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Defining the patient population: one of the problems for palliative care research

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There is a lack of clear definition and clear inclusion criteria in palliative care research. The aim of this study was to describe consequences of three inclusion criteria in the build up of different study populations, studied in terms of size, number of doctor-patient contacts and demographic characteristics. General practitioners received a questionnaire for all patients who died during the second Dutch National Survey of General Practice (n=2194), to determine whether (1) patients received non-curative treatment; (2) patients received palliative care; and (3) death was expected (total response rate=73%). The criterion 'death was expected' included most patients (62%) followed by 'palliative care' (46%) and 'noncurative treatment' (39%). Similarity between the definition-based populations was fair to moderate. More 'palliative care' and 'death was expected' in patients who had cancer than 'non-curative treatment' patients. The conclusions show substantial differences in populations according to the different inclusion criteria used to select them. Future research in palliative care should acknowledge the limitations of using certain inclusion criteria and explore potential bias.

INTRODUCTION

In 1990, the World Health Organization (WHO) defined palliative care as 'the active total care of people whose disease is not responsive to curative treatment. Control of pain, of other symptoms and of psychological, social, emotional and spiritual problems is paramount. The

goal of palliative care is achievement of the best possible quality of life for patients and their families. Many aspects of palliative care are also applicable earlier in the course of the illness in conjunction with anticancer treatment.¹ Nowadays, it is recognized that the principles of palliative care should be applied as early as possible in the course of any chronic disease. Hence, the WHO adapted the definition in 2002 to: 'an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.'² According to both WHO definitions, palliative care 'intends neither to hasten nor postpone death'.^{1,2}

Both definitions define the intentions or goals of palliative care, but are rather vague in describing the eligible population. While the goals are focusing on the symptoms and problems of the patients, the population in the WHO definitions is defined by the illness of the patient, ie, diseases not responsive to curative treatment (1990), or illnesses that are life-threatening (2002). As a consequence, palliative care populations have been defined by health policy makers or by researchers in many different ways.^{3,4} A major problem in the further development of palliative care is the lack of an accepted way of defining research populations.⁴ – ⁶ However, clear population criteria are essential to make possible the comparison of results across studies and countries.^{5,6} In the study of a general population, the effects of the chosen inclusion criteria on the outcome and characteristics of the population are, as yet, unknown. Therefore, it is useful to know the effects of using different inclusion criteria on the build up of the selected populations.

The aim of this study was to discover and describe the consequences of using different inclusion criteria on the selected populations. We used three criteria. The first criterion, treatment 'not directed at cure nor at lifeprolongation', is taken directly from the 1990 WHO palliative care definition.¹ The second criterion, the treating physician labels the patient as 'were provided with palliative care', has been chosen because it is the most commonly used concept. Furthermore, this subjective label allows all kinds of factors that are related to palliative care in the perception of the labeler to be taken into account. Finally, the third criterion, the death of the patient was not 'suddenly and unexpectedly', was chosen to include patients who were at risk of receiving palliative care because their death did not occur unexpectedly. This criterion has been used in different Dutch and European end-of-life studies.^{7,8}

The research question addressed in this study is: what are the similarities and differences in terms of size, number of doctor_patient contacts and demographic characteristics between the populations selected by the different criteria?

METHODS

Data collection

The data used in this study were obtained from the second Dutch National Survey of General Practice (DNSGP-2), in which a representative sample of 96 Dutch general practices participated with a total of 375 899 patients. The start of the one-year registration period in the study practices varied between April 2000 and January 2001.⁹ In the participating general practices, approximately 1.6 million contacts with patients were digitally recorded, and in these files the morbidity and diagnoses were registered according to the International Classification of Primary Care (ICPC-1).¹⁰ Data on the demographic and clinical characteristics of all patients were collected. The study was carried out according to Dutch legislation on privacy. The privacy regulation of the study was approved by the Dutch Data Protection Authority.⁹

Criteria for palliative care

In an additional questionnaire designed for this study, the patients who died during the period of registration were categorized according to the general practitioners' answers to three questions: (1) did this patient receive treatment directed at cure or life-prolongation? (2) did you or your co-operative provide palliative care? and (3) was the patient's death sudden and unexpected? We tried to make this text easier to read by translating these three questions into criteria, so that a 'yes' for a criterion meant that the patient received palliative care according to that criterion. We translated the questions as follows: if the general practitioner's answer to the first question was 'no, the treatment was not directed at cure nor at lifeprolongation', we categorized the patient as positive on criterion 1: 'non-curative treatment'. A positive answer to question two, 'yes', implied inclusion on criterion 2: 'palliative care'. If the answer to question 3 was 'no', the patient was categorized positively on criterion 3: 'death was expected'. Figure 1 illustrates this categorization and shows the eight possible combinations, where combination 8 represents patients who were categorized as negative on all three criteria. As all patients died during the year of registration, we had varying prior-to-death data. To analyse contact information, we defined a population of patients who died at least three months after the start of the study. In this population, we analysed the contact registration with regard to the number of doctor-patient contacts over a fixed period of three months before death.

[FIGURE 1]

Analysis

To determine differences in the size of outcome populations, we used frequency tables. To answer the question on similarity, we compared the frequencies of the variables gender, age and underlying diseases within the three criteria, using frequency tables and kappas (k) to express similarity: a value < 0.2 =poor similarity, between 0.21 and 0.40=fair, 0.41-0.60=moderate, 0.61-0.80=good, and a value > 0.80 =very good similarity.¹¹ This comparison was carried out for the variable gender and underlying disease, using data from the complete sample. Data from fewer patients were available for comparing the number of doctor_patient contacts in the last three months of life, since some patients were excluded because they died within the first three months of the study. To answer the question on differences between populations of patients who met the inclusion criteria, a pair-wise comparison was made of the differences between the categories which excluded each other. We used a χ^2 -test to determine whether the differences were statistically significant, with an alpha-level of 5%. The same variables as for similarity were included in this analysis.

RESULTS

Population size

In the 96 general practices, 2194 of the 375 899 patients died during the year of registration (0.6%). Of the 2194 questionnaires sent to the general practitioners, 1771 were returned (81%) and 1608 were filled in completely (73% valid response rate). Most patients (69%) were categorized as positive on at least one palliative care criterion, and 26% on all three (Table 1). For 62% of all included patients, death was expected, 46% received palliative care and 39% received non-curative treatment. In 31% of cases, the patients did not fit any of the criteria.

[TABLE 1]

[TABLE 2]

Characteristics and similarities of included populations There were no differences in the mean age and the gender proportions between the three criteria-based populations (Table 2). The similarity between the 'non-curative treatment' population versus both those defined as receiving 'palliative care' ($k=0.36$) and 'death was expected' ($k=0.39$) was fair; and between receiving 'palliative care' and 'death was expected' the similarity was moderate ($k=0.57$). In the 'non-curative treatment' population, there were relatively fewer cancer patients and more patients with other diseases than in the other populations, and in the 'palliative care' population there were relatively more cancer patients than in the 'death was expected' population. For cancer as the underlying disease, similarity was poor between the 'non-curative treatment' population and the 'palliative care' and 'death was expected' populations, and fair between the 'palliative care' and 'death was expected' populations. Between all populations, similarity for heart failure as the underlying disease was moderate, and for COPD it was poor to fair. The overall similarity between the three populations was fair to moderate. A higher proportion of patients receiving 'palliative care' had at least one doctor-patient contact in the last three months of life (95%) compared to those receiving 'non-curative treatment' and those whose 'death was expected' (90%). The mean number of doctor-patient contacts was 12.4 for the 'palliative care' population, 11.2 for the 'non-curative treatment' population and 10.9 for the 'death was expected' population.

Characteristics and differences in populations excluded by the criteria

In Table 3, we focus pair-wise on the differences between populations excluded by each other. A total of 940 patients were defined by either 'non-curative treatment' or 'palliative care', and there was an overlap of 431 patients (combinations 1 and 5). Excluded by palliative care and only included by 'non-curative treatment' were 197 patients (combinations 3 and 7), compared to 312 patients included only by 'palliative care' (combinations 2 and 6). Between these two sub-populations, there was no difference in gender distribution, but patients exclusively categorized as 'non-curative treatment' were significantly older than patients exclusively categorized as 'palliative care'. The 'palliative care' population had a higher proportion of cancer patients and a lower proportion of patients with other diseases than the 'non-curative treatment' population. A higher proportion of patients exclusively categorized as 'palliative care' had at least one doctor-patient contact during the last three months of life, and the mean number of doctor-patient contacts in the last three months of life was higher, compared to the population exclusively categorized as 'non-curative treatment'. Within the combination of 'non-curative treatment' and 'death was expected', there were 78 exclusive 'noncurative treatment' patients and 441 exclusive 'death was expected' patients. Between these two populations, there were no significant demographic differences, but the 'death was expected' population had a higher proportion of cancer patients and a lower proportion of patients with other diseases. No differences were found in the proportion of patients with at least one doctor-patient contact, but the mean number of doctor-patient contacts for 'death was expected' patients was higher than for 'noncurative treatment' patients. Within the combination of 'palliative care' and/or 'death was expected', there were 64 exclusive 'palliative care' patients and 312 exclusive 'death was expected' patients. Between these two sub-populations, there was no difference with regard to gender, age and underlying disease. Compared to the 'death was expected' patients, more 'palliative care' patients had at least one doctor-patient contact, and the mean number of doctor-patient contacts for these patients was higher.

[TABLE 3]

DISCUSSION

In this study, we applied three different criteria for palliative care to the same palliative care research population, namely (1) non-curative treatment, (2) palliative care or (3) death was expected. This made it possible to compare similarities and differences between the selected sub-populations. The criterion 'death was expected' included most patients (62%), followed by 'palliative care' (46%) and 'non-curative treatment' (39%). Similarity between the three definition-based populations was fair to moderate. More 'palliative care' and 'death was expected' patients had cancer than 'noncurative treatment' patients, and the 'palliative care' population had more doctor-patient contacts. This study was embedded in the second Dutch National Survey of General Practice (DNSGP-2), a nationwide study of doctor-patient contacts in a representative sample of general practices in the Netherlands.⁹ With mean non-response rates of 39% reported in published studies carried out in general practice, and a trend of decreasing rates of response to mail questionnaires, the total response rate of 73% for the additional questionnaire was high.¹² However, this study has some limitations. The DNSGP-2 was not designed specifically for palliative care research, so there was no data available on several items that are relevant for palliative care. For example, there is no data available on some important and relevant issues that might have influenced the need for palliative care and the number of doctor-patient contacts, eg, whether or not the patients had a reliable support system.¹³ The findings of this study have implications for the understanding of the composition of populations included in palliative care research. First, the overall distribution shows that there is little similarity between patient groups defined as 'end-of-life' patients. It also illustrates the extreme difficulty of defining groups in palliative care research. One explanation for this might be that the three pragmatically chosen criteria measure related but somewhat different concepts. 'Non-curative treatment' might measure the intention of palliative treatment, and the second criterion 'palliative care' might measure whether the general practitioner considers the care to be palliative. This may be linked to the severity of the problems and the frequency of doctor-patient contacts. The third criterion 'death was expected', might measure the likelihood that the patient would die soon. Hence, these three concepts are not fully interchangeable, and do not generate populations with a full overlap. Apparently, patients receiving palliative care can, at the same time, be receiving non-curative treatment, and their death is not always expected. Furthermore, the labeling of patients may possibly influence patient care itself. In a study focusing on patients with colon and lung cancer, patients whose general practitioner considered the care to be palliative, died earlier than those whose general practitioner did not.¹⁴ This might indicate that the label 'palliative care' is associated with a more serious illness. Our study shows that the 'palliative care' population included patients who had more doctor-patient contacts than patients included by the other criteria, and that most of these patients had cancer. This supports the argument that palliative care is related to intensified care. However, the question is: do these patients receive the label 'palliative care' because they have cancer, or because they need and receive intensified care? If it is the first reason, patients with a chronic illness who are labeled as 'death was expected', but not as 'palliative care' patients, might possibly be excluded from receiving the more intensified care that they might need. Given the major research consequences of applying different inclusion criteria, we still face the problem of choosing the best criterion for palliative care research. This study shows that there are substantial differences between populations when certain criteria are chosen. Future research should focus on further investigation of the diversity in characteristics of palliative care populations. This is only possible if future studies describe in more detail the way in which their population is included. If we want to describe differences between subpopulations without omitting any potential palliative care patients, we must apply the broadest possible inclusion criteria. Hence, we recommend the

use of a combination of different inclusion criteria, which should include at least 'palliative care' as labeled by (professional) carers, the intention of the palliative care treatment provided, and an assessment of the patient's life-expectancy, not meant to predict because this is rather difficult,¹⁵ but as an indicator of the possibility of a palliative care trajectory. To improve our current knowledge about palliative care, it would be preferable if we could find an internationally accepted combination of criteria to make it possible to compare palliative care in different settings, countries and sub-populations. This can be the starting point for the development of an internationally accepted research definition, something that is essential for the further development of palliative care research.

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FIGURES AND TABLES

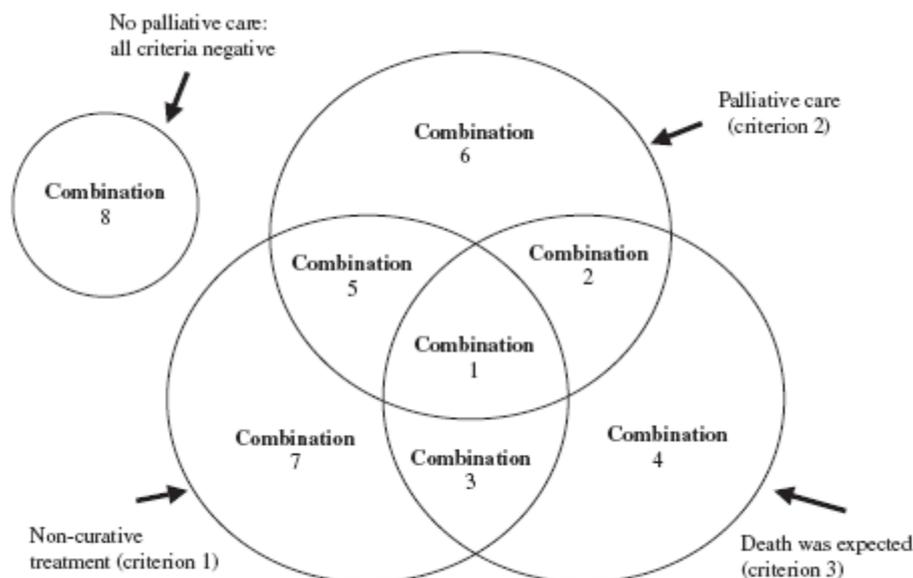


Figure 1 Distribution of a palliative care population divided into eight possible combinations of three criteria for palliative care: (1) non-curative treatment (1,3,5,7), (2) palliative care (1,2,5,6) and (3) death was expected (1,2,3,4).

Table 1 Size of palliative care population according to the three criteria studies: (1) non-curative treatment, (2) palliative care and (3) death was expected ($n = 1608$)

No. of combination (see Figure 1)	Criterion 1: 'non-curative treatment' ^a	Criterion 2: 'palliative care' ^b	Criterion 3: 'death was expected' ^c	No.	%
1	+	+	+	415	26
2	-	+	+	264	16
3	+	-	+	135	8
4	-	-	+	177	11
5	+	+	-	16	1
6	-	+	-	48	3
7	+	-	-	62	4
8	-	-	-	491	31
Total	628 (39%)	743 (46%)	991 (62%)	1608	100

^aIn the questionnaire we asked: 'did this patient receive treatment directed at cure or life-prolongation?' Criterion 1 was positive if the general practitioner answered 'no, the treatment was not directed at cure nor at life-prolongation'.

^bIn the questionnaire we asked: 'did you or your co-operative provide palliative care?' Criterion 2 was positive if the general practitioner answered this question with 'yes'.

^cIn the questionnaire we asked: 'was the patient's death sudden and unexpected?' Criterion 3 was positive if the general practitioner answered this question with 'no'.

Table 2 Demographic characteristics, underlying diseases and number of contacts in a palliative care population and similarities (κ)^a in variables between populations defined according to three criteria: (1) non-curative treatment (NCT), (2) palliative care (PC2) and (3) death was expected (DE) ($n = 1608$)

A: Total population ($n = 1608$)	Criterion 1: NCT %		Criterion 2: PC %		Criterion 3: DE %		1 versus 2 κ	1 versus 3 κ	2 versus 3 κ
Demographic characteristics									
Gender (male) (95% CI)	45	40–49	47	43–51	48	44–51	0.36	0.39	0.57
Mean age (SD)	79	13	75	15	76	14			
Underlying diseases									
Cancer	44	39–48	55	52–60	48	45–52	0.12	0.12	0.36
Heart failure	16	13–20	16	14–19	17	15–20	0.42	0.44	0.49
COPD	6.2	4.5–8.4	6.9	5.1–8.9	7.5	5.9–9.3	0.16	0.33	0.19
Other diseases	41	37–45	27	24–31	34	31–37	0.39	0.45	0.45
<i>n</i> Total	628		743		991		0.36	0.39	0.54
B: Complete data for the period three months before death ($n = 1122$)^b									
Doctor–patient contacts									
At least one contact (95% CI)	90	87–93	95	93–98	90	87–92	0.37	0.37	0.55
Mean number of contacts (SD)	11.2	8.0	12.4	8.2	10.9	8.1			
<i>n</i> Total	448		520		697				

^a κ : <0.2 poor similarity, 0.21–0.40 fair similarity, 0.41–0.60 moderate similarity, 0.61–0.80 good similarity and >0.80 very good similarity.

^bOnly patients who died at least three months after the start of the study were included.

Table 3 Demographic characteristics, underlying diseases and number of contacts of palliative care patients excluded by three criteria: (1) non-curative treatment (NCT), (2) palliative care (PC) and (3) death was expected (DE) and differences^a in variables between sub-populations ($n = 1608$)

	Criterion 1 (NCT) versus criterion 2 (PC)			Criterion 1 (NCT) versus criterion 3 (DE)			Criterion 2 (PC) versus criterion 3 (DE)		
	NCT (%)	PC (%)	P	NCT (%)	DE (%)	P	PC (%)	DE (%)	P
A: Total population ($n = 1608$)									
Overlap	431 (69%)	431 (58%)		550 (88%)	550 (55%)		679 (91%)	679 (69%)	
Excluded	197 (31%)	312 (42%)		78 (12%)	441 (45%)		64 (8.6%)	312 (31%)	
Demographic characteristics (%)									
Gender (male)	47	52	n.s.	45	51	n.s.	48	48	n.s.
Mean age	79	72	<0.001	78	74	n.s.	79	79	n.s.
Underlying diseases (%)									
Cancer	21	58	<0.001	10	48	<0.001	17	24	n.s.
Heart failure	18	18	n.s.	18	20	n.s.	33	24	n.s.
COPD	8	9	n.s.	2.6	8.4	n.s.	16	11	n.s.
Other diseases	60	22	<0.001	69	30	<0.001	42	51	n.s.
B: Complete data three months before death ($n = 1122$)^b									
Overlap	314 (70%)	314 (60%)		393 (88%)	393 (56%)		477 (92%)	477 (68%)	
Excluded	134 (30%)	206 (40%)		55 (12%)	304 (44%)		43 (8.3%)	220 (32%)	
Doctor–patient contacts									
At least one contact	78	96	<0.01	85	89	n.s.	95	78	<0.01
Mean number of contacts (SD)	6.1 (4.7)	11 (8.3)	<0.001	5.5 (4.0)	9.6 (7.9)	<0.01	8.1 (5.8)	6.0 (4.7)	<0.05

^aDifferences between sub-populations were calculated with a χ^2 -test. For means (age) we used a Student's t-test.

^bOnly patients who died at least three months after the start of the study were included.