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Study recruitment factors in advanced cancer: the Prognosis in Palliative care Study II (PiPS2) - a multicentre, prospective, observational cohort project

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ABSTRACT

Objectives The Prognosis in Palliative care Study II (PiPS2) was a large multicentre observational study validating prognostic tools in patients with advanced cancer. Many palliative care studies fail to reach their recruitment target. To inform future studies, PiPS2 rigorously monitored and identified any potential recruitment barriers.

Methods Key recruitment stages (ie, whether patients were eligible for the study, approached by the researchers and whether consent was obtained for enrolment) were monitored via comprehensive screening logs at participating sites (inpatient hospices, hospitals and community palliative care teams). The reasons for patients' ineligibility, inaccessibility or decision not to consent were documented.

Results 17 014 patients were screened across 27 participating sites over a 20-month recruitment period. Of those, 4642 (27%) were ineligible for participation in the study primarily due to non-cancer diagnoses. Of 12 372 eligible patients, 9073 (73%) were not approached, the most common reason being a clinical decision not to do so. Other reasons included patients' death or discharge before they were approached by the researchers. Of the 3299 approached patients, 1458 (44%) declined participation mainly because of feeling too unwell, experiencing severe distress or having other competing priorities. 11% (n=1841/17 014) of patients screened were enrolled in the study, representing 15% (n=1841/12 372) of eligible patients. Different recruitment patterns were observed across inpatient hospice, hospital and community palliative care teams.

Conclusions The main barrier to recruitment was 'accessing' potentially eligible patients.

Key messages

What was already known?

- Many studies don't reach recruitment targets.
- Few previous studies have rigorously documented reasons for this.

What are the new findings?

- Main recruitment barrier is accessing potentially eligible patients.
- 56% of those approached, agree to enrolment.

What is their significance?

- Even very ill patients are willing to participate in research.
- Close monitoring of recruitment practices can inform future study designs.

Monitoring key recruitment stages may help to identify barriers and facilitators to enrolment and allow results to be put into better context.

Trial registration number ISRCTN13688211.

INTRODUCTION

Palliative care is assuming greater importance as people are living longer with multimorbidity and terminal illnesses.¹ The number of patients with advanced cancer is anticipated to increase substantially over the next two decades.² Undertaking research in palliative care is relevant and important to public health systems, such as the UK National Health Service (NHS), and is necessary to guide clinical practice.³

Many palliative care studies fail to recruit adequately and on schedule^{4,5} and barriers to recruitment have been well documented.^{6–9} It is often difficult to identify eligible patients due to complex protocol designs, patients' discharge or death before they can be seen by researchers and heavy symptom burden.^{6–8} Scarce research resources and insufficient training of research personnel to approach patients and caregivers^{6,9} have also been described as major barriers to recruitment in palliative care research. Additionally, a key obstacle to recruitment that is widely acknowledged is the phenomenon of 'gatekeeping', which refers to the reluctance of clinicians to allow access to patients for research purposes.^{6–9}

Our research group has previously reported on the factors that adversely affected recruitment to the Prognosis in Palliative care Study (PiPS), which was a large, national, multicentre, observational study that developed predictive models of survival for use in patients with advanced cancer.^{10,11} Stone and coworkers¹⁰ identified the reasons why patients were or were not recruited at 18 sites, across different settings, including inpatient hospices, hospital and community palliative care teams. The results suggested that 'gatekeeping' may have acted as a barrier to recruitment. 'Gatekeeping' may stem from a well-intentioned desire to safeguard patients from burden, but it may deprive them of the opportunity to engage in autonomous decision-making about their own care.^{12,13} 'Gatekeeping' was found to occur least frequently in hospice inpatient settings.

The Prognosis in Palliative care Study II (PiPS2), was a national, multicentre, observational study to validate the PiPS prognostic models of survival, in a large independent cohort of patients with advanced cancer.^{14,15} Just as in the original study,¹⁰ we collected data relating to the challenges in identifying eligible patients, accessing and consenting them for participation. The main difference between this study and our previous report is that the PiPS2 patient sample represents a new and larger data set, recruited over a greater number of sites and using stricter data-quality control procedures, allowing for more robust evaluation of recruitment processes.

METHODS

Study design

PiPS2 opened to recruitment at 28 palliative care services across England and Wales. Patients were recruited from inpatient hospices, hospital and community palliative care teams.

Study population and assessments

Eligible patients were men and women, aged 18 years or over, who had locally advanced or metastatic incurable cancer and were no longer receiving treatment with curative intent. The study involved patients with or without capacity to consent to participate. Patients

with capacity were required to provide a blood specimen for routine haematological and biochemical analysis. For patients without capacity, there was no requirement for blood sampling. As one of the conditions of research ethics committee approval, the research site team needed approval from clinical staff before approaching patients (or caregivers) about possible participation in the study. Data, which included clinical assessments, key symptoms and measures of disease extent, were usually obtained from a review of the medical notes and/or discussion with clinical staff. Data could also be obtained by direct questioning of patients with capacity.

All patients with capacity provided written informed consent. For patients without capacity, a personal consultee (a relative or a carer), who was designated as next of kin, provided assent by signing a declaration form. For patients with no next of kin, a nominated consultee (a member of clinical staff with no connection to the research) signed the declaration form, if they thought it appropriate.

Details about inclusion and exclusion criteria, study assessments and death notification have been published elsewhere.¹⁴

Recruitment monitoring

To identify potential factors affecting recruitment, and to provide targeted support to the sites, if appropriate, recruitment was monitored using comprehensive screening logs (online supplemental appendix 1A), which were maintained at all participating sites. Logs recorded all patients who were referred to the service, so that they would be considered for inclusion in the study. However, because screening logs were anonymised, patients who were referred to the same service multiple times were allocated multiple screening ID numbers. Therefore, our data relate to 'patient episodes' rather than to 'patients'.

Logs recorded patients' age range, gender, capacity to consent, eligibility, whether they were approached by the research site team and whether consent was obtained for enrolment. Reasons for patients' ineligibility, inaccessibility and refusal to consent, were also documented using a predetermined coding list (online supplemental appendix 1B) using the following categories:

1. Ineligibility—Non-cancer diagnosis, potentially curable cancer, under 18 years, insufficient English language skills, already in the study, not classified as 'palliative' patient (ie, expected to live more than a year).
2. Inaccessibility—Approach was deemed inappropriate by clinical staff ('gatekeeping'), patient died or was discharged before review, patient previously refused study, patient was unavailable, personal or nominated consultee was unavailable, research staff were unavailable, other reasons.
3. Refusal to consent—No reason volunteered, patient unwilling to undergo venepuncture, other reasons.

Research site teams managed screening data on a day-to-day basis depending on the work schedule of research team members. They submitted screening logs for upload to the University College London (UCL) Data Safe Haven secure system once a week. At three participating sites, recruitment was supported by staff directly employed on the study grant. Research at other participating sites was supported by locally funded staff.

Given the large number of sites and screening data, it was not possible to review screening data in real time. It is possible that different sites coded reasons for ineligibility, inaccessibility or failure to consent, in different ways. Nonetheless, rigorous data quality control took place retrospectively, to identify missing data, discrepancies and duplicates.

To ensure high levels of consistency in return rates across sites, UCL central research team sent regular emails to sites to remind them to submit data. In case of delayed submissions, sites were contacted via email and/or telephone. Following data collection, grant-funded staff were re-deployed to carry out extensive data quality control on enrolled patient data; 100% of electronic case report forms (CRFs) were validated by comparing them against the paper CRFs.

Statistical methods

Descriptive statistics (proportions and percentages) were used to summarise data and were calculated using SPSS V.26. Statistical tests were not used for comparisons between groups because this was a descriptive rather than a hypothesis-testing study.

RESULTS

Patient recruitment

Twenty-eight sites opened to recruitment consisting of 17 inpatient units, 17 community teams and 6 hospital support services. Some sites offered more than one type of service. One site was unable to comply with study procedures and was therefore withdrawn. Between August 2016 and April 2018, 17 014 patients were screened for eligibility across the 27 remaining sites (inpatient hospice, n=8074; hospital, n=3225; community, n=5715). Of these patients, 1841/17 014 (11%) were enrolled in the study (inpatient hospice, n=1246; hospital, n=124; community, n=471).

Of the 17 014 patients, who were screened for eligibility, 12 372 (73%) individuals were eligible for inclusion (inpatient hospice, n=6520; hospitals, n=1592; community, n=4260). Of the 12 372 eligible patients, 3299 (27%) were accessed by the research site team and were informed about the study (inpatient hospice, n=2089; hospital, n=192; community, n=1018). Of these patients, 1841/3299 (56%) were subsequently enrolled in the study. Eight patients were withdrawn from the study, resulting in a final sample size of 1833. Patients' flow through the recruitment process is shown in [figure 1](#).

Eligible versus ineligible patients

The proportion of eligible patients was 81% (n=6520/8074) among hospice inpatients, 49% (n=1592/3225) in hospital palliative care services and 75% (n=4260/5715) in community settings.

The majority of eligible patients were between 55 and 84 years of age (75%, n=9226/12 372), 13% (n=1556/12 372) were below 55 years of age and 13% (n=1590/12 372) were above 84 years of age. Approximately 48% (n=5892/12 372) of eligible patients were women.

The most common reason for ineligibility was that the patient had a non-cancer diagnosis (n=3528/4644, 76%). This was more common in hospital patients (n=1489/1634, 91%) compared with patients in inpatient hospices (n=1027/1554, 66%) and community settings (n=1012/1256, 70%). Reasons why patients were regarded as being ineligible for the study are presented in [table 1](#).

Accessible versus inaccessible patients

The research site team was able to approach and inform 27% (n=3299/12 372) of eligible patients about the study. The proportion of eligible patients who were accessible to the research site team differed across recruitment settings (32% (n=2089/6520) in inpatient hospice, 12% (n=192/1592) in hospital and 24% (n=1018/4260) in community); most patients were approached in inpatient hospice and least in hospital.

The proportion of accessible patients, who fell within the age range of 55–84 years, was 77% (n=2544/3299) (55–64 years of age: 18%, n=584/3299; 65–74 years of age: 31%, n=1015/3299; 75–84 years of age: 29%, n=945/3299). The proportion of accessible patients aged above 85 years and of those aged below 55 years was 12% (n=408/3299) and 11% (n=347/3299), respectively. These figures are broadly similar to the age distribution of eligible patients. A slightly higher proportion of accessible patients compared with inaccessible patients were women (49% (n=1623/3298) vs 47% (n=4269/9072)).

Eligible patients were not approached or informed about the study mainly due to clinical reasons. This was most common in inpatient hospices and least common in community patients (inpatient hospice 39% (n=1743/4434), hospital 34% (n=470/1400), community 22% (n=701/3248)). The second most common reason was that the patient died before they or their caregivers were informed about the study. Early death was more common in community (27%, n=869/3248) and inpatient hospice patients (26%, n=1174/4434) compared with hospital patients (13%, n=181/1400).

A number of eligible patients were not accessed due to their discharge before being approached (17%, n=1532/9082) or unavailability of a researcher to provide information about the study within the specified time frame (14%, n=1242/9082). A number

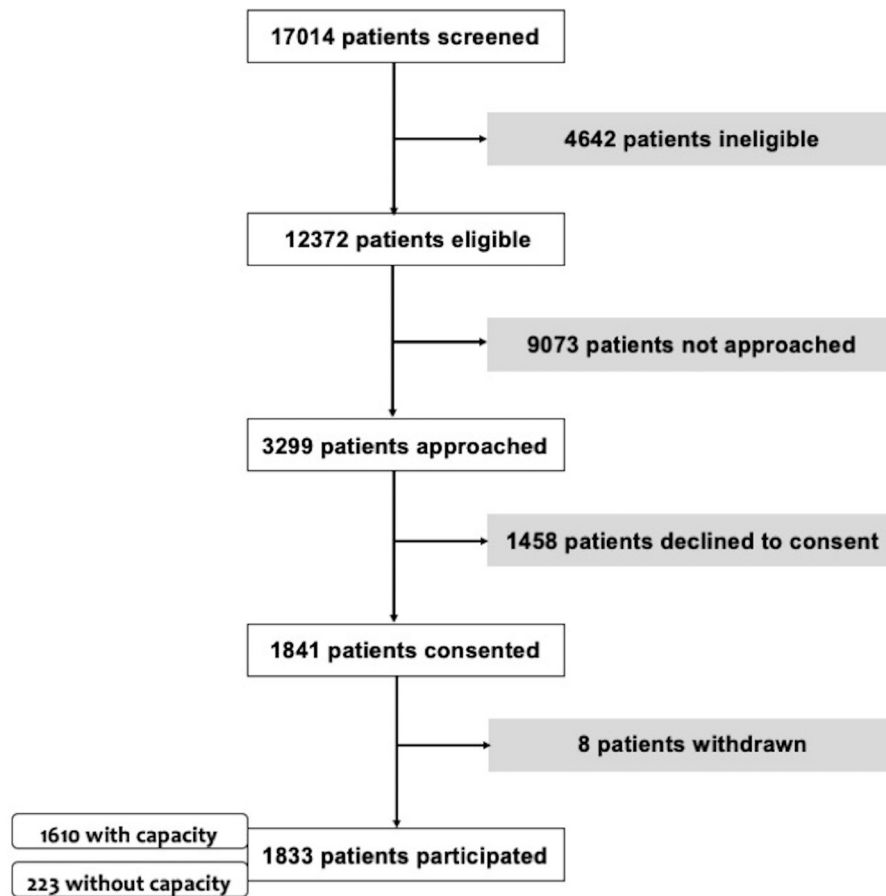


Figure 1 Flow chart displaying the recruitment to the Prognosis in Palliative care Study II (PiPS2).

of other unspecified reasons were reported (8%, $n=726/9082$). Based on research nurses' notes, the most common other reasons included that the patient was imminently dying, feeling too unwell, extremely tired, emotionally distressed, unaware of their diagnosis or unwilling to discuss their illness because they were struggling to come to terms with it. Reasons why eligible patients could not be accessed by the research site team are presented in [table 2](#).

Enrolled versus unenrolled

Approximately 56% ($n=1841/3299$) of patients who were approached by the research site team and informed about the study, consented to

participate. This represents 15% of all eligible patients ($n=1841/12\,372$). Fewer community patients consented (46%, $n=471/1018$) than inpatient hospice (60%, $n=1246/2089$) and hospital patients (65%, $n=124/192$).

Approximately 78% ($n=1438/1841$) of the enrolled patients were aged 55–84 years (55–64 years of age: 19%, $n=349/1841$; 65–74 years of age: 32%, $n=583/1841$; 75–84 years of age: 28%, $n=506/1841$), 11% ($n=206/1841$) were over 84 years of age and 11% ($n=197/1841$) were below 55 years of age. This was similar with the distribution of age groups among unenrolled patients; 55–84 years of

Table 1 Reasons for ineligibility across palliative care settings

Reason for ineligibility	Inpatient hospice, n (%)	Hospital, n (%)	Community, n (%)	Total, n (%)
Non-cancer diagnosis	1027 (66)	1489 (91)	1012 (70)	3528 (76)
Already in the study	306 (20)	15 (<1)	107 (7)	428 (9)
Not classified as 'palliative'*	108 (7)	59 (4)	174 (12)	341 (7)
Insufficient English language	86 (5)	24 (1)	138 (9)	248 (5)
Curative cancer	27 (2)	41 (3)	25 (2)	93 (2)
Under 18 years old	0 (0)	6 (<1)	0 (0)	6 (<1)
Total	1554 (100)	1634 (100)	1456 (100)	4644 (100)†

*Expected to live more than 1 year.

†Total number of ineligible patients, $n=4642$. For two patients there were more than one reasons for not being eligible for the study.

Table 2 Reasons for inaccessibility across palliative care settings

Reason for inaccessibility	Inpatient hospice, n (%)	Hospital, n (%)	Community, n (%)	Total, n (%)
Clinical reason	1743 (39)	470 (34)	701 (22)	2914 (32)
Died before review	1174 (26)	181 (13)	869 (27)	2224 (24)
Discharged before review	156 (4)	402 (29)	974 (30)	1532 (17)
Research staff unavailable	958 (22)	118 (8)	166 (5)	1242 (14)
Other	163 (4)	176 (13)	387 (12)	726 (8)
Previously refused study	103 (2)	18 (1)	61 (2)	182 (2)
Patient unavailable	60 (1)	4 (<1)	74 (2)	138 (2)
Consultee unavailable	77 (2)	31 (2)	16 (<1)	124 (1)
Total	4434 (100)	1400 (100)	3248 (100)	9082 (100)*

*Total number of inaccessible patients, n=9073. Eight patients were not approached for more than one reason.

age: 76%, n=1106/1458 (55–64 years of age: 16%, n=235/1458; 65–74 years of age: 30%, n=432/1458; 75–84 years of age: 30%, n=439/1458); above 84 years of age: 14%, n=202/1458; below 55 years of age: 10%, n=150/1458. Gender distribution was comparable between enrolled and unenrolled patients (49% (n=894/1840) vs 50% (n=729/1458) were women, respectively).

Patients (and personal or nominated consultees) had no obligation to provide any reason for refusing consent and 477 patients did not volunteer a specific reason. A few (n=83) patients reported that they did not want to undergo venepuncture and 898 did not consent due other reasons. Based on researchers' notes, these mainly included patients with extreme fatigue, distress or who were feeling too unwell. Of the 1841 enrolled patients, 8 were withdrawn either because they changed their mind regarding participation in the study (n=5) or due to other reasons (n=3).

DISCUSSION

To identify factors that may adversely affect recruitment, this study monitored three key stages of the recruitment process including the identification of eligible patients, the ability to access patients to discuss the study in detail and the proportion of participants who provided consent. This study found that 27% of all patients referred to the participating sites (n=4642/17 014) were ineligible for the PiPS2 study, 73% of the eligible patients were inaccessible to the research site team (n=9082/12 372) and that 44% of the patients or caregivers, who were approached and informed about the study declined to consent (n=1458/3299).

Overly restrictive eligibility criteria have previously been described as a major obstacle to recruitment to cancer and palliative care clinical studies.^{7 16 17} In the PiPS2 study, however, more than two-thirds of screened patients were deemed to be eligible to participate. This reflects the fact that PiPS2 was designed to be a pragmatic study for which most patients who had cancer palliative care should have been suitable for enrolment. This contrasts with the PiPS development study¹⁰ in which 43% (5394/12 412) of referrals

were deemed to be ineligible, with the most common reason (60%, 3259/5394) being on-going use of disease-directed therapies. In the light of this finding, and the fact that palliative care patients are increasingly receiving 'active' treatment even towards the end of life, the eligibility criteria for PiPS2 were relaxed to enable patients who were receiving palliative cancer therapies to participate.

Indeed, PiPS2 contained relatively few exclusion criteria and no restrictions in terms of type of metastatic cancer, patients' capacity or the existence of comorbidities.^{7 16–18} The main reason for patients' ineligibility was a non-cancer diagnosis (21%, n=3528/17 014). Although there is a growing recognition of the need to offer palliative care to patients without cancer,^{19 20} the majority of referrals to palliative care services still have cancer.²¹ Interestingly, we found that non-cancer diagnoses were more common among hospital rather than among hospice and community palliative care referrals, suggesting that hospital teams are providing more accessible services.

We found that eligible patients were inaccessible to the research site teams primarily due to 'clinical reasons' (24%, n=2914/12 372). This category covered any reason why clinicians deemed patients' approach as inappropriate and reflected the role of clinicians as gatekeepers to study participation. Other reasons for patients' inaccessibility included unavailability of researchers (10%, n=1242/12 372). Some of the eligible patients, who were not approached, such as those who died too quickly (18%, n=2224/12 372) or were discharged (12%, n=1532/12 372) before the research site team had the opportunity to approach them, could probably never have been enrolled in the study.

In both the original PiPS development study and in PiPS2, access to eligible patients was regulated by clinicians. Clinicians may prevent end-of-life patients from participating in research because of fear of burdening them or because of clinicians' limited research expertise or the lack of a research-friendly culture, and doubts about the value or quality of the research.¹² Although, we did not explicitly investigate the underlying

reasons why clinicians deemed it inappropriate to approach some patients about this study, researchers' notes suggested that eligible patients were sometimes not approached because clinical staff judged that they were imminently dying, were feeling too unwell or tired, were emotionally distressed or were unaware of their diagnosis. These may all be considered good reasons for 'protecting' patients from involvement in research. But it is relevant that imminent death or being too unwell were not exclusion criteria for the study, and such patients may have been eligible, and they (or their caregivers) may have been agreeable to their involvement in the study if only they had been approached and informed about it.

Many palliative care patients value their own autonomy and want to be able to make their own decisions about participation in research.^{12 13} Even in non-interventional studies (where there is seldom any direct benefit to participants) patients value the opportunity to be altruistic and to contribute to the community.^{22 23} Better education and training of clinicians in research methodology²⁴ and use of structured frailty assessments¹² have been proposed as ways to eliminate paternalistic clinician behaviours for patients' protection.

The unavailability of research staff was another factor that affected the number of patients who were approached in PiPS2. Research staff are generally only available during office hours, and many staff only work part-time. However, most care occurs outside of office hours and at weekends. In the PiPS2 study, it was quite possible for patients to be admitted on a Friday afternoon and to have died or been discharged from the service before any research staff were back on duty. Similarly, when research staff were on annual leave or ill, it was not possible for patients to be recruited to the study. Hospices were affected more severely by staff unavailability compared with hospitals and community teams in the PiPS2 study possibly due to more limited resources, such as only having part-time research staff or limited cover for staff absences.

Most studies only report patients who are given participant information sheets as being potentially available for the study. In the PiPS2 study, we rigorously collected data on all referrals to the participating units throughout the duration of the research project (even when research staff were absent). This provided a greater appreciation of the potential pool of participants available for the study. However, in reality, limited resources meant that only a proportion of the total referrals could ever be considered for enrolment. Other studies have also highlighted the importance of access to sufficient and dedicated research personnel, while acknowledging that this would require greater investment.^{6 9} Consistent with existing literature, this study also identified that patients' precipitous death or discharge were barriers to approaching them about participation in clinical research.^{6 10 17 25}

Approximately half of the patients (or their caregivers), who were informed about the study agreed to participate, this is in line with findings from other recent studies.^{26 27} Prior to conducting the study, we had been concerned that patients might refuse consent because of the need for a blood test. In fact, very few patients regarded this as a reason to decline to participate. Invasive procedures have previously been described as a barrier to recruitment in palliative care studies whereas simple non-invasive and non-drug studies have been acknowledged as being more attractive.^{23 28} Studies investigating strategies to improve accrual in palliative care studies have also emphasised the importance of using trained recruitment personnel, simplified consent processes, explanation of the meaningfulness of the research and expressing gratitude for patients' time.^{6 29}

There were considerable differences in eligibility, accessibility and recruitment rates in different settings. We found that it was easiest to identify and approach eligible patients in hospices and hospital palliative care services, and that more hospice patients gave consent. In keeping with previous research, we found that recruitment of patients with advanced cancer in the community setting is extremely challenging.³⁰ Higher rates of eligibility and accessibility to inpatient hospice patients may partly be explained by the fact that patients near the end of life, no longer undergoing curative treatment, are more likely to be found in hospices.^{31 32} On the other hand, a greater proportion of hospital patients may be willing to participate in research possibly because they are less ill than those in the hospice and are often supported by better research infrastructure.³³ These findings may help guide other researchers about optimising recruitment strategies for their own studies.

Strengths and limitations

Most previous studies have only described the number of patients who are approached about the study and the proportion providing consent. Although this provides some understanding about the representativeness of the sample, it neglects to consider the majority of patients in most studies who are either ineligible or are never given the opportunity to consider participation. Our data set allows greater insight into the potential barriers and facilitators to research participation. However, given the large number of sites and potential participants that the PiPS2 study involved, it was not possible to systematically check the accuracy of the screening data and it is possible that different sites coded the reasons for ineligibility, inaccessibility or failure to consent, in different ways. Our data quality control procedures were time consuming and for this reason future studies that wished to rigorously collect such data would need to consider the resource implications on study funding. Our study also lacked a qualitative evaluation of 'gatekeeping', which would

have provided a richer understanding of the phenomenon of interest.

CONCLUSION

Many factors can affect recruitment to palliative care studies. In the PiPS2 study the key barrier was difficulty accessing potential research participants rather than refusal to consent. Although time-consuming and requiring extra resources to achieve, researchers should consider monitoring the key stages of recruitment (identifying eligible patients, approaching them about the study and obtaining consent) in order to identify barriers and facilitators to recruitment in their own studies and to allow research results to be put into better context.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study received ethical approval from the Yorkshire & the Humber - Leeds East Research Ethics Committee on 12 April 2016 (Ref: 16/YH/0132).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The study included de-identified participant data, which are available upon reasonable request from Professor Paddy Stone, who is the corresponding author.

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Appendix 1. PiPS2 a) screening log template and b) coding list

a) PiPS2 screening log template

CHIEF INVESTIGATOR NAME	SITE PRINCIPAL INVESTIGATOR NAME	REFERENCE NUMBERS	SITE ID	SITE NAME	PALLIATIVE CARE SETTING RECRUITED FROM
ID		REC: 16/YH/0132			Name:
					ID Number:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
DATE OF REFERRAL TO TEAM (dd/mm/yyyy)	SITE ID	SETTING ID	PATIENT ID (4 digits)	AGE GROUP	GENDER	ELIGIBLE	REASON FOR INELIGIBILITY	APPROACHED	REASON NOT APPROACHED	CAPACITY	CONSENTED or Agreement of consultee	REASON for not consenting	DATE OF REDCAP UPLOAD (dd/mm/yyyy)
			0 0 0 1										
			0 0 0 2										
			0 0 0 3										
			0 0 0 4										
			0 0 0 5										
			0 0 0 6										
			0 0 0 7										
			0 0 0 8										
			0 0 0 9										
			0 0 1 0										
			0 0 1 1										
			0 0 1 2										
			0 0 1 3										
			0 0 1 4										
			0 0 1 5										

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b) PiPS2 coding list

5		6		7		8		9		10		11		12		13	
AGE GROUP		GENDER		ELIGIBLE		REASON FOR INELIGIBILITY		APPROACHED		REASON NOT APPROACHED		CAPACITY		CONSENTED or Agreement of consultee		REASON for not consenting	
0	Under 18	1	Male	0	No	1	Non-cancer diagnosis	0	No	1	Clinical reason	0	No	0	No	0	No reason volunteered
1	18-24	2	Female	1	Yes	2	Curative cancer	1	Yes	2	Died too soon	1	Yes	1	Yes	1	Did not want blood test
2	25-34	3	Don't want to tell			3	Under 18 years old			3	Discharged too soon					2	Other
3	35-44					4	Insufficient English language skills			4	Previously refused study						
4	45-54					5	Already in study			5	Patient not available						
5	55-64					6	Not "palliative" – expected to live more than one year			6	Consultee not available						
6	65-74									7	Staff not available						
7	75-84									8	Other						
8	85-94																
9	95+					7	No routine blood specimen due to be taken and not able to consent to fresh specimen										

Code 7 only to be used in second phase of study

PiPS2 Coding list for screening and enrolment log Version 1.0 13-June-2016