Pilot Testing of the First Version of the European Association for Palliative Care (EAPC) Basic Dataset: a mixed methods study

Katrin R. Sigurdardottir[1,2,3], Marianne J. Hjermstad[2], Marilene Filbet[4], Colombe Tricou[4], Regina McQuillan[5], Massimo Costantini[6], Cristina Autelitano[7] Michael I. Bennett[8] and Dagny Faksvåg Haugen[1,9]

[1]Regional Centre of Excellence for Palliative Care, Western Norway, Haukeland University Hospital, Bergen, Norway

[2]European Palliative Care Research Centre (PRC), Department of Oncology, Oslo University Hospital, and Institute of Clinical Medicine, University of Oslo, Oslo, Norway

[3]Sunniva Centre for Palliative Care, Haraldsplass Deaconess Hospital, Bergen, Norway

[4]Department of Palliative Care, Centre Hospitalier de Lyon-Sud, Hospices Civils de Lyon, Pierre-Bénite, France

[5]St Francis Hospice, Raheny, Dublin 5, Ireland

[6]Scientific Directorate, Azienda USL-IRCCS di Reggio Emilia, Italy

[7]Palliative Care Unit, Azienda USL-IRCCS di Reggio Emilia, Italy

[8]Academic Unit of Palliative Care, Leeds Institute of Health Sciences, School of Medicine, University of Leeds, Leeds, UK

[9]Department of Clinical Medicine K1, University of Bergen, Bergen, Norway

Corresponding author:

Katrin Ruth Sigurdardottir, Regional Centre of Excellence for Palliative Care, Western Norway, Haukeland University Hospital, Haukelandsbakken 15, NO-5021 Bergen, Norway. Email: katrin.sigurdardottir

Telephone:+4793260266

Abstract

Background: Inadequate description of patients with cancer receiving palliative care in research studies often leads to results having limited generalizability. The need to standardize the description of the sample led to the development of the European Association for Palliative Care (EAPC) Basic Dataset consisting of 31 core demographic and disease-related variables, divided between a patient form and a health care personnel form.

Aim: To pilot-test the dataset to check acceptability, look for possible sources of error or shortcomings, and identify possible needs for changes.

Design: International multi-centre pilot study at 9 study sites in 5 European countries. Mixed methods were used.

Setting/Participants: Adult cancer patients and staff in palliative care units, hospices, and one municipal home care service.

Results: 191 patients (544 screened) and 190 health care personnel were included. Median time to fill in the patient form was 5 minutes, the health care personnel form 7 minutes. Ethnicity was the most challenging item for patients and requires decisions at a national level about whether or how to include. Health care personnel found weight loss, principal diagnosis, additional diagnoses, and stage of non-cancer diseases most difficult to respond to. Registration of diagnoses will be changed from ICD-10 code to a predefined list, while weight loss and stage of non-cancer diseases will be removed. The pilot study has led to rewording of items, improvement in response options, and shortening of the dataset to 29 items.

Conclusion: Pilot testing of the first version of the EAPC Basic Dataset confirmed that patients and health care personnel understand the questions in a consistent manner and can answer within an acceptable timeframe. The pilot testing has led to improvement and the new version is now subject to further testing.

Keywords: neoplasms, palliative care, patient outcome assessment, questionnaire design, standards, dataset, pilot study.

What is already known about the topic?

There is a need to standardize the description of a palliative care cancer patient population.

The EAPC Basic Dataset has been developed to standardize research reporting.

The dataset is a combination of patient reported outcome measures (PROMs) and disease related variables recorded by health care personnel.

What this paper adds?

The first version of the EAPC Basic Dataset has been quality assured through thorough and systematic pre-testing in the two target groups, patients and health care personnel, across five European countries.

Pilot-testing has led to a shortened dataset with better clarity and more suitable response options.

Implication for practice, theory or policy

The resulting EAPC Basic Dataset is an international, consensus-based, quality assured tool that may increase external validity of research results. Further testing will make this tool a more robust standardized research reporting dataset.

Introduction

Are these findings relevant for my own patients? This is a question all clinicians should ask after having read a report on a clinical study within their field. Palliative care is no exception, and palliative care populations are even more heterogeneous than in many other areas of medicine. Within the palliative care cancer population, differences in patient characteristics such as cancer diagnosis, disease status, symptoms, physical functioning, cancer-directed treatment, and estimated survival, as well as differences in the organisation and delivery of services, are a major concern when considering both applicability and generalizability of research findings [1-5]. These challenges call for uniform standards on how to describe the population and the setting of the study.

Four literature reviews have examined how palliative care populations were described in research reports [6-9]. All four concluded that the populations were inconsistently and insufficiently described. The authors highlighted the need for a set of common descriptors to be used when reporting sample characteristics, a need also acknowledged in several other publications [10-14].

As a response to this, the European Palliative Care Research Centre (PRC) [15] in collaboration with the European Association for Palliative Care Research Network (EAPC-RN) [16] and the EU-funded PRISMA project [17] launched a project to develop and reach consensus on a basic set of variables to describe a palliative care cancer population. Through an international Delphi process of five rounds, consensus was reached on a set of 31 core variables (the first version of the EAPC Basic Dataset) to be used to describe a palliative care cancer population in research, and on how the variables should be measured and recorded [18] (Figure 1).

The aim of the present study was to pilot test the first version of the EAPC Basic Dataset in palliative care cancer patients and health care personnel to assess its acceptability, comprehensibility, and feasibility, and to use this information to adapt the dataset if needed.

Methods

Study design and setting

This was an international multi-centre study using pre-testing survey procedures combining quantitative and qualitative methods [19, 20], conducted at the following sites:

- Norway; five specialist palliative care (SPC) inpatient units, four in hospitals (35 beds in all) and one in a nursing home (8 beds), one SPC outpatient service and one municipal home care service (5 sites in all)
- France; one SPC service with a 12 bed inpatient unit and outpatient services
- Italy; one hospital-based SPC team serving both inpatients and outpatients
- Ireland; one hospice with two inpatient units (43 beds in all) and two day care units
- UK; one hospice (32 beds)

The centres were recruited through an open invitation presented at palliative care conferences, and from established collaborative research networks. Each centre contributed a minimum of 15 patients to the study.

In each country, an experienced researcher (MF, MIB, MC, RM, KRS) was responsible for recruiting local study coordinators/interviewers. The local study coordinators had different professional backgrounds (registered nurse, research nurse, physician, medical student), research credentials, and research experience.

Data were collected in the period September 2015-December 2016.

Translation

The first version of the EAPC Basic Dataset was developed in English. Translation into the native language was performed in France, Norway, and Italy. The national study coordinators (MF, MC, KRS) were responsible for the translations. In France, the translation was carried out according to the European Organization for Research and Treatment of Cancer (EORTC) procedure [21]. In Norway and Italy, the translation process involved one forward translation from English into the target language by a translator with medical background, good command of English, and the target language as his/her native language. The translated

version of the dataset was then checked by two independent persons fluent in the target language and with good knowledge of English, and consensus was reached in case of incongruence. Following the translation, the dataset was completed by a small sample of the target population to check comprehensibility.

Two other documents were translated in the same way; 'Pilot testing the EAPC Basic Dataset: structured interview guide' and 'Guidelines for using the EAPC Basic Dataset'.

The qualitative data were translated into English by one of the local study coordinators in France. In Italy, data were translated by one physician and reviewed by another. Qualitative data from participants in Norway were analysed without being translated.

Participants

Participants for the pilot testing were

1. Patients admitted to palliative care services as described above. Patients were eligible for the study if they had incurable cancer, age ≥18 years, and the ability to give informed consent. Patients who fulfilled the inclusion criteria, but did not speak the language in question, were excluded. Seven of the nine participating study centres screened potential participants. The remaining two centres recruited per convenience.
2. The patient's responsible health care provider (physician and/or nurse).

Study measures

With the aim to assess acceptability, comprehensibility, and feasibility of the EAPC Basic Dataset, the following information was collected:

1. Non-participating patients

Age group, gender, diagnostic group, and the Australia-modified Karnofsky Performance Scale (AKPS) [22] score were recorded for all non-participating patients. The reason for not participating was noted, using predefined categories.

2. Participants

After the included patients had read and signed the consent form, they were asked to complete the EAPC basic dataset patient form. The responsible health care provider (physician and/or nurse) was asked to complete the health care personnel form. The forms were completed on paper, followed by a standard structured interview for both respondent groups, with the

questions indicated below. By the end of the interview, the participants were asked about the layout of the form, if any items were irrelevant, if the sequence of items was appropriate, and if they had any other comments about the questionnaire. Only one study entry per patient was allowed. Information about the health care provider's age, gender, profession, and years working in palliative care was recorded.

Acceptability was assessed by asking the participants if they found any question annoying, confusing, upsetting, had comments re acceptability, or found the response options unsuitable. Poor acceptability for an item was judged if > 10% of participants answered positively to these questions, which is a commonly used cut-off in survey pre-testing [20].

Comprehensibility was determined insufficient if at least 10% of participants found any question difficult to respond to, if the answer was obviously incorrect or missing, or if they commented on a poorly understandable question or response option.

Feasibility was judged by how long it took the participants to complete the questionnaire, if assistance was needed, and whether the requested information was readily available for the health care professionals. The ratio included/non-participating was also measured.

Data analysis

Data were entered into an online database. Analysis was by mixed methods; quantitative data were analyzed using descriptive statistics, and qualitative data by the first author (KRS) using content analysis [23]. The researcher read all the comments for each item many times before dividing the text into meaning units. The next step was to develop codes as descriptive labels for the meaning units, before sorting the codes into categories. Afterwards the categories were assorted into three groups: comments on difficulties, proposals on how to improve the dataset, and other comments.

Based on the analysis, decisions to change, add, delete, or reword items were made by two of the authors (KRS and DFH).

We have followed the Consolidated criteria for reporting qualitative research (COREQ) checklist [24].

Results

Screening

A total of 544 patients were screened; 353 did not participate or were excluded. Two study sites did not screen and recruited per convenience; one did not have access to interviewer on a daily basis, and the other was a home care service. Table 1 presents recruitment, characteristics of the non-participating patients, and the reasons for not participating. The most common reasons given were 'too unwell' (26%), 'not advanced cancer' (18%), and 'unable to give informed consent' (13%). There were great differences in the ratio included/non-participating, ranging from 0.2 to 2.6 between centres.

Pilot-testing

Included patients

Altogether, 191 patients participated (Table 1).

Patient characteristics

The patients' mean age was 67.6 years, median 69 (range 25-90). Sixty-five percent were ≥ 65 years old. The most common cancer group for included patients (n=172) was cancer in digestive organs (ICD-10 codes C15-26), 24%; followed by breast (C50), 15%; respiratory and intrathoracic (C30-39), 14%; male genital organs (C60-63), 13%; and lymphoid and hematologic malignancies (C81-96), 9%; 79% had metastatic /disseminated disease, and 36% were not receiving anticancer therapy. Seventy-five percent had performance status ≥ 60. Further details are given in Tables 2 and 3.

Patient responses

Median time to fill in the patient form was 5 minutes (range 1-60 minutes). One hundred and twenty-eight patients completed the form without assistance. Fifty-five patients required assistance; of these 46 received assistance from health care providers, seven from a family caregiver or friend, and two from a family caregiver /friend and health care provider. In five cases, the form was filled in by health care providers alone, and in two by a family caregiver or friend.

Table 2 shows the number of responses for each variable in the patient part of the dataset, and missing data for each item. The most challenging variable for patients was ethnicity. The question 'What is your ethnicity?' was answered by 127 patients (66%), out of whom 108 stated their nationalities. Thirty-two patients found the question difficult to respond to, 11 found the question annoying, confusing, or upsetting, and 37 gave other comments (Figure 2), the most common being 'don't understand the word ethnicity'. Figure 2 shows the participants' responses to the standardized questions asked by the interviewers, and Table 2 participants' comments and suggestions for improvement. Based on these findings, ethnicity will be replaced with an open question about nationality in some countries, others will find a predefined list appropriate, while yet others will have to exclude this variable.

Many patients had the same comments for more than one symptom (Table 2). One of the remarks was the order of symptoms on the form. Both patients and health care providers recommended grouping related symptoms together.

Age and gender were the only variables without any form of modifications. Living situation and highest completed level of education have been modified as shown in Table 2.

Health care professionals

Health care professional characteristics

One hundred and ninety health care professionals gave information about themselves: Mean age was 42.7 years; 165 were females; 103 were physicians, and 84 nurses. The median working time within palliative care was six years (range 0-40). Some of the health care professionals probably filled in more than one form.

Health care professional responses

Median time to fill in the health care personnel form was 7 minutes (range 2-195).

Sixteen health care professionals needed assistance to complete the health care personnel form, most commonly nurses needing information from physicians about ICD-10 codes, medications, performance status, or cognitive functioning.

Eight variables were perceived as challenging in the health care personnel part, as based on questions about responding difficulties, completion, missing data, and comments: Principal diagnosis, date of the principal diagnosis, stage of the cancer disease, additional diagnoses, stage of the non-cancer disease, weight loss, place of care, and performance status. Figure 2 shows the participants' responses to the standardized questions asked by the interviewers, and Table 3 sums up the comments.

- The principal and additional diagnoses

The health care personnel were supposed to fill in the principal diagnosis using an ICD-10 code. ICD-10 codes were used in 59% of cases, and type of cancer using free text in 24%. The cancer diagnosis was missing in 11%, while 6% used various other codes. Eighty-seven participants found the item difficult to respond to; the most common reason was, 'don't know the ICD-10 code' (Table 3). One recommendation for improvement was to make a standardized list of cancer diagnoses. As a result, ICD-10 codes will be replaced by a standardized list based on ICD chapters and blocks (Table 3).

Some of the same challenges applied to the additional diagnoses. ICD-10 codes were used in 83 cases (46 were non-cancer diagnoses, 29 were cancer or metastases, and eight ICD-10 Z or R codes). The disease was written as text in 25 cases. The result will be to replace the ICD-10 code by a standardized list (Table 3).

- Stage of the non-cancer disease

Fifty-five patients were distributed between the following categories: New York Heart Association (NYHA) Functional Classification class I (19), II (2), III (3), IV (1); Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages 1 (10), 2 (4), 3 (1), 4 (4), and Functional Assessment Staging (FAST) scale, 1 (10), 2 (1). The response distributions with dominance of the first stages caused suspicion about incorrect answers. Sixty-four health care

professionals reported difficulties completing this item, and the most common comment was; 'don't know the classification systems' (Table 3). Several participants proposed to exclude this variable, or make it optional. This has resulted in removal of the variable.

- Date of the principal diagnosis

Date of the principal diagnosis was reported as intended in 138 cases (72%) with month and year; 46 with only year, and seven missing. Thirty-nine found the item difficult to respond to, and the most common reason was 'hard to find'. No proposals for change were received. The variable will remain unchanged.

- Weight loss

Only 38 participants (20%) filled in weight loss in percentage and duration of weight loss in months. This item was clearly the most difficult one to respond to (Figure 2). Comments are given in Table 3. As a consequence, the variable has been removed.

- Performance status

Sixteen percent of the participants found the question difficult to respond to. The most common comment was 'challenging to choose the right category', and only 59% found the response options suitable. Three times two categories were marked. However, there were only 2% missing data. The AKPS is a validated tool, and in this first version of the dataset it was decided not to change the response options.

Date of the principal diagnosis and performance status were the only variables without any form of modification. The rest of the variables have been modified as shown in Table 3.

The layout of the forms was suitable for the majority; however, there were a few comments that it was hard to read the black numbers and text on the dark green background. The green colour will consequently be changed to a brighter one.

Discussion

The first version of the EAPC Basic Dataset has been pilot-tested by altogether 381 individuals from the target groups, in five different European countries. Our results show that palliative care cancer patients and health care professionals are willing and able to use the

dataset. The majority of study participants reported to understand the instructions and questions. The following five variables were perceived as most challenging: ethnicity, principal diagnosis, additional diagnoses, stage of the non-cancer disease, and weight loss. Consequently, the pilot-testing has led to changes in the first official version of the dataset.

Feasibility

Median time to fill in the form was 7 minutes for health care personnel and 5 minutes for patients, and 67% of the patients filled in the form alone. The acceptable time expenditure and the fact that two-thirds of the patients completed the form without assistance, support the feasibility of the dataset. However, many palliative care cancer patients were unable to participate, as only 191 out of 544 were included, with an inclusion rate of 44% for the sites that performed screening. The most common reason for not participating was being too unwell, confirming that many palliative care cancer patients are frail. The non-participants were slightly older and had a lower mean AKPS score than the participants; 53% of the non-participants had AKPS score ≤ 50, compared to 24% of the included patients. However, we believe it is also possible to use the EAPC Basic Dataset for some of these patients. The patient part can be completed by a caregiver, and rating of symptoms based either on input from the patient or by observer assessment as recommended in Guidelines for using the Edmonton Symptom Assessment System revised (ESAS-r) [25]. Further testing is required to test our assumption.

Probably, more patients could have been able to complete the dataset and participate in the pilot. Stone et al found that gate keeping by clinical staff in palliative care research was the second most common reason for inaccessibility, with 24% of eligible patients not available for the research team [26]. Inaccessibility or unavailability of researcher and eligible patients is also an issue. In our material, 17% of the cases not participating were due to this mismatch.

One can also speculate that the need for interview after completion has been a limitation and that in reality there are more patients able to complete the dataset.

Acceptability

There were very few negative comments regarding acceptability, and few patients reported finding questions annoying, confusing or upsetting. The wellbeing item was the one with most patients (10%) reporting 'annoying, confusing or upsetting'. The majority found the word and the scale confusing, with best wellbeing as 0 and worst wellbeing as 10. Only one patient reported to be upset. No change was made, based on the finding that 96% were able to respond to the item; another reason is that the item comes from ESAS-r. ESAS has evolved over the last 27 years and is a robust symptom assessment instrument used both in research and clinical practice [27].

We conclude that both patients and health care providers find the EAPC basic dataset acceptable for use.

Comprehensibility

The participants understood the majority of the questions. The frequency of missing answers corresponded to the responses that the participants found the item difficult to respond to, however, the comments demonstrated that this was not due to finding the questions difficult to understand. The main reasons were that information was not available in the patient records, e.g. concerning weight, or the respondents did not know or use the ICD-10 system. Ethnicity was the item most patients found difficult to understand.

Changes in the EAPC Basic Dataset

The fact that this pilot study had almost 400 participants gives reason to believe that the resulting changes are well founded and will give a better version of the dataset. Five variables were found to be most challenging. Two of these, ethnicity and weight loss, were variables on which consensus on method of assessment was not achieved in the Delphi process. For the purpose of the pilot testing, the research group based their choice of assessment method on comments from the Delphi panel [18]. However, the pilot testing showed that ethnicity is a tricky variable, requiring decisions at a national level about whether or how to include this item. For instance, France has a law prohibiting individuals being enumerated by ethnicity without their consent or a state committee waiver.

The use of ICD-10 for principal and additional diagnoses was also problematic. To improve the next version, individual coding will be exchanged with a standardized list based on the ICD structure. This may be more sensible, as researchers are accustomed to reporting diseases in wider categories. Hopefully also clinicians will find this solution more agreeable and less time consuming.

The pilot testing also resulted in some adjustments in response options, both by adding new categories and by giving the option to specify in free text when answering 'other'. Relevant symptoms in the patient form have been grouped together, based on feedback from both patients and health care providers.

Strength and limitations

All nine study sites had interviewers without any connection to the development of the EAPC Basic Dataset. By using a standardized interview guide we tried to minimize interviewer bias.

Our study has some limitations. The fact that the translation was not performed according to the EORTC translation guidelines [21] in two countries may represent a problem. The reason for deviating from these guidelines was that many of the variables within the dataset, and especially the PROMs, originate from internationally established and validated tools and manuals such as the ESAS-r [28], the AKPS, and ICD-10 [29], and were taken from authorized translations. The additional items concern objective information only.

Screening was not performed at all the participating centres. There were big differences in the ratio included/ not participating between the study sites, an observation which cannot be explained by differences in average age or mean AKPS at the different sites. The reasons are probably multifactorial, relating to all the three main 'bottlenecks' to recruitment to a multicentre palliative care study; eligibility, accessibility and consent, as identified by Stone et al [26]. The two centres with the highest numbers of non-participating patients were hospices with the most beds. However, there were differences in the case mix between the centres. One of the centres with the lowest ratio had 20% non-cancer patients in the population, while the centre with the highest ratio only served cancer patients. Unavailability of the researcher or patient was also more common at the sites with high numbers of non-participating patients. The researcher's personal traits, the way patients were informed and invited to participate, and

the personal interaction between researcher and clinicians have probably also affected inclusion rates. For instance, the recruitment rate improved at one site after the researcher recognized the high rate of poor literacy and offered to read the information to the patients.

Health care personnel were not supposed to participate in the study more than once. Unfortunately this was insufficiently addressed in the study protocol. The results indicate that some professionals participated more than once, but as this deviation only concerned one of nine study sites, we consider it of minor influence.

Despite the above mentioned limitations, the pilot testing has given results leading to rewording, improvements in response options, and removal of items from the dataset. We strongly encourage researchers to use the dataset as part of the case report form for studies in cancer palliative care, realizing, however, that supplementary modules may be needed for specific purposes. Using the dataset in research reporting will lead to a thorough description of the study sample, which is a prerequisite for judging the external validity of the study results [30]. Further work will be needed to test the revised version of the dataset. The EAPC Basic Dataset is available at https://oslouniversitetssykehus.no/avdelinger/kreftklinikken/avdeling-for-kreftbehandling/prc-research-results#eapc-basic-dataset.

Conclusion

The first version of the EAPC basic dataset has undergone pilot-testing confirming that patients and health care personnel understand the questions in a consistent manner. The pilot testing has led to rewording, changes in response options, and shortening of the dataset, which is now ready for use and further testing.

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Data sharing

The corresponding author may be contacted regarding access to data.

Declaration of conflict of interest

The authors declare no conflict of interest with respect to the research, authorship, and/or publication of this article.

Ethics and consent

Application for ethical approval was sent to the Regional Committee for Medical and Health Research Ethics (REC), North Norway. Due to the nature of the study approval was not needed, except for the screening process and for recording information about patients who were not included. For the latter purpose, dispensation from confidentiality was granted (11th June 2015, 2015/1056/REC North). The protocol was also approved by the institutional review board at St. Olavs Hospital, Trondheim University Hospital, and by Comité de Protection des Personnes Sud-Est (08/11/2016) and the Comission Nationale de l'Informatique et des Libertés des Hospices Civils de Lyon (n°17-125), France; NRES Committee North East - Newcastle & North Tyneside 1 (26/05/2016, ref 16/NE/0184), UK; St Francis Hospice Research Ethics Committee (13/04/2016, ref 71), Ireland; and the Ethics Committee of Reggio Emilia (17/12/2015, code 1732/2015), Italy. Patients gave written informed consent.

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ORCID iD

Katrin Ruth Sigurdardottir ID https://orcid.org/0000-0001-8192-7470

Marianne J. Hjermstad ID https://orcid.org/0000-0003-4606-0503

Marilene Filbet ID https://orcid.org/0000-0002-3776-2063

Colombe Tricou ID https://orcid.org/0000-0001-5473-9044

Michael I. Bennett ID https://orcid.org/0000-0002-8369-8349

Dagny Faksvåg Haugen ID https://orcid.org/0000-0002-8592-4995

Massimo Costantini ID https://orcid.org/0000-0002-5293-7079

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	PATIENT FORM												
	What is your:	**Please fill in or tick the right box as appropriate.**											
1	Date of birth	*(Day.Month.Year)*											
2	Gender	☐ Male ☐ Female											
3	Living situation	☐ Alone ☐ With spouse/partner ☐ With spouse/partner and children ☐ With children ☐ With other adult(s) ☐ In an institution ☐ Other											
4	Highest completed level of education	☐ Primary school ☐ Secondary school / high school ☐ College/university											
5	Ethnicity												
	Symptoms. Please mark the number that best describes how you feel NOW:												
6	No Pain	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Pain
7	No Tiredness *(Tiredness = lack of energy)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Tiredness
8	No Drowsiness *(Drowsiness = feeling sleepy)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Drowsiness

9	No Nausea	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Nausea
10	No Lack of	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
	Appetite	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Lack of Appetite
11	No Shortness	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
	of Breath	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Shortness of Breath
12	No Depression	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
	(Depression = feeling sad)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Depression
13	No Anxiety	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
	(Anxiety = feeling nervous)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Anxiety
14	Best Wellbeing	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
	(Wellbeing = how you feel overall)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Wellbeing
15	Best Sleep	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Sleep
16	No Constipation	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Constipation
17	No Vomiting	0	1	2	3	4	5	6	7	8	9	10	Worst Possible
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Vomiting

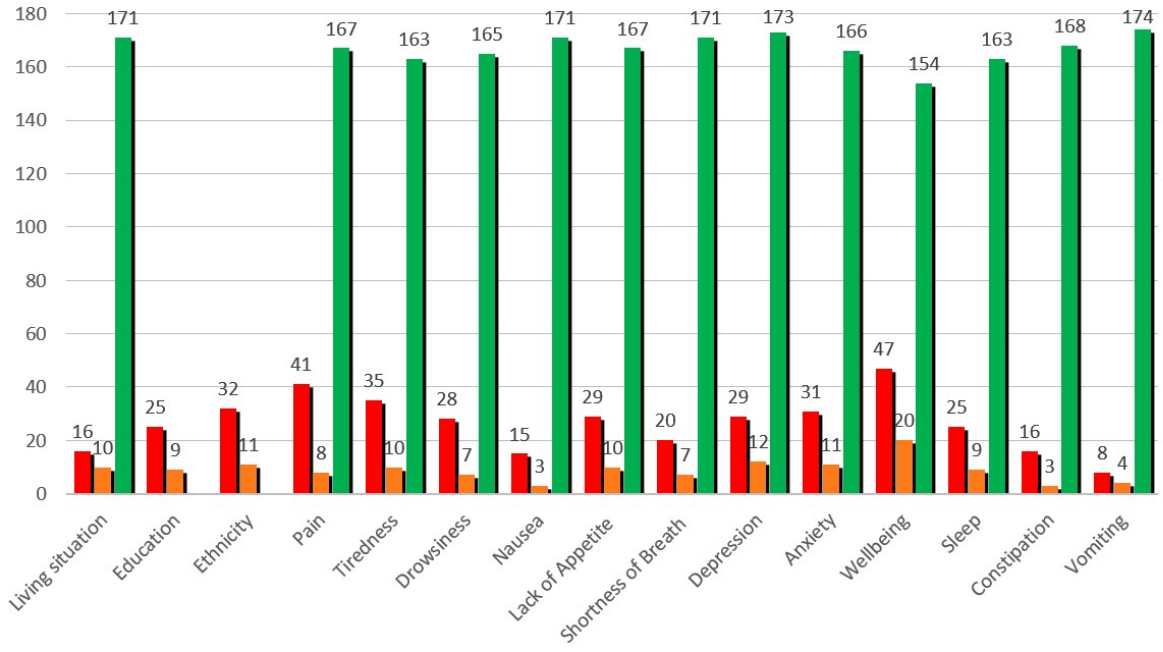
HEALTH CARE PERSONNEL FORM		
	Patient's:	**Please fill in or tick the right box as appropriate**
18	Date of birth	(Day.Month.Year)
19	Principal diagnosis	ICD-10 code
20	Date of the principal diagnosis	(Month.Year)
21	Stage of the cancer disease	☐ Local ☐ Locally advanced ☐ Metastatic/disseminated
22	Site of metastases	☐ Bone ☐ Liver ☐ Lung ☐ CNS ☐ Other
23	Present anticancer treatment	☐ Radiotherapy ☐ Chemotherapy ☐ Hormone therapy ☐ Other anticancer therapy ☐ No anticancer therapy
24	Additional diagnoses	ICD-10 code(s):
25	Stage of the non-cancer disease	Chronic heart failure (CHF): The New York Heart Association (NYHA) Functional Classification; NYHA class: I ☐, II ☐, III ☐ , IV ☐
		Chronic obstructive pulmonary disease (COPD): GOLD classification; stage: I ☐, II ☐, III ☐, IV ☐
		Dementia: FAST scale; stage: 1 ☐, 2 ☐, 3 ☐, 4 ☐, 5 ☐, 6 ☐, 7 ☐
26	Medication	☐ Non-opioid analgesics ☐ Opioids ☐ Co-analgesics ☐ Corticosteroids ☐ Antidepressants ☐ Antiemetics ☐ Neuroleptics ☐ Sedatives/anxiolytics ☐ Drug(s) for acid related disorders

		☐ Laxatives ☐ Antibiotics ☐ Diuretics ☐ Heart medication / antihypertensives ☐ Other
27	Weight loss	Involuntary weight loss ____% and duration of weight loss ____months
28	Performance status	☐ 100 Normal; no complaints; no evidence of disease. ☐ 90 Able to carry on normal activity; minor signs or symptoms. ☐ 80 Normal activity with effort; some signs or symptoms of disease ☐ 70 Cares for self; unable to carry on normal activity or to do active work. ☐ 60 Requires occasional assistance but is able to care for most of his needs. ☐ 50 Requires considerable assistance and frequent medical care. ☐ 40 In bed more than 50% of the time. ☐ 30 Almost completely bedfast. ☐ 20 Totally bedfast and requiring extensive nursing care by professionals and/or family. ☐ 10 Comatose or barely arousable. ☐ 0 Dead
29	Cognitive function	The patient has cognitive impairment; ☐ No ☐ Mild ☐ Moderate ☐ Severe
30	Place of care	☐ Home ☐ Long-term care facilities ☐ Hospice / Palliative care unit ☐ Hospital ☐ Other
31	Provision of care	☐ Inpatient ☐ Outpatient ☐ Day care

Figure 1. EAPC Basic Dataset first version.

A.

- Was this question difficult to respond to?
- Was it annoying, confusing or upsetting?
- Were the response options suitable?



B.

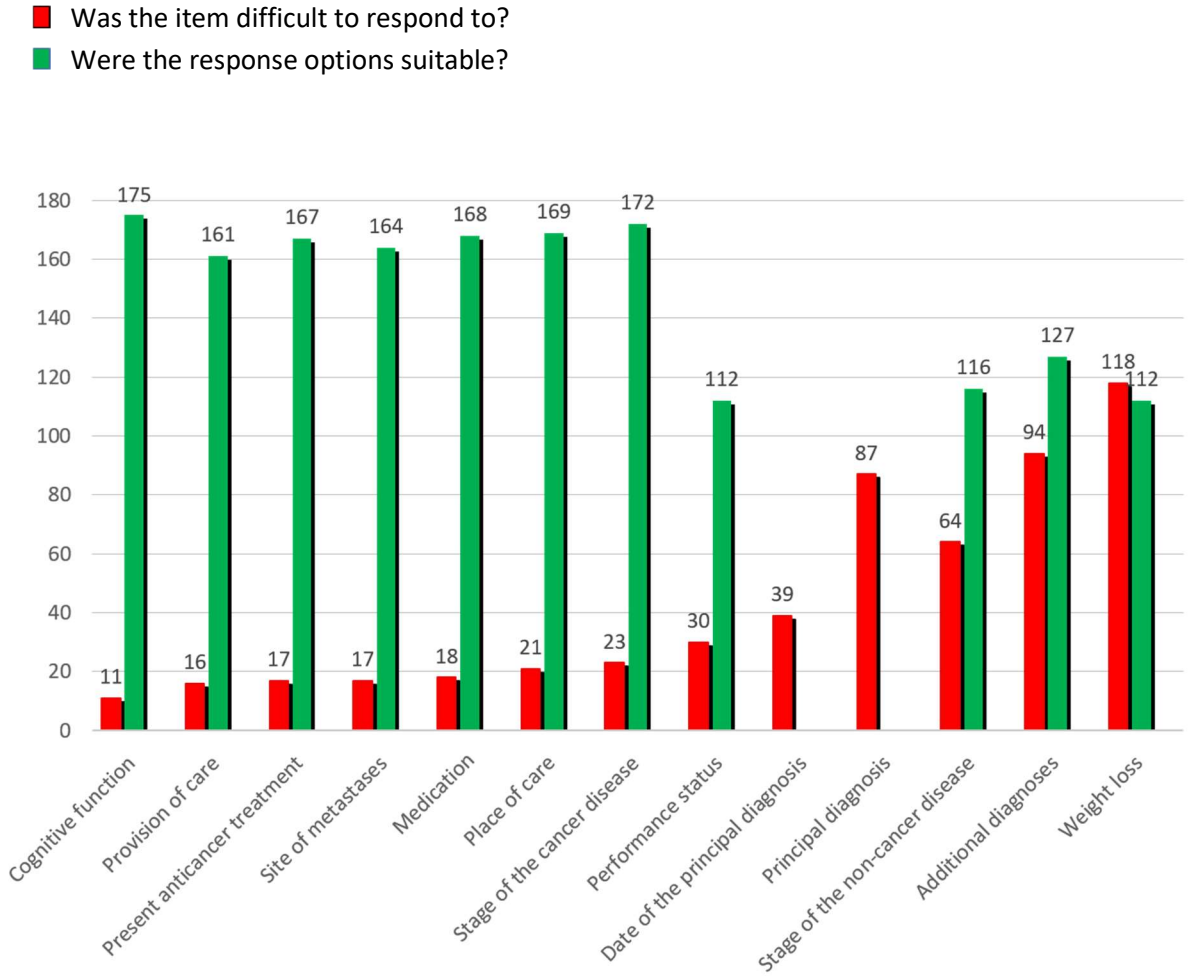
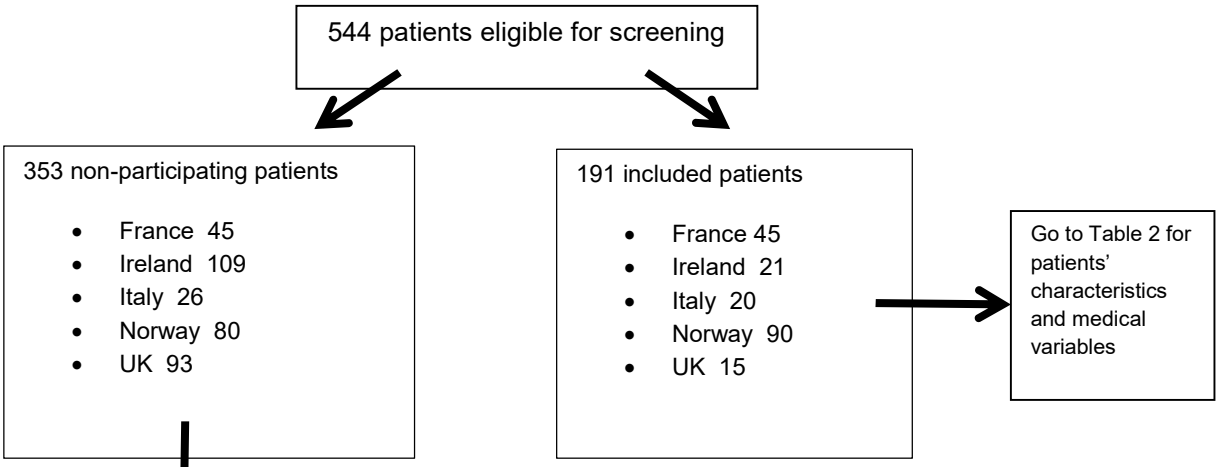


Figure 2. Pilot-testing the EAPC Basic Dataset: The number of patient participants (n=191; A) and health care professionals (n=190; B) who answered Yes to the standardized questions asked by the interviewers.

Table 1. Recruitment to pilot-testing of the EAPC Basic Dataset, characteristics of non-participating patients, and reasons for not participating.



		Number (%)
Age groups	25 - 34 years	3 (1)
	35 - 44 years	11 (3)
	45 - 54 years	36 (10)
	55 - 64 years	72 (20)
	65 - 74 years	102 (29)
	75 - 84 years	93 (26)
	85 years and over	34 (11)
Gender	Male	183 (52)
	Female	166 (48)
Cancer diagnoses by site (ICD 10 codes)	Lip, oral cavity & pharynx (C00-14[#])	4 (1)
	Digestive organs (C15-26[#])	85 (27)
	Respiratory & intrathoracic (C30-39[#])	44 (14)
	Breast (C50[#])	52 (16)
	Female genital organs (C51-58[#])	14 (4)
	Male genital organs (C60-63[#])	23 (7)
	Urinary tract (C64-68[#])	13 (4)

	Eye, brain & CNS (C69-72[#])	16 (5)
	Lymphoid, haematopoietic (C81-96[#])	34 (11)
	Other specified sites (C40-49, and 73-75[#])	15 (5)
	Independent multiple sites (C97[#])	1 (0)
	Ill-defined, secondary, unspecified including carcinomatosis (C76-80[#])	11 (3)
	Not recorded	5 (2)
Non-cancer diagnoses (ICD-10 codes)	Motor neurone disease (G12[#])	6 (3)
	Neurological conditions (G00-99[#]), excluding G12[#] and G30[#]	11 (5)
	Dementia including Alzheimer's disease (G30 and other, F00-03[#])	5 (2)
	Heart failure (I50[#])	17 (7)
	Other heart and circulatory conditions (I00-99, excluding I50[#])	40 (17)
	Chronic respiratory disease (J40-70[#])	28 (12)
	Chronic renal failure (N18[#])	13 (5)
	All other non-cancer diagnoses	45 (19)
	Diagnosis not recorded	72 (30)
Patient's performance status	100 Normal; no complaints; no evidence of disease	8 (2)
	90 Able to carry on normal activity; minor signs or symptoms	28 (8)
	80 Normal activity with effort; some signs or symptoms of disease	26 (8)
	70 Cares for self; unable to carry on normal activity or to do active work	31 (9)
	60 Requires occasional assistance but is able to care for most of his needs	66 (19)
	50 Requires considerable assistance and frequent medical care.	72 (21)
	40 In bed more than 50% of the time	35 (10)

	30 Almost completely bedfast	25 (7)
	20 Totally bedfast and requiring extensive nursing care by professionals and/or family	41 (12)
	10 Comatose or barely arousable	8 (2)
Reason for not participating	Not advanced cancer	67 (18)
	Unable to give informed consent	46 (13)
	Has already participated in the pilot-testing	6 (2)
	Too unwell	92 (26)
	Patient 'didn't want to'/ 'Not interested'	33 (9)
	Weekend/evening admission (researcher unavailable)	25 (7)
	Declined consent, reason unknown	21 (6)
	Other, please specify*	64 (18)

*Other; attends daycare on a day researcher is not available (24), time issues (lack of time, patient had left before researcher had time) (12), mental health issues (5), speech difficulties (4), does not speak the language (3), hearing impairment (2), patient too tired/fatigued (4), and diverse (10). #ICD-10 codes.

Table 2. Results of pilot-testing the EAPC Basic Dataset patient form: Characteristics of the included patients (n=191); number of responses and missing data for each item; qualitative responses grouped as comments on difficulties and proposals for improvement; resulting changes made to the dataset.

Patient form		**Number of responses (%)**	**Mean (range)**	**Missing data, Number (%)**	**Comments on difficulties**	**Proposals on how to improve the dataset**	**Resulting changes in the EAPC Basic Dataset**
Age		191 (100)	67.6 (25-90)				
Gender	Male	97 (51)					
	Female	94 (49)					
Living situation	Alone	59 (31)		2 (1)	Living with adult child A temporary stay in an institution	Define a child (< 18 years old) Specify living situation as NOW	Current living situation With spouse / partner and children (< 18 years old) With children (< 18 years old)
	With spouse/partner	70 (37)					
	With spouse / partner and children	33 (17)					
	With children	4 (2)					
	With other adult(s)	9 (5)					
	In an institution	4 (2)					
	Other	13 (7)					
Highest completed level of education	Primary school	43 (22)		2 (1)	Education was completed long ago, and schools and systems have changed	To add one more category; other; please describe	Other; please describe_____
	Secondary school / high school	87 (45)					
	College/university	65 (34)					

					4 patients had vocational training and missed an option for that 2 patients had not completed primary education		
Ethnicity		127 (66)		64 (33)	Don't understand the word ethnicity, what it means Didn't understand the question Unsure about what to answer	Ask for nationality instead of ethnicity To use tick boxes with predefined categories	Nationality Predefined categories at the national level
Symptoms	Pain	191 (100)	3.1 (0-10)		Many patients had the same comments for more than one symptom. The comments could be categorized into the following: - Difficult to quantify symptom and to use numerical rating scale - Using the time frame now when symptoms fluctuate	To change the order of symptoms	Pain Shortness of Breath Tiredness Drowsiness Lack of Appetite Nausea Vomiting Constipation Depression
	Tiredness	183 (96)	4.8 (0-10)	8 (4)			
	Drowsiness	187 (98)	3.7 (0-10)	4 (2)			
	Nausea	188 (98)	1.2 (0-8)	3 (2)			
	Lack of Appetite	190 (99)	3.2 (0-10)	1 (1)			
	Shortness of Breath	189 (99)	2.9 (0-10)	2 (1)			
	Depression	188 (98)	2.5 (0-10)	3 (2)			
	Anxiety	187 (98)	2.4 (0-10)	4 (2)			
	Wellbeing	184 (96)	3.9 (0-10)	7 (4)			

	Sleep	186 (97)	3.3 (0-10)	5 (3)	- Difficult to differentiate between symptoms - Understanding and meaning of words - The order of symptoms		Anxiety Sleep Wellbeing
	Constipation	188 (98)	2.9 (0-10)	3 (2)			
	Vomiting	187 (98)	0.7 (0-9)	4 (2)			

Table 3. Results of pilot-testing the EAPC Basic Dataset health care personnel form: Medical variables for the included patients; number of responses and missing data for each item; qualitative responses grouped as comments on difficulties and proposals for improvement; and resulting changes made to the dataset.

Health care personnel form		**Number of responses (%)**	**Missing data, Number (%)**	**Comments on difficulties**	**Proposals on how to improve the dataset**	**Resulting changes in the EAPC Basic Dataset**
Principal diagnosis	ICD-10 code	113 (59)	21 (11)	Don't know the ICD-10 code Hard to find Don't use it Only used in hospitals Only used in death certificates Time-consuming to find the code	Write the diagnosis Use a standardized list of cancer diagnoses	□ Malignant neoplasms of lip, oral cavity and pharynx (C00-14#) □ Malignant neoplasms of digestive organs (C15-26#) □ Malignant neoplasms of respiratory and intrathoracic organs (C30-39#) □ Malignant neoplasms of bone and articular cartilage (C40-41 #) □ Melanoma and other malignant neoplasms of skin (C43-44#) □ Malignant neoplasms of mesothelial and soft tissue (C45-49#) □ Malignant neoplasm of breast (C50#) □ Malignant neoplasms of female genital organs (C51-58#)

						□ Malignant neoplasms of male genital organs (C60-63#) □ Malignant neoplasms of urinary tract (C64-68#) □ Malignant neoplasms of eye, brain and other parts of central nervous system (C69-72#) □ Malignant neoplasms of thyroid and other endocrine glands (C73-75#) □ Malignant neoplasms of ill-defined, secondary and unspecified sites (C76-80#) □ Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue (C81-96#) □ Malignant neoplasms of independent (primary) multiple sites (C97#) □ Benign neoplasms (D10-36#) □ Neoplasms of uncertain or unknown behaviour (D37-48#)
Date of the principal diagnosis	Month. Year	138 (72)	7 (4)	Hard to find, especially the month Need to look for it Time-consuming to find		

Stage of the cancer disease	Local	12 (6)	4 (2)	Hard to find Hematologic cancer Now or at the time of diagnosis Don't know the difference between local and locally advanced	Specify now Specify solid cancer disease Add no/missing information	Current stage of the cancer disease
	Locally advanced	27 (14)				
	Metastatic/disseminated	152 (79)				
Site of metastases	Bone	76 (40)		Hard to find Now or at the time of diagnosis	Add lymph nodes The possibility to specify other using free text	Other, please specify _____
	Liver	62 (32)				
	Lung	61 (32)				
	CNS	18 (9)				
	Other	80 (42)				
Present anticancer treatment	Radiotherapy	38 (20)	2 (1)	Difficult to find out what is meant by present, some of the patients had a pause from treatment	Add surgery Add targeted therapy Add immunotherapy	Surgery Immunotherapy Other anticancer therapy, please specify _____
	Chemotherapy	75 (39)				
	Hormone therapy	24 (12)				
	Other anticancer therapy	11 (6)				
	No anticancer therapy	69 (36)				
Additional diagnoses	ICD-10	83 (43)		Don't know ICD-10 Don't use ICD-10 Hard to find Time consuming	Use standardized list of relevant diagnoses To be able to write out the name of the diseases Opportunity to tick Yes or No	Additional diagnoses (other diagnoses than the cancer diagnose, having substantial impact on the patient's health)

				What is meant by additional diagnose	To specify in the text what is meant by additional diagnoses	□ Certain infectious or parasitic diseases (A00-B99#) □ Neoplasms (C00-D48#) □ Diseases of the blood or blood-forming organs and certain disorders involving the immune mechanism (D50-89#) □ Endocrine, nutritional or metabolic diseases (E00-90#) □ Mental and behavioural disorders (F00-99#) □ Diseases of the nervous system (G00-99#) □ Diseases of the eye and adnexa (H00-59#) □ Diseases of the ear or mastoid process (H60-95#) □ Diseases of the circulatory system (I00-99#) □ Diseases of the respiratory system (J00-99#) □ Diseases of the digestive system (K00-93#) □ Diseases of the skin and subcutaneous tissue (L00-99)

						□ Diseases of the musculoskeletal system or connective tissue (M00-99#) □ Diseases of the genitourinary system (N00-99#)
Stage of the non-cancer disease	Chronic heart failure (CHF): The New York Heart Association (NYHA) Functional Classification; NYHA class I - IV	25 (13)		Don't know the classification systems Hard to find Too complicated	Exclude it from the dataset Add if needed	Removed
	Chronic obstructive pulmonary disease (COPD): GOLD classification; stage I - IV	19 (10)				
	Dementia: FAST scale; stage: 1 - 7	11 (6)				
Medication	Non-opioid analgesics	108 (56)		Information not available Difficult to place drugs in categories Uncertainty about the medication, if it is by the clock or as needed or both	To add new categories; no medication, information not available Add anticoagulation, antiepileptic, antidiabetic Others have the opportunity to write free text	Antidiabetics Anticoagulants Antiepileptics Other, please specify _____
	Opioids	129 (67)				
	Co-analgesics	39 (20)				
	Corticosteroids	84 (44)				
	Antidepressants	43 (22)				
	Antiemetics	75 (39)				
	Neuroleptics	22 (11)				
	Sedatives/anxiolytics	63 (33)				
	Drug(s) for acid related disorders	94 (49)				
	Laxatives	119 (62)				
	Antibiotics	24 (12)				

	Diuretics	34 (18)				
	Heart medication / antihypertensives	50 (26)				
	Other	78 (41)				
Weight loss	Involuntary weight loss ____ % and duration of weight loss ____months	38 (20)	153 (80)	No routine for weighing patients Information not available Difficult to use percentage	To use kilograms instead of percentage Fixed timeframe over 6 months Weight gain should also be an option	Removed
Performance status	100 Normal; no complaints; no evidence of disease.	4 (2)	3 (2)	Challenging to choose the right category, did not fit the case Accustomed to use WHO/ECOG scale	To use combined ECOG/Karnofsky scale	
	90 Able to carry on normal activity; minor signs or symptoms.	22 (11)				
	80 Normal activity with effort; some signs or symptoms of disease.	31 (16)				
	70 Cares for self; unable to carry on normal activity or to do active work.	41 (21)				
	60 Requires occasional assistance but is able to care for most of his needs.	47 (25)				
	50 Requires considerable assistance and frequent medical care.	28 (15)				
	40 In bed more than 50% of the time.	8 (4)				
	30 Almost completely bedfast.	8 (4)				
	20 Totally bedfast and requiring extensive nursing care by professionals and/or family.	2 (1)				

	10 Comatose or barely arousable.					
	0 Dead					
Cognitive function The patient has cognitive impairment;	No	160 (84)	2 (1)	Lack of definitions No formal assessment, only based on clinical judgment Fluctuates	Add “fluctuating cognitive impairment = delirium”	Fluctuating cognitive impairment added
	Mild	27 (14)				
	Moderate	2 (1)				
	Severe					
Place of care	Home	60 (31)	3 (2)	Usual or now	Specify current Specify only one option	Place of current care Other, please specify _____
	Long-term care facilities	2 (1)				
	Hospice / Palliative care unit	75 (39)				
	Hospital	65 (34)				
	Other	2 (1)				
Provision of care	Inpatient	93 (49)	2 (1)	What is the difference between outpatient and day care?	Specify current	Provision of current care
	Outpatient	63 (33)				
	Day care	33 (17)				

#ICD-10 code