to < 2 years; 2 to < 3 years; 3 to < 5 years; 5 to 10 years); tumour stage at diagnosis (I; II; III; IV); treatment (no chemotherapy (CT) no radiotherapy (RT); RT only; CT only; RT + CT); hormonal therapy (current hormonal therapy (HT); HT past and current; never HT); age (younger than 40; 40 to < 50; 50 to < 60; 60 to < 70; 70 +); and sex (male; female). If the criteria were met in at least one of these subgroups, items were retained to ensure that all items relevant for each of these subgroups would be included in the final questionnaire.

Qualitative data analyses

To investigate whether there were any significant concerns expressed by patients about the questionnaire items (e.g. items that were upsetting or ambiguous), all debriefing

interviews and remarks on the questionnaires were analysed using QSR NVivo 10 software [15]. Each entry was classified according to cancer site, language, country, and educational level of the respondent. For details regarding the qualitative data analyses, see the technical appendix in Online Resource 1.

Proposed scale structure

Confirmatory factor analyses (CFA) were conducted in Mplus 6.1 [16] to examine the hypothesized scales (see Table 1) based on our three dimensional measurement model [3]. The conditional items (S62, S87, S88, S101, S102, S105, and S106) were excluded from these analyses. Each hypothesized scale was modelled in a separate factor model, as our sample was not large enough to evaluate all elements of our complete measurement model simultaneously. For the scales for which a factor model could not be fitted due to limited degrees of freedom (df), Cronbach's alpha or Spearman's r were calculated. In the cases where our hypothesized factor model did not fit well and we did not have an alternative hypothesis, we investigated the scale structure using exploratory factor analysis (EFA) in Mplus 6.1 [16] or correlational analyses in case of insufficient *df*. To test goodness of fit of the CFA and EFA models, the comparative fit index (CFI) and the Tucker-Lewis Index (TLI) were used. For both, values ≥ 0.97 indicate a good fit, between 0.95 and 0.97 an acceptable fit, and below 0.95 a poor fit [17]. For details of these analyses, see Online Resource 1.

Preliminary item reduction using item response theory (IRT) modelling

For the proposed scales of the QLQ-SURV111 consisting of five items or more, we applied IRT modelling to exclude redundant items, i.e. multiple items covering the same trait level or items that do not discriminate well between various trait levels. The IRT analysis was only carried out for the scales for which the CFA showed a good fit (unidimensionality). When this condition is fulfilled, items are expected only to be correlated because any covariation between them can be ascribed to their relationship with the latent trait, and when controlling for the latent trait, all pairs of items within a domain should be uncorrelated, and consequently the residual correlation should be below 0.2 [18]. To evaluate the scales of the QLQ-SURV111, we took the assessed trait levels of each of the response categories into account, using category threshold parameters (*b*). Items with high thresholds provide most information for respondents who score high on a particular trait, and items with low thresholds provide most information for respondents who score low on a particular trait. In case the thresholds are disordered (i.e. the *b2* is lower than *b1*), an item is weak, as it is not able to discriminate between different trait levels. The item discrimination parameter *a* informs how well an item is able to discriminate between various trait levels. For additional details regarding the IRT analyses, see Online Resource 1.

Essential and optional scales

To meet the needs for a shorter version of the survivorship questionnaire that is suitable for evaluating long-term HRQOL outcomes in clinical trials, we made a distinction between "essential" and "optional scales" of the QLQ-SURV. In the clinical trial context or routine clinical settings with repeated assessments over time, the measurement strategy would be to always include the essential scales and to have the optional scales available, if deemed useful. The full length questionnaire, including both the essential and optional scales, would be more suitable for use in observational/epidemiologic and intervention studies aimed at identifying and/or improving the long-term physical and psychosocial problems of cancer survivors or when specific populations are targeted like young survivors.

As the QLQ-C30 was primarily designed to evaluate HRQOL outcomes in clinical trials, we have based our selection of essential scales of the QLQ-SURV on their correspondence with the QLQ-C30 and its underlying constructs. Correspondence was evaluated by matching QLQ-SURV scales to the QLQ C30 dimensions based on degree of overlap in content between items in both questionnaires. Also scales that correlated 0.5 or higher with the QLQ C30 summary score [19] were added as essential survivorship scales, as they measure HRQOL constructs that are of importance to cancer survivors and are related to the HRQOL construct of the QLQ-C30 (for details, see Online Resource 1).

To validate our selection of essential versus optional scales, we conducted a Delphi survey [20–22] using DelphiManager software[23] with 3 groups of experts (patients, healthcare professionals (HCPs), and HRQOL researchers). In three consecutive rounds, these expert groups were asked to rate the importance of the scales of the QLQ SURV that had not already been identified as essential based on their correspondence with QLQ-C30 scales and/or correlation with the QLQ-C30 summary score [19]. Our goal was to include 23 experts per group, as Akins et al. [24] have shown that a group of 23 individuals with the same type of expertise can arrive at stable outcomes (for further details, see Online Resource 1).

The final set of essential QLQ-SURV scales consisted of scales that were originally C30 scales, whose item content by definition corresponded with that of QLQ-C30 items/scales, scales that correlated relatively highly (i.e. 0.5 or higher) with the QLQ-C30 summary score, and scales that were defined as essential based on expert consensus in the Delphi survey.

The essential and optional scales were grouped by time frame: i.e. each time frame starts with the essential scales in this time frame and ends with the optional scales in the same time frame. In addition, to rule out item-order effects between the QLQ-C30 and the QLQ-SURV, the order of the items existing in both questionnaires was placed in the same order [25, 26].

Pretesting the updated QLQ-SURV

The items that were reformulated and the updated order of items were pretested in semi-structured interviews held in the Netherlands, Belgium, the UK, Croatia, and Spain. We aimed to include 55 to 110 interviews, in total. The aim of this pretesting was to determine if any of the rephrased items were too difficult, confusing, or upsetting and whether the updated order of the questionnaire was acceptable.

Results

Survivor characteristics

Between January 2018 and April 2019, 515 cancer survivors from 27 centres in 17 countries completed the questionnaires, of whom 388 did so in a face-to-face setting or by telephone with an interviewer being present and 127 did so by mail. Twenty-three questionnaires were excluded because the survivors did not meet the inclusion criteria.

Table 2 reports the demographics and disease and treatment characteristics of the survivor sample ($N=492$). The mean age was 60 years (range 22 to 89 years), 46% were female, and mean time since last treatment was 3.8 years (SD 2.39 years). The median time needed to complete the questionnaire without the cancer site-specific modules and the debriefing questionnaires was 25 min.

Item selection based on descriptive statistics

All items of the provisional questionnaire were considered to be relevant and worthy of inclusion in the definitive version by 84 to 97% of the respondents. For all items, the range of responses was 3 response categories. Missing data analysis at the individual item level indicated that between 7 and 15% of the items related to sexuality were missing. As sexuality is an important aspect of HRQOL and missing responses to sensitive questions like sexuality are common with existing EORTC modules [27, 28], we did not exclude them from the questionnaire. For all other items, 5% or less had missing responses. The only exceptions were three conditional items about fertility (S62), loss of income (S92), and lack of support of colleagues (S93). However, we believe that the missingness for these

Table 2 Characteristics of the survivors included in the quantitative analyses

Survivors ($N=492$)	#	
Cancer site		
Breast	104	21%
Colorectal	102	21%
Prostate	97	20%
Bladder	21	4%
Glioma	24	5%
Gynaecological	24	5%
Head and neck	22	4%
Lung	23	5%
Lymphoma	36	7%
Melanoma	18	4%
Testicular	21	4%
Time since completing last treatment		
1 to 2 years since last treatment	124	25%
2 to 3 years since last treatment	106	22%
3 to 5 years since last treatment	143	29%
5 to 10 years since last treatment	119	24%
Region		
English speaking	79	16%
Northern Europe	159	32%
Southern Europe	174	35%
Outside Europe	80	16%
Age		
Mean ± SD (years)	60	13
Younger than 40 years	42	9%
40 to < 50 years	55	11%
50 to < 60 years	108	22%
60 to < 70 years	159	32%
70 years and older	127	26%
Sex (%)		
Male	268	54%
Marital status[a] *(%)*		
Married/living with partner	372	76%
In relationship living apart	8	2%
Widower	41	8%
Divorced/separated	31	6%
Single	50	10%
Living arrangements (%)		
Alone	84	17%
Partner	358	73%
Children under 18	71	14%
Children above 18	88	18%
Parents	16	3%
Others	17	3%
Education (%)		
None or primary school only	112	23%
High school	193	39%
College or university	176	37%

Table 2 (continued)

Survivors ($N=492$)	#	
Work status (%)		
Full-time	142	29%
Part-time	59	12%
Unemployed	19	4%
Homemaker	33	7%
Student	6	1%
Retired	202	41%
Disabled	22	4%
Others	16	3%
Time since completing primary treatment		
Mean (SD) (years)	4.3	3.21
Time since completing last treatment		
Mean (SD) (years)	3.8	2.39
Disease recurrence (%)		
Yes	55	11%
Tumour stage[b] (%)		
Stage I	129	26%
Stage II	149	30%
Stage III	130	26%
Stage IV	41	8%
Stage unknown/not determined/missing	19	4%
Therapy[a] (%)		
Surgery	387	79%
Chemotherapy	271	55%
Radiotherapy	242	49%
Hormonal therapy	106	22%
Active surveillance	43	9%
Monoclonal antibodies	33	7%
Stem cell transplantation	6	1%
Current maintenance therapy	57	12%

N number, *SD* standard deviation

[a]Categories are not mutual exclusive, e.g. one can be a widower and have a new relationship

[b]For glioma survivors grading was used, we included per tumour grade: grade 1, 1 survivor; grade 2, 5 survivors; grade 3, 16 survivors; grade 4, 2 survivors

items was primarily related to the instructions used, which we have subsequently refined (e.g. for item S62, fertility, we have added the instruction "If you did/do not want to have (more) children, please select "not applicable".

The items regarding taking a short walk (S7), help with self-care (S9), nail problems (S26), and thin skin (S28) did not reach the thresholds of the decision rules for inclusion (mean > 1.5 and prevalence ratio > 30%) in any of the relevant subgroups. Since item S7 and S9 were QLQ-C30 items, they were evaluated further in the IRT analyses before taking any decisions about in- or exclusion. Items S26 and S28 were excluded from the QLQ-SURV.

Qualitative data analysis

Less than 3% of the sample considered the questionnaire too lengthy. In general, we detected relatively few problems with the questionnaire. Based on the qualitative analyses we updated 11 items (see Table 1 of Online Resource 1 for the updated items). We rephrased the introductory text of items S69 and S70 from "Has your physical condition or medical treatment with your *family life/ social activities* to "Have cancer-related physical problems…", as participants thought these items referred to their active treatment period. Therefore, these items became too similar to S76 "Have cancer-related physical problems interfered with your life?" For that reason, we deleted the more generic item S76. The items relating to sexual issues were considered too personal by approximately 6% of the respondents. However, given the sensitive nature of sexuality for many people, we considered this acceptable and chose to retain these items in the QLQ-SURV. Details regarding the updated items can be found in Online Resource 1.

Proposed scale structure

For the majority of scales, we first tested a one-factor model (see Table 1 for scales and model fit results). Based on these findings and further modelling, (1) the health awareness scale was converted into two scales: symptom awareness and positive health behaviour change; (2) posttraumatic growth was divided into three scales: positive social functioning, positive life outlook, and positive impact on behaviour towards others; (3) social functioning negative was split into two scales and one single item: social interference, social isolation, and treated differently; and (4) the items assessing sexuality scale were divided into a sexual problems and a sexual functioning scale. Details of these analyses can be found in Online Resource 1 including the factor loadings of the items of the scales, Cronbach's alpha and Pearson's *r*.

As the symptoms assessed by items S19, S20, S22-S25, S27, and S29-S37 can be caused by multiple treatments and also because different types of chemotherapy can result in different constellations of symptoms, we had no clear hypotheses about the factor structure underlying these symptoms. Therefore, we carried out EFA to investigate whether symptoms tended to cluster. As the results of the EFA were not interpretable (for details, see Online Resource 1), we decided to treat this set of 15 symptoms as a simple, additive checklist. The checklist can be used to see which of chronic physical side effects are present, and when they are present to see how severe they are. The total score of the symptom checklist will give an indication of symptom burden. A symptom checklist seemed more appropriate than a psychometrically coherent subscale, because we could not assume that items within these factors correlated strongly with one

another due to a common cause, which is the underlying assumption in factor analyses [29–32].

Preliminary item reduction using IRT modelling

The scales assessing physical functioning, fatigue, body image, cognitive functioning, emotional functioning, and health distress consisted of five items or more and were unidimensional, with residual correlations well below 0.2, and therefore met the criteria to carry out IRT analyses.

Table 4 in Online Resource 1 shows the parameter estimates from the IRT modelling for the six QLQ-SURV111 scales and the result section of Online Resource 1 explains the findings of the IRT analyses in more detail.

Physical functioning scale

IRT analyses (see Online Resource 1 for further details, including the parameter estimates, the category response curves, and the information curves) showed that items S7 (trouble taking a short walk) and S8 (stay in bed or chair), both originating from the QLQ-C30, provide most information for survivors who score poorly on physical functioning, that item S9 (help with eating, dressing, etc.) was weak, and that items S8 and S9 were the least discriminative items of the physical functioning scales. Items S1 and S6 and items S2, S3, and S4 covered the same levels of physical functioning. The IRT analyses indicated further that item S7 was highly informative for poor physical functioning. Since, from a clinical perspective, information about a survivor's poor physical functioning is very relevant, we decided to retain this item in the survivorship questionnaire. Combining the results from the IRT analysis with the percentage of missing responses, the percentage of respondents who indicated that they would include the items in the questionnaire, and the number of comments in the debriefing interview led to the retention of items S2, S3, S5, S6, and S7. Items S8 and S9 did not appear to provide clear information on the level of physical functioning and therefore will not be used to calculate the physical functioning level in survivors. We will include these two items as optional in the QLQ-SURV to still be able to calculate physical functioning as assessed by the QLQ-C30. In phase IV, the international field study, we will investigate in a larger sample if these two items indeed should be excluded in the assessment of physical functioning in survivors.

Fatigue

The parameter estimates of the fatigue scale are presented in Online Resource 1. As item S14 (sudden fatigue) was the least discriminative item and targeted levels of fatigue already assessed by the other items, we have excluded it from the QLQ-SURV.

Body image

Items S38 (feeling unattractive), S42 (feeling embarrassed), and especially S41 (cannot trust body) were the least discriminative items (see Online Resource 1). Further, items S38 and S42 items appeared to cover a smaller bandwidth of the trait body image, and in addition, items S38 and S41 were considered difficult to understand or unnecessary. Therefore, we retained only items S39 (feeling older than age) and S40 (dissatisfied with appearance) to assess body image.

Cognitive functioning

Item S45 (performing two tasks simultaneously) showed the lowest discriminative value compared to the other cognitive items that we added to the two-item cognitive functioning scale of the QLQ-C30 (see Online Resource 1). In addition, this item targets levels of cognitive functioning already assessed by the other items. Therefore, this item was excluded.

Emotional functioning

Item S55 (need for psychological help) had the lowest discriminative value and was a weak item as can be seen in Online Resource 1. For these reasons, S55 was excluded.

Health distress

Items S56–S58 did not discriminate well on the latent trait health distress (see Online Resource 1). This suggests that fear of late effects (S56), fear for cancer among family members (S57), and fear of dying (S58) are not assessing the same construct as the other three items assessing fear of cancer for oneself (S59 and S60) and fear for own health (S61). Further inspection of item S56 "Have you worried about your treatment causing (future) health problems?" and the qualitative analyses showed that this item needed to be reworded, as survivors are no longer under active treatment. Therefore, it was rephrased to read: "Have you worried that your previous cancer treatment may cause (more) health problems in the future?" We have added this rephrased item and the item about dying (S58) to the Negative Health Outlook scale, as it seemed more appropriate there. In phase IV, we will be able to test whether this was appropriate. Fear about cancer in family members will be scored as a single item scale.

Resulting EORTC survivorship core questionnaire (QLQ-SURV100)

After deletion of the items whose prevalence was very low (S28 and S26) and/or were redundant (S1, S4, S14, S38, S41, S42, S45, S55, and S76), 100 items remained. Some of the items were rephrased and instructions for conditional items were added based on qualitative and missing data analyses. This cancer survivorship core questionnaire (QLQ-SURV100) consists of 13 functional scales assessing physical functioning (5 + 2 optional items to assess QLQ-C30 physical functioning), body image (2), cognitive functioning (4), emotional functioning (7), symptom awareness (2), positive health behaviour change (2), positive life outlook (4), positive impact on behaviour towards others (2), positive social functioning (2), work (4), role functioning (3), sexual functioning (2), and global quality of life (2); 9 symptom scales assessing fatigue (4), sleep problems (4), pain (2), health distress (3), negative health outlook (7), social interference (2), social isolation (2), sexual problems (2), and sexual problems when sexually active (2), a symptom checklist of chronic side effects of treatment (17); and 12 single items assessing financial difficulties, loss of income, problems (insurances, loans, and mortgages), deeper meaning, fertility, partner relation stronger, sexual pleasure, sexual problems (female), sexual problems (male), treated differently, worry impact of cancer on children, and risk of cancer in family members. Of these 100 items, 14 are conditional (see Table 3).

Essential and optional scales

Table 4 presents the correlation between the survivorship scales and the QLQ-C30 summary score. The symptom checklist, negative health outlook, work, body image, and health distress scales all correlated 0.5 or higher with the QLQ-C30 sum score. Together with financial impact and global health status, the scales that are included both in the QLQ-C30 and the SURV100, these scales form the essential scales of the QLQ-SURV100. In total, these scales comprise 67 items.

In total, 113 experts participated in the Delphi survey: 34 patient representatives, 43 healthcare professionals, and 36 researchers. Ninety-three percent of the experts participated in round 2 and 91% in round 3. Based on the ratings of the experts, loss of income; symptom awareness; problems with insurances, loans, and mortgages; and social isolation were added to the essential scales (see Table 3 for an overview of the items included in the essential scales), bringing the total number of items included in the essential scales to 73. More details about the selection of essential scales are reported in Online Resource 1.

Pretesting the updated QLQ-SURV100

In total, 76 survivors completed the semi-structured interview. The interviews indicated that the revised item ordering is acceptable and that there were no issues with the updated items. However, respondents did indicate that the instruction at the start of the questionnaire needed to be improved to draw their attention to the fact that the questionnaire consists of multiple time frames. Finally, because many respondents spontaneously wrote comments at the end of the questionnaire, we have decided to include an open-ended question that offers respondents the opportunity to provide additional information (e.g. about how their HRQOL has also been impacted by other life events, like ageing, other diseases, etc.).

An overview of all major changes to the items and scales of the QLQ-SURV111 can be found in Online Resource 2.

Discussion

The QLQ-SURV100 was developed, according to the rigorous standards of the EORTC [6] and based on a conceptual framework including all aspects of HRQOL, to comprehensively assess the HRQOL of disease-free cancer survivors at least 1 year after completion of treatment with curative intent. This core questionnaire can be used as a stand-alone questionnaire or in combination with cancer site-specific (survivorship) modules or items from the EORTC item library. Although a questionnaire with 100 items is quite long, only 1.4% of the survivors in this phase III study indicated that they felt that the questionnaire was too long. In many studies, different questionnaires are combined (e.g. HRQOL, symptoms, fatigue, work or relationship issues, positive growth after cancer) that often add up to much more than 100 items. As the QLQ-SURV100 is designed to be comprehensive, in principle, no additional questionnaires, except for cancer site-specific modules or items and questionnaires that need to be included in clinical trials for regulatory requirements, are necessary to assess HRQOL. Further, we assume that, in most studies and clinical practice, the HRQOL of survivors who are 1 year or longer after treatment completion will not be assessed as frequently as in patients who are still in in the active treatment phase. Only few long-term trials collect follow-up data more frequently than once a year [33].

Nevertheless, to accommodate the request from researchers in the field to develop a shorter questionnaire, we have made a distinction between essential and optional scales. The essential survivorship scales are those scales that measure the same HRQOL construct as the QLQ-C30 and the scales that were regarded as essential by patient representatives, healthcare professionals, and cancer researchers. As the

Table 3 Scales and items of the QLQ-SURV100

Scales QLQ-SURV100			
	Item	*Item # in QLQ-SURV111*	Essential
Physical functioning *(functional scale, also included in C30)*			
PF1	Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	*S2*	*e*
PF2	Do you have any trouble running a short distance, such as to catch the bus?	*S3*	*e*
PF3	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	*S5*	*e*
PF4	Do you have any trouble taking a long walk?	*S6*	*e*
PF5	Do you have any trouble taking a short walk outside of the house?	*S7*	*e*
PF6	Do you need to stay in bed or a chair during the day?	*S8*	C30
PF7	Do you need help with eating, dressing, washing yourself or using the toilet?	*S9*	C30
Cognitive functioning *(functional scale, also included in C30)*			
CF1	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	*S43*	*e*
CF2	Have you had difficulty remembering things?	*S44*	*e*
CF3	Have you had problems thinking clearly?	*S46*	*e*
CF4	Have you felt that your ability to think (to process information) has slowed down?	*S47*	*e*
Emotional functioning *(functional scale, also included in C30)*			
EF1	Did you feel tense?	*S49*	*e*
EF2	Did you worry?	*S48*	*e*
EF3	Did you feel irritable?	*S53*	*e*
EF4	Did you feel depressed?	*S50*	*e*
EF5	Have you felt frustrated?	*S51*	*e*
EF6	Have you felt angry?	*S52*	*e*
EF7	Have you had mood swings?	*S54*	*e*
Role functioning *(functional scale, also included in C30)*			
RF1	Were you limited in doing either your work or other daily activities?	*S66*	*e*
RF2	Were you limited in pursuing your hobbies or other leisure time activities?	*S67*	*e*
RF3	Have you been limited in doing physically demanding recreational activities (e.g. swimming or cycling)?	*S65*	*e*
Fatigue *(symptom scale, also included in C30)*			
FA1	Did you need to rest?	*S13*	*e*
FA2	Have you felt weak?	*S12*	*e*
FA3	Were you tired?	*S11*	*e*
FA4	Have you felt exhausted?	*S10*	*e*
Sleep problems *(symptom scale, also included in C30)*			
SL1	Have you had trouble sleeping?	*S16*	*e*
SL2	Have you woken up during the night?	*S17*	*e*
SL3	Have you woken up too early?	*S18*	*e*
SL4	Have you had difficulty falling asleep?	*S15*	*e*
Pain *(symptom scale, also included in C30)*			
PA1	Have you had pain?	*S21*	*e*
PA2	Did pain interfere with your daily activities?	*S68*	*e*
Social interference *(symptom scale, also included in C30)*			
SIf1	Have cancer-related physical problems interfered with your family life?	*S69*	*e*
SIf2	Have cancer-related physical problems interfered with your social activities?	*S70*	*e*
Body Image *(functional scale)*			
BI1	Have you felt older than your age?	*S39*	*e*
BI2	Have you been dissatisfied with your physical appearance?	*S40*	*e*
Symptom awareness *(functional scale)*			
SA1	Are you alert for symptoms that may signal a return of your cancer?	*S72*	*e*
SA2	Are you more likely to contact your doctor when you experience symptoms?	*S73*	*e*
Health distress *(symptom scale)*			
HD1	Have you worried about your cancer coming back or that it may spread to other parts of your body?	*S60*	*e*
HD2	Have you worried about getting another type of cancer?	*S59*	*e*
HD3	Have you worried about your health?	*S61*	*e*

Table 3 (continued)

Scales QLQ-SURV100			
Negative health outlook *(symptom scale)*			
NHO1	Have you worried that your previous cancer treatment may cause (more) health problems?	*S56*	*e*
NHO2	Have you worried about dying?	*S58*	*e*
NHO3	Have you felt you were still a cancer patient?	*S63*	*e*
NHO4	Have you felt uncertain about the future?	*S77*	*e*
NHO5	Have you worried about your future health?	*S78*	*e*
NHO6	Have you had to limit your life plans or goals?	*S95*	*e*
NHO7	Do you feel that your life has been on hold?	*S96*	*e*
Social isolation *(symptom scale)*			
SI1	Do you feel that your family and/or friends do **not** understand the impact of having (had) cancer?	*S85*	*e*
SI2	Do you feel that your acquaintances do **not** understand the impact of having (had) cancer?	*S86*	*e*
Symptom checklist: chronic side effects of cancer treatments			
SC1	Were you short of breath?	*S37*	*e*
SC2	Have you had aches or pains in your joints?	*S19*	*e*
SC3	Have you had aches or pains in your muscles?	*S20*	*e*
SC4	Have your hands and/or feet been sensitive to hot and cold?	*S22*	*e*
SC5	Have you had pale/cold fingers or toes?	*S23*	*e*
SC6	Have you had tingling or numbness in your fingers or hands?	*S24*	*e*
SC7	Have you had tingling or numbness in your toes or feet?	*S25*	*e*
SC8	Have you had skin problems (e.g. itchy, dry, flaky)?	*S27*	*e*
SC9	Have you experienced restless legs (uncontrollable urge to move your legs)?	*S29*	*e*
SC10	Have you had problems standing for a long time?	*S30*	*e*
SC11	Have you had swelling in your legs, ankles or feet?	*S31*	*e*
SC12	Have you had muscle cramps?	*S32*	*e*
SC13	Have you had muscle weakness?	*S33*	*e*
SC14	Have you felt cold easily?	*S34*	*e*
SC15	Have you had indigestion or heartburn?	*S35*	*e*
SC16	Have you felt ill or unwell?	*S36*	*e*
SC17	Do you currently have problems controlling your weight?	*S71*	*e*
Positive health behaviour change *(functional scale)*			
PHBC1	Do you take better care of yourself?	*S74*	
PHBC2	Have you made positive lifestyle changes (e.g. more exercise, healthy food, cutting down smoking)?	*S75*	
Posttraumatic growth scales (Positive life outlook, positive impact on behaviour towards others, positive social functioning)			
Positive life outlook *(functional scale)*			
PAf1	Do you feel that your life has more purpose?	*S94*	
PAf2	Do you appreciate life more?	*S79*	
PAf3	Has the experience of cancer helped you to distinguish between important and unimportant things in life?	*S80*	
PAf4	Have you been better able to cope with problems?	*S81*	
Positive impact on behaviour towards others *(functional scale)*			
PIBO1	Have you been more willing to help others?	*S82*	
PIBO2	Have you been more understanding of other people's feelings?	*S83*	
Positive social functioning *(functional scale)*			
PSF1	Are your relationships with family and/or friends stronger?	*S97*	
PSF2	Are your relationships with family and/or friends more important to you?	*S99*	
Sexual functioning *(functional scale)*			
SF1	Have you been interested in sex?	*S108*	
SF2	Have you been sexually active?	*S109*	
Sexual problems *(symptom scale)*			
SP1	Have you felt uncomfortable about the idea of being sexually intimate?	*S104*	
SP2	Have you avoided having sex?	*S107*	
Single items			
FD	Has your physical condition or medical treatment caused you financial difficulties?	*S70*	*e*
WF	Have you worried that your family members are at risk of getting cancer?	*S57*	
DM	Have you given a deeper meaning to the fact that you have (had) cancer?	*S84*	

Table 3 (continued)

Scales QLQ-SURV100			
TD	Do you feel that people treat you differently?	*S100*	
Conditional scales/ items			
Work *(functional scale)*			
WO1	Have your career/job opportunities been limited?	*S89*	*e*
WO2	Do you work fewer hours than you would like?	*S90*	*e*
WO3	Do you perform your work less well?	*S91*	*e*
WO4	Do you lack support and understanding from colleagues and or/management?	*S93*	*e*
Sexual problems when sexually active *(symptom scale)*			
SPa1	Have you had problems being sexually intimate?	*S101*	
SPa2	Have you had problems becoming sexually aroused?	*S103*	
Single items			
PILM	Have you had problems with obtaining insurance, loans, and/or a mortgage?	*S88*	*e*
LI	Have you lost income?	*S92*	*e*
Fert	Have you been concerned about your ability to have children?	*S62*	
WIC	Do you worry about the impact of your cancer on your children?	*S87*	
PRS	Is your relationship with your partner stronger?	*S98*	
SPf	**For women only:** Have you experienced a dry vagina during sexual activity?	*S105*	
SPm	**For men only**: Have you had problems getting or maintaining an erection?	*S106*	
SPl	Has sexual activity been enjoyable for you?	*S102*	
Global health status			
QL1	How would you rate your overall quality of life during the past week?	*S110*	*e*
QL2	How would you rate your overall health during the past week?	*S111*	*e*

The table presents the scales and items of the QLQ-SURV 100. The number in the second-last column refers to the item number of the QLQ-SURV111 on which the item is based on. Items containing an "e" in the last column indicate essential items. C30 in the last column indicates that an item is not essential, but necessary to calculate C30 physical functioning

narrower QLQ-C30 HRQOL construct has been designed to evaluate HRQOL outcomes in clinical trials, the 73-items making up the essential survivorship scales will be suitable to evaluate the long-term HRQOL outcomes in clinical trials. The other scales will be optional and will provide, in combination with the essential scales, a more complete picture of the HRQOL of cancer survivors.

In contrast to the HRQOL questionnaires designed for cancer patients under active treatment such as the QLQ-C30 [34] and the Functional Assessment of Cancer Therapy Scale (FACT-G) [35], the QLQ-SURV100 does not assess acute treatment-related symptoms (e.g. vomiting or diarrhoea). Moreover, scales that are particularly relevant for survivors like fatigue, physical functioning, and emotional functioning are extended to assess these functional domain and symptoms more precisely and at a level that is relevant for disease-free survivors. In addition, the QLQ-SURV100 includes scales that address typical survivorship issues like fear of recurrence, post-traumatic growth, and long-term side effects of treatment.

Compared to the existing questionnaires that have been developed for (long-term) cancer survivors like the Cancer Problems in Living Scale (CPILS) [36], Impact of Cancer (IOC/IOCv2) [37–39], Long-Term Quality of Life (LTQL) [40, 41], Quality of Life in Adult Cancer Survivors (QLACS) [42, 43], Brief Cancer Impact Assessment (BCIA) [44, 45], Quality of Life Cancer Survivors (QoL-CS) [46], and Satisfaction with Life Domains Scale for Cancer (SLDS-C) [47]), the QLQ-SURV100 has the advantage that it has been developed in multiple cancer survivor populations (11 different tumour types and 17 different countries) following the rigorous guidelines for questionnaire development of the EORTC QLG [6]. Next to the psychological and social aspects of having had cancer, our questionnaire also addresses specifically the longer-term physical aspects of having had cancer, which reflects the multidimensional aspect of HRQOL [48] and is in line with the EORTC QLG approach. Further, our questionnaire maps all functional domains relevant for survivors unidimensionally. Moreover, it has the advantage that it can be supplemented with compatible cancer-site specific modules, which facilitates the assessment of both generic and condition-specific health issues. Finally, because all functional scales of the QLQ-C30 and most of the symptom scales are also included in the QLQ-SURV100, it is possible to conduct longitudinal studies with a combination of both instruments. Patients can complete the QLQ-C30 from diagnosis and during treatment, and then after a year switch to completing the QLQ-SURV100, while the continuity in measuring the same scales is guaranteed.

HRQOL and other types of patient-reported outcomes are now increasingly being recognized by international health

Table 4 The correlation of the survivorship scales with the summary score of the Quality of Life of Cancer Patients questionnaire

Scale	Pearson's *r*	N
Physical Functioning (5)	.723**	483
Cognitive Functioning (4)	.703**	483
Emotional Functioning (7)	.715**	483
Role functioning (3)	.810**	483
Social interference (2)	-.759**	483
Fatigue (4)	-.806**	483
Sleep problems (4)	-.677**	483
Pain (2)	-.773**	483
Symptom checklist (17)	-.822**	483
Negative health outlook (7)	-.694**	483
Work (4)	.626**	325
Health distress (3)	-.542**	483
Body image (2)	.541**	482
Loss of income	-.442**	459
Worry cancer risk family	-.433**	480
Sexual problems female	-.369**	141
Ability to have children	-.364**	180
Sexual problems	-.361**	432
Treated differently	-.358**	479
Problems insurances, loans, mortgages	-.351**	331
Worry impact of cancer on children	-.343**	384
Sexual problems when sexually active	-.331**	422
Social isolation	-.280**	479
Symptom awareness	-.263**	483
Deeper meaning	-.250**	474
Partner relation stronger	-.249**	368
Positive social functioning	-.243**	479
Sexual problems male	-.240**	229
Positive life outlook	-.184**	483
Positive impact on behaviour towards others	-.174**	478
Positive health behaviour change	-.164**	482
Pexual pleasure	.096	319
Sexual functioning	.067	436

Table 4 (continued) The table presents the correlation of the survivorship scales with the summary score of the Quality of Life of Cancer Patients questionnaire (EORTC QLQ-C30). Note: The shaded cells consist of the scales which were used to calculate the EORTC QLQ-C30-based summary score (see Online Resource 1 for details). Between the brackets are the number of items of the scales that correlate .5 or more with the summary score. **Correlation is significant at the 0.01 level (2-tailed)

policy and regulatory authorities [49, 50] and patients [51, 52] as pivotal outcomes [48] in cancer research, complementing the more traditional outcomes and having the potential to inform clinical decision making, pharmaceutical labelling claims, product reimbursement, and healthcare policy [53]. PRO measures (PROMs) are of particular importance in clinical trials aimed at improving (long-term) HRQOL in cancer patients with curable disease. Moreover, because of the improvement in cancer survival, a large group of patients is experiencing extended post-treatment periods without recurrent disease, making it more important to add HRQOL as primary outcome to disease-free survival and overall survival to assess treatment effectiveness [54] and also feasible because of the increased number of patients available for long-term follow-up [33]. The value of long-term follow-up has become apparent from trials showing that some important clinical effects appear only 10 or even 20 years after treatment has been delivered [33]. To be able to inform important clinical decisions based on HRQOL in clinical trials, it is fundamental that these PROMs are of high quality [51, 53] and developed in a rigorous manner [6] including all HRQOL domains as is the case for the QLQ-SURV100.

Because our measure is comprehensive, it is also suitable to assess HRQOL in non-pharmacological trials aimed at improving HRQOL, psychological, and/or physical functioning in cancer survivors [55–57], in observational population-wide studies in cancer survivors to investigate the impact of cancer on HRQOL [58, 59] or to evaluate the effectiveness of survivorship programs [60].

In conclusion, we have developed a core questionnaire to assess HRQOL of disease-free cancer survivors, which consists of essential scales that form a core measure for evaluating HRQOL in clinical trials and optional scales that can be used to generate a more comprehensive picture of the overall HRQOL of cancer survivors or when specific populations are targeted (e.g. younger survivors). In the next phase of our work, the international field test (phase IV), we will evaluate the proposed scale structure more rigorously by confirming the provisional scale structure as reported here in a new sample of 1600 survivors, assessing the reliability of the scales by means of test–retest stability, and assessing the validity of the scales using known-groups validity testing. We also intend to generate IRT scoring algorithms, in addition to the more traditional sum scores for the questionnaire scales.

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Author contribution All authors contributed to the study conception and design. Material preparation performed by Marieke van Leeuwen, Neil Aaronson, Lonneke van de Poll-Franse, and Teresa Young. Data analysis was carried out by Marieke van Leeuwen, Neil Aaronson, Jacobien Kieffer, and Lonneke van de Poll-Franse. All authors, except for Neil Aaronson, Jacobien Kieffer, and Lonneke van de Poll-Franse, participated in data collection. The first draft of the manuscript was written by Marieke van Leeuwen, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Availability of data and material The data that support the findings of this study are available from the Division of Psychosocial Research and Epidemiology of the Netherlands Cancer Institute (contact person: L.V. van de Poll-Franse), but restrictions apply to the availability of these data due to an agreement between the Netherlands Cancer Institute and the European Organisation for Research and Treatment of Cancer Quality of Life Group, and so they are not publicly available. Data are available pending approval of both the Netherlands Cancer Institute and the EORTC.

The QLQ-SURV100 can be requested on the website of the EORTC QLG: EORTC Quality of Life Website https://qol.eortc.org/quality-of-life-group/.

Code availability Not applicable.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Institutional Review Board of the Netherlands Cancer Institute; M17QOL) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication Not applicable.

Conflict of interest The authors declare no competing interests.

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