NATIONAL BOWEL CANCER AUDIT

The feasibility of reporting Patient Reported Outcome Measures as part of a national colorectal cancer audit

NBOCA: Feasibility Study

Date of publication: Thursday 9th August 2018

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Introduction

As survival from colorectal cancer improves, there are an increasing number of people living with or beyond this diagnosis in the United Kingdom (UK)[1]. However, many of these patients will have undergone treatment such as surgery, radiotherapy and chemotherapy. As a result of this, the quality of life of survivors may be significantly reduced.

The Independent Cancer Taskforce report - published in 2015 - provided a wide range of recommendations on how the National Health Service (NHS) can reduce preventable cancers, increasing cancer survival and improving patient experience and quality of life by 2020. NHS England and other Arm's Length Bodies commitment to driving the local delivery of these recommendations and improving the long term quality of life of people diagnosed with cancer is a key part of this.

NHS England's National Cancer PROMs Programme of the National Survivorship Initiative[2] collected Patient Reported Outcome Measures (PROMs) for colorectal cancer patients in a one-off study in 2013. Patients were between one- and three-years from diagnosis at the point of being surveyed.

The aim of this study was to link the PROMs survey data to the National Bowel Cancer Audit (NBOCA) data to establish the feasibility of reporting PROMs as part of a national clinical audit. This was assessed according to i) the characteristics of responders compared to all eligible patients ii) the representativeness of the responders at different points along their pathway from diagnosis, iii) hospital trust variation in response rate, and iv) the validity of the measures in comparison to NBOCA measures.

Methods

Public Health England PROMs survey

A survey was sent out in January 2013 to a cohort of individuals identified via the National Cancer Registration Service, now known as the National Cancer Registration and Analysis Service (NCRAS). The following inclusion criteria were used:

- Aged over 16 years
- Diagnosed with colorectal cancer (International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD10) codes C18-20) in 2010 or 2011 and still alive in January 2013
- Treatment received in the NHS in England.

34,467 individuals in the NCRAS data who met the inclusion criteria were sent the questionnaire by post. Of these, 21,802 individuals returned partially or fully completed questionnaires, giving a response rate of 63.3%.

The questionnaire comprised of 76 questions with an additional comments box. These questions were divided into the following sections:

- General questions - types of treatment received

- Outcome questions - EQ-5D health-related quality of life measure[3], a subset of questions from the Functional Assessment of Cancer Therapy (FACT) instrument and the Social Difficulties Inventory (SDI) instrument.
- Overall support and care - questions covering primary and secondary care received
- About you - demographic questions

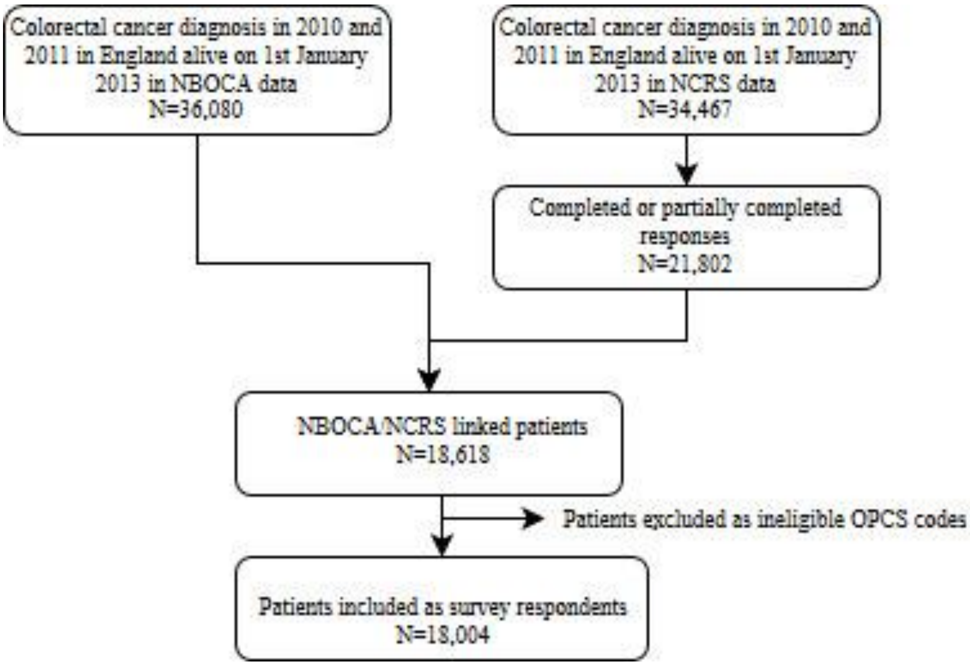
Linkage to National Bowel Cancer Audit data

There were 36,080 eligible patients identified in the NBOCA data diagnosed between 1st January 2010 and 31st December 2011 and alive on 1st January 2013.

Linkage of the two datasets was performed based on NHS number, sex, date of birth and postcode. Data from 18,618 out of the 21,802 (85.4%) individual responses were linked to NBOCA data.

The NBOCA data were linked to Hospital Episode Statistics (HES) data for additional clinical variables such as stoma formation and closure. There was a linked HES record for 16,147 patients with a survey response. Some patients had to be excluded due to ineligible Office of Population Censuses and Surveys (OPCS) codes meaning that procedural details could not be obtained. Full details of linkage and included patients are shown in Figure 1.

Figure 1 - Flow diagram of study inclusion and data linkage



Feasibility analyses

***i)** Characteristics of respondents compared to all eligible patients*

The characteristics of the 18,004 NBOCA patients with a survey response were compared to those of the 18,076 patients identified as eligible in the NBOCA dataset for whom there was no linked survey response.

ii) Representativeness of the responders at different points from diagnosis

NBOCA data was used to identify date of diagnosis to compare patient characteristics according to time from diagnosis to survey completion.

iii) Hospital trust variation in response rate

To examine regional variation in response rate, trust and network of diagnosis was ascertained from NBOCA data.

iv) Validity of measures

For assessing the validity of the survey data, firstly, the agreement between survey responses and NBOCA/ HES data was compared for whether patients reported undergoing surgery, receiving radiotherapy or having a stoma.

Secondly, to assess the validity of the EQ-5D health-related quality of life measure, its correlation with patient demographics, tumour characteristics and treatment modalities was measured. The five-level version of EQ-5D scores on five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) which are then summed to give a single index score. Scores range from -0.5 to 1, where 1 is the maximum score for an individual reporting no problems in any domain.

It was not possible to use the Functional Assessment of Cancer Therapy (FACT) instrument to measure quality of life as it has only been validated when all items are measured, and only a subset of its items were included in the survey.

Results

i) Characteristics of respondents

The clinico-pathological characteristics of patients with survey responses and those with no responses are shown in Table 1. There was no difference in response according to age in patients under 85 years. Very elderly patients were, however, less likely to respond. Patients with a completed survey also tended to have less co-morbidities, be less deprived, and were more likely to have had a major resection. Patients without a response were also more likely to have missing NBOCA data.

The clinico-pathological characteristics of patients who underwent a major resection with survey responses and those with no responses are shown in Table 2. Patients with a survey response tended to have a lower American Society of Anaesthesiologists (ASA) grade but, generally, the exclusion of those who did not have a major resection made those patients with a response more representative.

Table 1 - Characteristics of patients according to PROMS survey response or no response

		No response (%) N=18076	**Response (%) N=18004**
Time from diagnosis	12-18 months	5258 (54)	4505 (46)
	18-24 months	4577 (50)	4663 (50)
	24-30 months	4188 (47)	4789 (53)
	30-36 months	4053 (50)	4047 (50)
Age at diagnosis (years)	≤64	5755 (50)	5879 (50)
	65-74	5641 (47)	6491 (53)
	75-84	5058 (52)	4684 (48)
	≥85	1622 (63)	950 (37)
Charlson co-morbidity score*	0	11206 (46)	13322 (53)
	1	3787 (43)	3306 (57)
	≥2	1298 (59)	913 (41)
	Missing	1785	463
Index of multiple deprivation quintile**	1 (most deprived)	3199 (60)	2157 (40)
	2	3413 (54)	2933 (46)
	3	3770 (49)	3862 (51)
	4	3932 (47)	4352 (53)
	5 (least deprived)	3540 (43)	4656 (57)
	Missing	222	44
Emergency admission	No	13744 (47)	15549 (53)
	Yes	2384 (56)	1906 (44)
	Missing	1948	549
T-stage* **	0	240 (48)	265 (52)
	1	1808 (62)	1105 (38)
	2	2381 (45)	2964 (55)
	3	7265 (45)	8958 (55)
	4	2797 (49)	2861 (51)
	Missing	3585	1851
N-stage* **	0	8901 (47)	9906 (53)
	1	3553 (46)	4147 (54)
	2	1896 (48)	2018 (52)
	Missing	3726	1933
M-stage* **	No	13161 (47)	14872 (53)
	Yes	1626 (53)	1436 (47)
	Missing	3289	1696
Major resection	No	5375 (67)	2692 (33)
	Yes	12701 (45)	15312 (55)

*Charlson co-morbidity score – contains 19 categories of co-morbidity and predicts ten-year mortality for a patient who may have a range of co-morbid conditions. Each condition is assigned a score dependant on its contributing risk of death.

**Index of Multiple Deprivation (IMD) – measure of socioeconomic status. The IMD ranks 32 482 geographical areas of England according to their level of deprivation measured across seven domains. Patients are grouped in to five socioeconomic categories based on quintiles of the national ranking of these areas.

***TNM staging – describes the stage of a cancer with alphanumeric codes. T describes the size of the tumour and whether it has invaded surrounding tissue. N describes involvement of lymph nodes. M describes distant metastasis. Increasing numerical values correspond to advancing disease.

Table 2 - Characteristics of patients undergoing major resection according to response

		No response (%) N=12701	**Response (%) N=15312**
Time from diagnosis	12-18 months	3493 (48)	3747 (52)
	18-24 months	3258 (45)	3972 (55)
	24-30 months	3042 (42)	4165 (58)
	30-36 months	2908 (46)	3428 (54)
Age at diagnosis (years)	≤64	4108 (45)	4981(55)
	65-74	3972 (42)	5569 (58)
	75-84	3685 (48)	4035 (52)
	≥85	936 (56)	727 (44)
Charlson co-morbidity score	0	8426 (42)	11468 (58)
	1	2839 (50)	2829 (50)
	≥2	925 (55)	752 (45)
	Missing	511	263
Index of multiple deprivation quintile	1 (most deprived)	2243 (55)	1825 (45)
	2	2439 (50)	2476 (50)
	3	2618 (44)	3337 (56)
	4	2771 (43)	3676 (57)
	5 (least deprived)	2475 (38)	3970 (62)
	Missing	155	28
Emergency admission	No	10318 (44)	13384 (56)
	Yes	1773 (53)	1598 (47)
	Missing	610	330
ASA grade	1	1662 (41)	2402 (59)
	2	6228 (43)	8192 (57)
	3	3017 (51)	2915 (49)
	4	283 (60)	192 (40)
	Missing	1511	1611
T-stage	0	214 (47)	244 (53)
	1	1054 (54)	894 (46)
	2	1996 (53)	2696 (57)
	3	6312 (43)	8258 (57)
	4	2398 (48)	2594 (52)
	Missing	727	626
N-stage	0	7494 (45)	9142 (55)
	1	2953 (44)	3738 (56)
	2	1540 (46)	1780 (54)
	Missing	714	652
M-stage	0	11017 (45)	13709 (55)
	1	1132 (50)	1142 (50)
	Missing	552	461
Operative urgency	Elective/Scheduled	10794 (45)	13407 (55)
	Emergency/Urgent	1720 (50)	1674 (49)
	Missing	187	231

ii) Representativeness of the responders at different points from diagnosis

The response rate by patient characteristics according to months from diagnosis are shown in Table 3. Response rate according to characteristics did not appear to change over time except for the response rate for patients with more advanced tumours (i.e. those with T3/4, N2 and M1 disease) which appeared to increase up until 24-30 months and then reduce again in the 30-36 month period.

Table 3 - Response rate by patient characteristics according to months from diagnosis

		12-18 months N=4505	**18-24 months N=4663**	**24-30 months N=4789**	**30-36 months N=4047**
Gender	Male	2657 (57)	2684 (51)	2795 (54)	2332 (51)
	Female	1848 (45)	1976 (50)	1993 (52)	1715 (48)
Age	18-64	1411 (47)	1582 (51)	1546 (53)	1340 (44)
	65-74	1608 (50)	1640 (54)	1740 (57)	1502 (54)
	75-84	1223 (45)	1200 (49)	1259 (52)	1002 (47)
	≥85	263 (33)	241 (37)	243 (41)	203 (38)
Charlson co-morbidity score	0	3232 (50)	3467 (55)	3606 (58)	3017 (54)
	1	876 (44)	842 (45)	852 (49)	736 (48)
	≥2	278 (41)	231 (41)	208 (40)	196 (43)
Index of multiple deprivation quintile	1 (most deprived)	535 (37)	562 (40)	572 (43)	488 (41)
	2	744 (43)	782 (48)	781 (49)	626 (46)
	3	957 (47)	1021 (52)	992 (53)	892 (51)
	4	1030 (45)	1109 (53)	1197 (57)	1016 (54)
	5 (least deprived)	1225 (54)	1176 (56)	1239 (61)	1016 (55)
Emergency admission	No	3871 (49)	4037 (54)	4129 (56)	3512 (53)
	Yes	498 (41)	485 (44)	511 (48)	412 (46)
T-stage	0	48 (45)	83 (56)	84 (56)	50 (50)
	1	290 (36)	274 (38)	300 (40)	241 (37)
	2	731 (51)	799 (58)	789 (59)	645 (54)
	3	2253 (51)	2295 (55)	2397 (59)	2013 (56)
	4	759 (47)	735 (50)	748 (54)	619 (53)
N-stage	0	2385 (49)	2602 (54)	2690 (56)	2229 (52)
	1	1113 (51)	1039 (53)	1092 (58)	903 (54)
	2	566 (48)	526 (50)	511 (55)	415 (56)
M-stage	0	3668 (49)	3861 (54)	4017 (56)	3326 (53)
	1	425 (43)	374 (44)	365 (52)	272 (51)
Major resection	No	758 (30)	691 (35)	624 (35)	619 (35)
	Yes	3747 (52)	3972 (55)	4165 (58)	3428 (54)

iii) Hospital trust variation in response rate

There was significant variation in the proportion of patients with a completed questionnaire according to hospital trust of diagnosis as shown in Figure 2. There were 64/142 hospital trusts outside the 95% confidence intervals (up to 7 would be expected by chance alone). The range in response rate by hospital trust was large. There were 26 trusts with a response rate lower than 40% and 13 trusts with a response rate over 60%.

Table 4 demonstrates the age groups and index of multiple deprivation quintile of patients according to quintile of trust response rate. Age group did not markedly vary according to Trust response rate quintiles. Trusts within the quintile with the lowest response rate clearly had a higher proportion of more deprived patients and lower proportion of less deprived patients. Similarly, trusts within the quintile with the highest response rate clearly had a higher proportion of less deprived patients and lower proportion of most deprived patients.

Figure 2 - Funnel plots of proportion of patients with completed questionnaire according to hospital trust of diagnosis

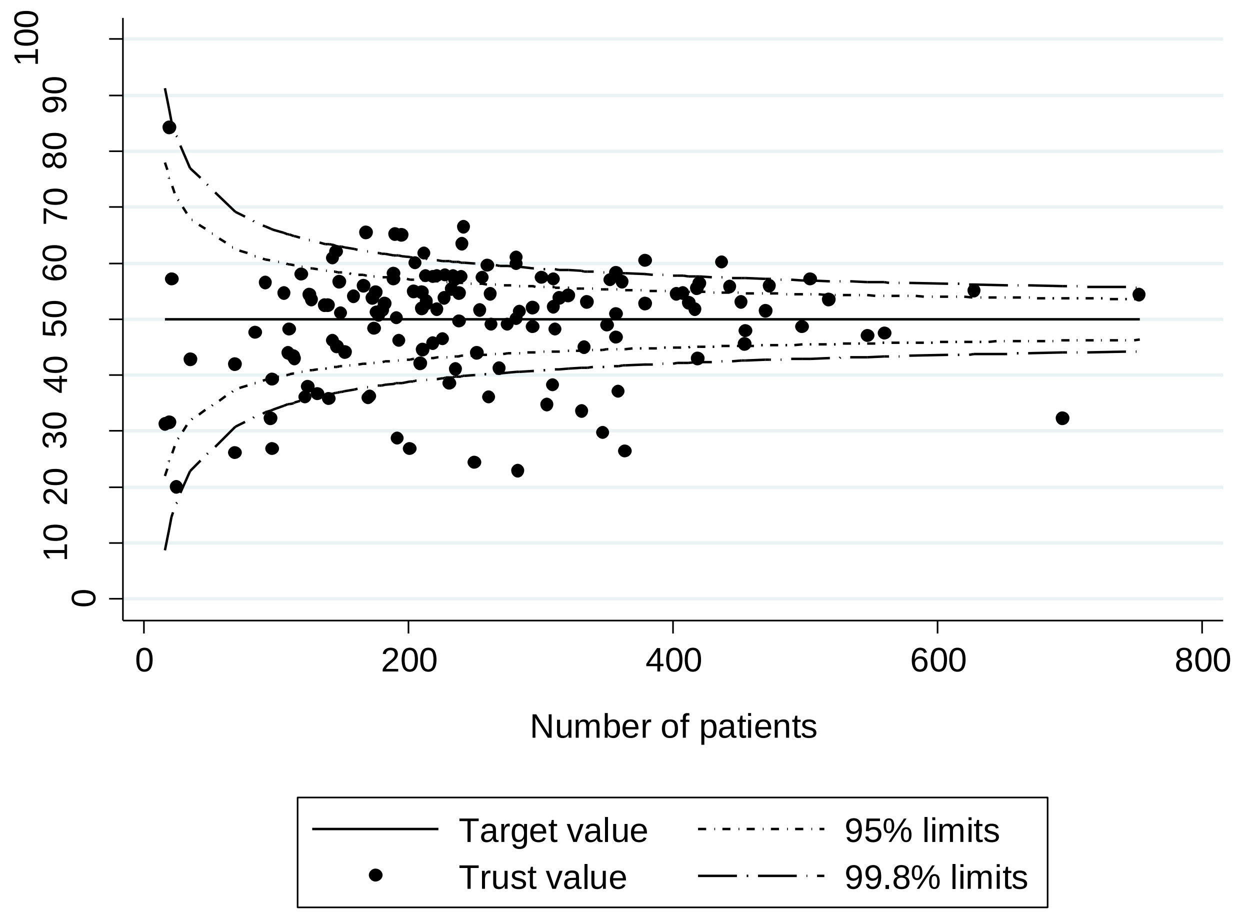


Table 4 - Age groups and Index of multiple deprivation (IMD) quintile of patients according to quintile of trust response rate.

		Quintile of trust according to response rate*				
		1 (lowest response rate)	**2**	**3**	**4**	**5 (highest response rate)**
Total patients in each quintile		N=7290	N=7264	N=7146	N=7335	N=7014
Mean response rate per trust quintile		35%	48%	52%	55%	60%
Age Group	18-64	2506 (22)	2358 (20)	2250 (19)	2194 (19)	2311 (20)
	65-74	2356 (19)	2402 (20)	2444 (20)	2588 (21)	2332 (19)
	75-84	1950 (20)	1969 (20)	1923 (20)	2011 (21)	1884 (19)
	≥85	478 (19)	535 (21)	529 (21)	542 (21)	487 (19)
Index of multiple deprivation quintile*	1 (most deprived)	1941 (35)	1306 (24)	1013 (18)	803 (15)	420 (8)
	2	1651 (26)	1219 (19)	1185 (19)	1266 (20)	1036 (16)
	3	1398 (18)	1525 (20)	1598 (21)	1684 (22)	1452 (19)
	4	1379 (17)	1592 (19)	1728 (21)	1729 (21)	1880 (23)
	5 (least deprived)	913 (11)	1620 (20)	1619 (20)	1852 (23)	2225 (27)

* Numbers in brackets are row percentages (% patients in each quintile of trust response rate for each category of age and IMD quintile).
**15 patients had missing IMD rank

iv) Validity of measures

Accuracy

Of the 16,654 patients who reported undergoing surgery in the survey, 15,760 (95%) had a record of surgery in NBOCA data. Of the 3,232 patients who reported undergoing radiotherapy in the survey, 2,914 (90%) had a record of radiotherapy in NBOCA-linked RTDS data.

Out of the 15,259 patients with a linked HES record who responded to the survey question regarding the presence of a stoma, the stoma status was in agreement for 14,194 (93.0%) (Table 5). There were 625 patients who reported having a stoma at the time of survey completion who did not have evidence of this in HES, and 440 patients who appeared to have a stoma from HES data at the time of survey completion, who reported no stoma in the questionnaire.

Table 5 - Validation of presence of stoma against NBOCA/HES data

	Survey question: do you have an ostomy appliance/ stoma?	
Stoma present in January 2013 according to NBOCA/HES data	**No (N=12005)**	**Yes (N=3254)**
No (N=12190)	11565	625
Yes (N=3060)	440	2629

Clinical correlation

Older and more deprived patients, and those with more co-morbidities, emergency presentation, more advanced disease and stomas tended to have lower scores in the EQ-5D quality of life instrument, as would be clinically expected (Table 6).

Table 6 - Mean EQ-5D score according to patient clinico-pathological characteristics. The EQ-5D score has a range of -0.5 (worst quality of life) to 1 (best quality of life).

		Mean EQ-5D score
Time from diagnosis	12-18 months	0.79
	18-24 months	0.80
	24-30 months	0.79
	30-36 months	0.79
Age at diagnosis (years)	18-64	0.80
	65-74	0.82
	75-84	0.76
	≥85	0.67
No. of comorbidities (Charlson score)	0	0.81
	1	0.74
	≥2	0.64
IMD deprivation quintile	1 (most deprived)	0.71
	2	0.76
	3	0.79
	4	0.81
	5 (least deprived)	0.83
Emergency admission	No	0.80
	Yes	0.73
Colorectal cancer site	Right	0.79
	Left	0.81
	Rectum	0.77
T-stage	0	0.79
	1	0.84
	2	0.81
	3	0.79
	4	0.76
N-stage	0	0.81
	1	0.78
	2	0.77
M-stage	No	0.80
	Yes	0.73
Major resection	No	0.74
	Yes	0.80
Presence of a stoma	No	0.81
	Yes	0.72

There were 4,004 patients identified as having a major resection for rectal cancer. Of these, 3,827 were survey respondents. 1,909 of these respondents having major resection for rectal cancer underwent radiotherapy, with 1,677 patients having clearly defined pre- or post-operative regimens.

In rectal cancer patients who had undergone major resection, those who had received long course radiotherapy pre-operatively tended to have a lower EQ-5D score than patients with no record of radiotherapy (Table 7).

Table 7 - Mean EQ-5D score according to patient clinico-pathological characteristics in rectal cancer patients undergoing major resection according to radiotherapy received (N=3595).

	Mean EQ-5D score
Long-course (pre-surgery) N=1067	0.75
Long-course (post-surgery) N=75	0.80
Short-course (immediately before surgery) N=510	0.77
Short-course (with delay) N=25	0.75
No radiotherapy N=1918	0.80

Summary and conclusions

This report details the results of a study examining the feasibility of reporting PROMs as part of a national audit of colorectal cancer patients in order to assess the quality of life in survivors.

Overall, PROMs survey responses did differ according to patient characteristics. Patients were less likely to respond if they were elderly, co-morbid, deprived or admitted as an emergency. Response rates did not vary considerably suggesting no optimal time for survey completion.

A slightly higher number of eligible patients were identified by NBOCA than NCRAS. There was reasonable linkage of the two datasets and linkage to HES. Improvements are required in overall response rate to the survey, as well as optimisation of linkage of NBOCA records to PROMs surveys. There was wide variation in response rate according to hospital trust of diagnosis. This may, in part, be explained by differences in deprivation and linkage rates between trusts, but requires further investigation.

This report demonstrates good accuracy and validity of survey responses such as whether patients underwent surgery, had radiotherapy or have a stoma, when compared to NBOCA data. It also showed that quality of life scores tended to be lower in patients that we would expect to have a poorer quality of life (e.g. elderly patients, those with advanced disease, those with stomas).

Overall, this study supports the accuracy and validity of Patient Reported Outcome Measures in a national study of colorectal cancer survivors. Clinical correlation of results has been demonstrated providing evidence to support the PROMs survey as a useful tool in measuring quality of life.

The study demonstrates the value of linking PROMs with national clinical datasets; such linkage allows validation of patient responses and access to more detailed data facilitating improved understanding and interpretation of these responses. Linkage of national clinical audit data to quality of life indicators would allow the assessment of the impact of different treatment modalities on survivors' quality of life and target important areas for improvement. It could also provide a source of information for patients at the start of their cancer pathway in terms of helping them to make more informed decisions about their choice of treatment and facilitate discussion of expectations.

Unfortunately the cancer-specific quality of life instrument included in the survey was only collected for a selection of items and therefore could not be used in this feasibility study. However, as recommended by the Independent Cancer Taskforce Report, NHS England is piloting a quality of life metric in three tumour sites (breast, colorectal and prostate), prior to national roll-out. This should provide further evidence of the effectiveness of PROMs as a tool for measuring quality of life in cancer survivors.

This study demonstrates the value of collection of PROMS data on a national level. It highlights, however, lower response rates for certain patient groups, and particularly large variation in response rate by hospital trust. Currently, NBOCA performance indicators are clinical measures and incorporation of patient perspectives via PROMs would be invaluable in further evaluating quality of care. However, given the variation in response rate by trust, and the lack of representativeness of responders, monitoring of provider performance based on PROMs data, collected by postal survey, can only be used if the impact of patient characteristics on response rates is taken into account.

References

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