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Efficacy of data capture for patient-reported toxicity following radiotherapy for prostate or cervical cancer

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ABSTRACT

We investigated the efficacy of data capture of patient-reported toxicity following radiotherapy by comparing electronic and paper formats. Patient-reported toxicity questionnaires based on items from the NCI Common Terminology Criteria for Adverse Events (CTCAE) were created for patients receiving radiotherapy. Electronic and paper questionnaires had identical questions. Thirty seven gynaecological cancer and 40 prostate cancer patients completed questionnaires. Both questionnaire formats (electronic and paper) were completed by each patient at time points before and after radiotherapy. The average questionnaire and subsection scores for each format were compared directly and by using intraclass correlation (ICC) coefficients. The internal consistency/reliability was assessed by determining Cronbach's α coefficient. Patient preference for questionnaire format including clarity and ease-of-use was recorded. 324 questionnaires were collected as part of this study. A similar pattern of average subsection scores was found for the electronic and paper questionnaires. ICC coefficients for the mean overall questionnaire scores and subsection scores were high (>0.8). Cronbach's α was generally greater than 0.6, indicating that the reliability was high. Of the patients that responded, 27.3% preferred the electronic format, 25.7% preferred the paper format and 47% had no preference. The average time taken to complete a questionnaire was about 9 minutes for each format. The different questionnaire formats measured toxicity effects consistently and were reliable for both gynaecological cancer and prostate cancer patients. The survey indicated that patients found the questionnaires clear, easy to understand and straightforward to complete. Electronic data capture of patient-reported toxicity for CTCAE is feasible and acceptable.

1. Introduction

Although there is a widespread use of measurement tools for recording toxicity in radiotherapy, there is a need to continue to improve and extend the collection of data. The LENT SOMA scales [1,2] provide a useful framework to generate questionnaires to collect treatment-related side-effect data and the LENT SOMA scheme has been incorporated into the National

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Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events (CTCAE) [3]. Inconsistency in the use of grading systems, time points for recording effects and methods for data collection hampers comparisons between studies and limits progress in the field. Treatment morbidity is under-reported [4] and there is insufficient detail on some scoring systems [5]. Online patient-reported outcomes (PROs) have been shown to be a feasible and reliable [6–8] method for monitoring the symptoms of long-term toxicity. It has been proposed recently [8] that online collection might be more efficient and accurate than equivalent paper versions. Quality of life (QoL) studies [9] using the EORTC QLQ C30 computer touchscreen QoL questionnaires agreed well with paper versions, well-accepted by patients, and finally they provided good data quality and reliability. Recent evidence shows [10] that computer-based QoL questionnaires can contribute to patient-doctor interactions in oncology. Patients found them useful for communicating symptoms to doctors. Clinicians thought that QoL data broadened the scope of their enquiries and helped identify areas for discussion with the patient. In particular, Velikova et al. [10] stated recently that 'having symptoms and functional problems expressed quantitatively on a scale was useful for detection of change over time'. Patient-report toxicity questionnaires have been developed by us for the LENT SOMA framework for prostate and gynaecological cancer. These have recently been adapted to collect CTCAE data [11]. The prospective study reported here compared paper and electronic formats for collecting patient-reported CTCAE data on patients with prostate and gynaecological cancer undergoing radiotherapy.

2. Patients and methods

2.1. *Patients*

Following local ethical approval, patients attending the Christie Hospital for treatment for cervical or prostate cancer were approached to take part in the study. Forty patients with prostate cancer and 37 patients with gynaecological cancer were recruited prospectively. Both groups were treated with radical external beam radiotherapy. The median age of the prostate cancer group was 71 years and the median age of the gynaecological cancer group was 61 years. The patient and treatment details are summarised in Table 1.

Table 1 – Patient and Treatment Characteristics for the Prostate and Gynaecological Cancer Patients

	Prostate	Gynaecological
Number	40	37
Age (years)		
Mean	70	56
Median	71	61
Range	49 - 79	25 - 72
Disease Stage	TNM	FIGO
I	16	20
II	16	12
III	8	4
IV		1
Treatment		
Radiotherapy alone	16	3
Radiotherapy and surgery	2	15
Radiotherapy and hormones	21	
Radiotherapy and surgery and hormones	1	
Radiotherapy and chemotherapy		11
Radiotherapy, chemotherapy and surgery		8

2.2. *Questionnaires for collecting toxicity data*

The prostate cancer questionnaire contained 56 items and the gynaecological cancer questionnaire contained 78 items. These items included stem questions that lead to another question (e.g. 'Have you had any diarrhoea recently?' and 'If yes, how many times do you have diarrhoea each day?'). For the cervical cancer patients, the subsites (used below) were: uterus/cervix; ovary/reproductive; rectum/bowel; bladder/urethra; vagina; and sexual function. For the prostate cancer patients, the subsites were: rectum/bowel; bladder/urethra; ureter/kidney; and sexual function.

The questionnaires were administered in paper and electronic formats. At the start of the treatment patients completed either a paper or an electronic version of the questionnaire. After two further treatments, they were then asked to complete the other type of questionnaire. At the end of the treatment, the patients were invited to complete the electronic questionnaire and then the paper version at home several days later. The two formats were completed a median of 3 days apart (range 2-6 d). Two patient surveys were also then carried out regarding a format comparison and a content questionnaire. Comments were requested on the questionnaire format and patients were asked to give reasons for their preferences. The clarity and the amount of help needed to complete the questionnaires were also investigated. The content questionnaire was used by the EORTC group with work on the cervix module EORTC CX 24 (used with permission E Greimel).

2.3. *Development of the electronic format of the questionnaire*

A computerised 'questionnaires' program was developed by using Visual Basic version 6. The graphical use interface (shown in Fig. 1) used a number of external text files that contained the exact wording for each question, the responses available, and any help text that each question required. It also specified whether the questions were mandatory or not. The user interface could therefore be set to any spoken language because all the questions and related information displayed were read from these text files. The user interface/data entry program saved the answers to a CSV (comma separated variables) text file, which could then be imported into MS Excel or another suitable database program. On saving the data, a report could be instantly produced that displayed the questions and responses as well as toxicity scores. The font size could be changed by the user, as required, and a change of question was indicated on the user interface by a change in background colour (see Fig. 1). An entry of the data was made using a laptop computer in clinic, where answers were selected by using function keys. A data-

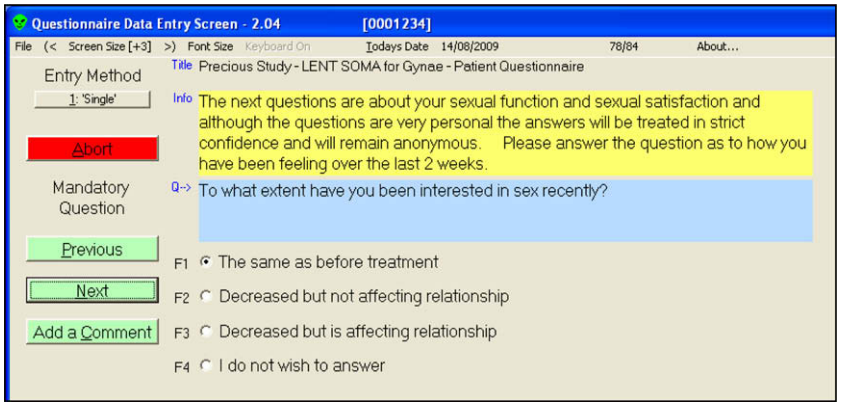

Fig. 1 – The user interface used in this study in order to input electronic data.

base program was also created into which the patient-generated data could be imported. This program has an export feature that enabled creation of an SPSS data file with all labelling and data being intact.

2.4. *Statistics*

Average scores using either format for the entire questionnaire and separately for individual subsites were obtained. The Wilcoxon signed-rank test was used to detect significant differences with respect to a questionnaire score and individual subsite scores. The reliability/internal consistency was investigated by determining Cronbach's α. The repeatability of the results for the electronic versus paper questionnaires was assessed by using the intra-class correlation coefficient for the average overall questionnaire scores and average scale scores. All calculations were carried out using the SPSS version 14.0 statistical package.

3. Results

3.1. *Toxicity scores*

Results for the average scores for the electronic and paper formats of the entire questionnaire and individual subsite scores are shown in Figs. 2 and 3. There was a good agreement between the average scores of the two formats for the entire questionnaire and all the individual subsites for both the prostate and gynaecological cancer patient groups. The differences between the average scores of the electronic and paper questionnaires were generally not significant using the Wilcoxon signed-rank test at 95% confidence levels (shown in Tables 2 and 3). As expected, the toxicity scores increased directly at the end of the treatment for both patient groups and were shown by both formats. The intra-class correlation (ICC) coefficients between the average questionnaire scores for both formats of the questionnaire are presented in Tables 4 and 5. For the prostate cancer patients, the ICC coefficients (shown also in Table 4) were 0.87 at the start of treatment (P<0.001; N=38); 0.90, directly post-treatment (P<0.001; N=34); and 0.83 at 12 months post-treatment (P<0.001; N=10). For the gynaecological cancer patients, the ICC coefficients (shown also in Table 5) were 0.91 at the start of treatment (P<0.001; N=35); 0.96, directly post-treatment (P<0.001; N=28); and 0.98 at 12 months post-treatment (P<0.001; N=13). The ICC coefficients in Tables 4 and 5 for individual subsites and individual items were generally high (>0. 6; P<0.001). 324 questionnaires were completed as part of this study. The reliability/internal consistency of the questionnaires shown by Cronbach's α coefficient is given in Tables 4 and 5. Cronbach's

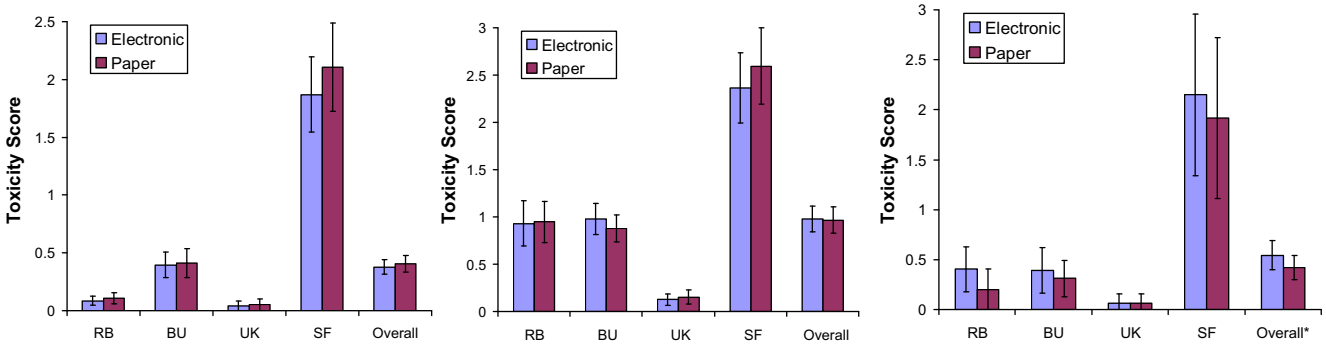

Fig. 2 – Results for the average overall questionnaire scores and average subsection scores (with 95% confidence intervals) for the paper versus electronic formats for the prostate questionnaire (left) pre-treatment, (middle) directly post-treatment and (right) 12 months post-treatment. (RB=Rectum/Bowel; BU=Bladder/Urethra; UK=Ureter/Kidney; SF=Sexual Function; and Overall=entire questionnaire.) Significant differences (P<0.05) between electronic and paper toxicity scores are shown by the symbol '*'.

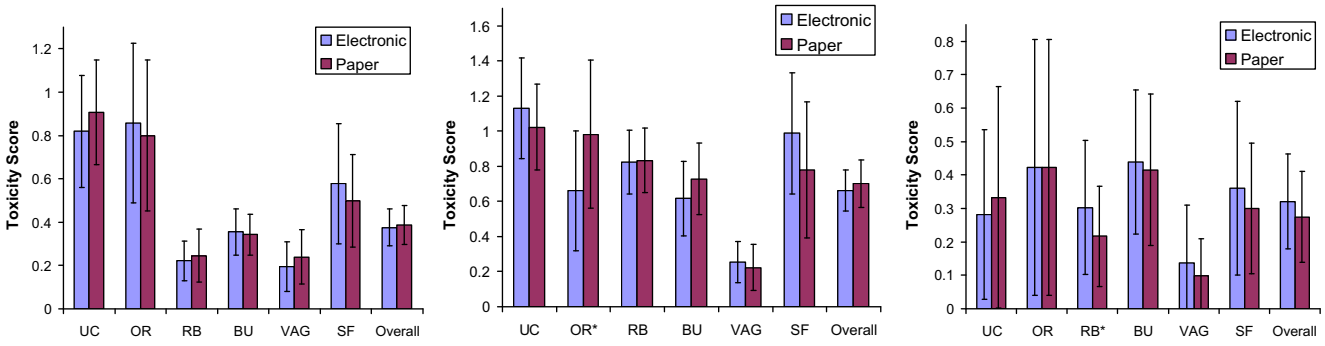

Fig. 3 – Results for the average overall questionnaire scores and average subsection scores (with 95% confidence intervals) for the paper versus electronic formats for the gynaecological cancer questionnaire (left) pre-treatment, (middle) directly post-treatment and (right) 12 months post-treatment. (RB=Rectum/Bowel; BU=Bladder/Urethra; UK=Ureter/Kidney; UC=Uterus/Cervix; OR=Ovary/Reproductive; VAG=Vagina; SF=Sexual Function; and Overall=entire questionnaire.) Significant differences (P<0.05) between electronic and paper toxicity scores are shown by the symbol '*'.

Table 2 – Results for the mean overall questionnaire scores and subsection scores for the paper and electronic formats for the prostate questionnaire.

	Pre-Treatment		Post-Treatment		12 Months Post-Treatment	
	Electronic	Paper	Electronic	Paper	Electronic	Paper
RB	0.09 (0-0-0)	0.11 (0-0-0.11)	0.93 (0.3-0.67-1.18)	0.95 (0.4-1-1.33)	0.41 (0-0.33-0.82)	0.20 (0-0-0.43)
BU	0.40 (0.13-0.38-0.50)	0.41 (0.11-0.38-0.63)	0.98 (0.75-1-1.33)	0.88 (0.56-1-1.22)	0.39 (0-0.5-0.56)	0.31 (0-0.29-0.5)
UK	0.04 (0-0-0)	0.05 (0-0-0)	0.13 (0-0-0.33)	0.15 (0-0-0.33)	0.07 (0-0-0)	0.07 (0-0-0)
SF	1.87 (1.33-2-2.5)	2.10 (1.5-2-3)	2.36 (2-2.33-2.75)	2.59 (2-2.33-3.5)	2.15 (0.5-1.75-3.5)	1.92 (0.75-1.67-3)
Overall	0.38 (0.24-0.42-0.54)	0.41 (0.30-0.39-0.6)	0.98 (0.64-1.04-1.19)	0.97 (0.75-0.96-1.27)	0.54* (0.31-0.57-0.77)	0.42* (0.25-0.46-0.63)

Figures in parentheses (LQ-MED-UQ) indicate the lower quartile, median and upper quartile, respectively. (RB=Rectum/Bowel; BU=Bladder/Urethra; UK=Ureter/Kidney; SF=Sexual Function; and Overall=entire questionnaire.) Significant differences (P<0.05) between electronic and paper toxicity scores are shown by the symbol '*'.

Table 3 – Results for the mean overall questionnaire scores and subsection scores for the paper and electronic formats for the gynaecological cancer questionnaire.

	Pre-Treatment		Post-Treatment		12 Months Post-Treatment	
	electronic	paper	electronic		electronic	paper
UC	0.82 (0-0.67-1.33)	0.91 (0.33-1-1.33)	1.13 (0.67-1.33-1.67)	1.02 (0.67-1-1.33)	0.28 (0-0-0)	0.33 (0-0-0.67)
OR	0.86 (0-0-2)	0.80 (0-0-1.5)	0.66* (0-0-1.5)	0.98* (0-1.5-2)	0.42 (0-0-0)	0.42 (0-0-0)
RB	0.22 (0-0-0.5)	0.25 (0-0-0.33)	0.82 (0.45-0.7-1)	0.83 (0.44-0.44-1.4)	0.30* (0-0.33-0.44)	0.22* (0.25-0.33-0.33)
BU	0.36 (0.11-0.13-0.38)	0.34 (0.11-0.2-0.5)	0.62 (0.3-0.6-1.2)	0.73 (0.3-0.8-1.2)	0.44 (0.1-0.3-0.5)	0.42 (0.1-0.3-0.3)
VAG	0.20 (0-0-0.43)	0.24 (0-0.14-0.43)	0.26 (0-0.14-0.33)	0.22 (0-0-0.57)	0.14 (0-0.17-0.33)	0.10 (0-0-0.14)
SF	0.58 (0-0.2-1)	0.50 (0-0.4-0.8)	0.99 (0.33-1-1.4)	0.78 (0.2-0.5-1.2)	0.36 (0-0.4-0.4)	0.30 (0.2-0.2-0.2)
Overall	0.38 (0.2-0.24-0.57)	0.39 (0.2-0.31-0.49)	0.66 (0.57-0.85-1)	0.70 (0.46-0.75-1.16)	0.32 (0.15-0.28-0.44)	0.27 (0.19-0.33-0.34)

Figures in parentheses (LQ-MED-UQ) indicate the lower quartile, median and upper quartile, respectively. (RB=Rectum/Bowel; BU=Bladder/Urethra; UK=Ureter/Kidney; UC=Uterus/Cervix; OR=Ovary/Reproductive; VAG=Vagina; SF=Sexual Function; and Overall=entire questionnaire.) Significant differences (P<0.05) between electronic and paper toxicity scores are shown by the symbol '*'.

Table 4 – Results for prostate patient group for the intra-class correlation (ICC) coefficients for mean scores of the paper and electronic formats.

		Pre-Treatment	Post-Treatment	12 Months Post-Treatment
ICC coefficients	Overall	0.87	0.90	0.83
	RB	0.52	0.83	0.76
	BU	0.84	0.91	0.94
	UK	0.86	0.65	1
	SF	0.85	0.91	0.99
Electronic	N	40	34	10
	α	0.63	0.60	0.37
Paper	N	38	38	10
	α	0.61	0.73	0.63

The number (N) of subjects returning questionnaires at a given time-point and Cronbach's α coefficient for each questionnaire format are also given. (RB=Rectum/Bowel; BU=Bladder/Urethra; UK=Ureter/Kidney; SF=Sexual Function; and Overall=entire questionnaire.)

Table 5 – Results for gynaecological cancer patient group for the intra-class correlation (ICC) coefficients for mean scores of the paper and electronic formats.

		Pre-Treatment	Post-Treatment	12 Months Post-Treatment
ICC coefficients	Overall	0.91	0.96	0.98
	UC	0.89	0.88	0.70
	OR	0.96	0.97	1.00
	RB	0.83	0.94	0.96
	BU	0.90	0.89	0.99
	VAG	0.94	0.79	0.95
	SF	0.91	0.86	0.87
Electronic	N	35	28	13
	α	0.68	0.34	0.76
Paper	N	36	29	13
	α	0.71	0.60	0.78

The number (N) of subjects returning questionnaires at a given time-point and Cronbach's α coefficient for each questionnaire format are also given. (RB=Rectum/Bowel; BU=Bladder/Urethra; UK=Ureter/Kidney; UC=Uterus/Cervix; OR=Ovary/Reproductive; VAG=Vagina; SF=Sexual Function; and Overall=entire questionnaire.)

α was in the range of 0.3 to 0.8, indicating that the internal consistency was high for both questionnaire formats (electronic and paper). Generally, α was greater than 0.6.

3.2. *Time to complete questionnaires and patient preference for format*

The overall average time taken to complete the questionnaire was calculated at pre-treatment. For the gynaecological cancer group, the electronic questionnaire took on average 10 minutes and the paper questionnaire took on average 6.6 minutes. For the prostate cancer group, the electronic questionnaire took on average 10.4 minutes and the paper questionnaire took on average 9.4 minutes. Sixty-six of the 76 prostate and cervix cancer patients responded to questions on questionnaire format preference. Of the 66 patients, 27.3% preferred the electronic version, 25.7% preferred the paper version and 47% had no preference. This preference was not dependent ($P>0.05$) on the level of experience of computer or other technical equipment such as calculators or video recorders, or patient group (prostate or gynaecological cancer). Format preference did not correlate with the patients' age for either patient group.

47% of the patients reported no preference regarding questionnaire format and most gave no reason. Those patients that preferred the electronic version found it quicker and easier to complete. One patient stated that the electronic version seemed less ambiguous. Those patients that preferred the paper format stated that they were able to take the paper questionnaire home and fill it in later; thus also giving more time to consider their answers. Some patients mentioned that they lacked experience or confidence with computers, and one patient felt 'pressured' using the electronic version.

3.3. *Questionnaire content survey*

Seventy patients completed the questionnaire content survey once the first set of both electronic and paper versions of the questionnaire had been completed, thus 2–6 days after the start of treatment. Only 29% of 70 patients found some of the questions to be confusing or difficult, whereas the rest did not. However, the number of questions that they found difficult or confusing was small (<5). Only 1 patient (1.5%) out of 68 (of the 70 that responded) that responded found any of the questions to be upsetting, and these were all in the sexual function section. The sexual function questions were most often quoted as confusing or difficult to answer. Thirty percent of the 70 patients that responded stated that some help was required to complete the questionnaires. However, all patients that responded said the help was minimal and/or only

at the start of the study. This help could be provided by a research nurse, although one patient specified that his/her spouse helped. Of the patients who required help, they needed assistance with instructions/clarification and help with specific questions such as control and sexual function questions. However, there were also practical difficulties such as one patient needed help with the weight question, another with keyboard handling, and another with reading. Items in the questionnaire were not found to be upsetting to the vast majority of patients with one patient reporting on the contrary.

In invited final comments, two patients mentioned that they had undergone surgery and so various subsequent questions did not apply to them. One person mentioned that he/she thought that some of the questions were not relevant as he/she had only just started treatment and another mentioned that it might be 'too early' to give answers regarding treatment. One patient stated that the computer program was an improvement from the paper version, another patient stated that the electronic version was as easy to complete as the paper version, and yet another patient stated that the questionnaire was 'very easy to do'.

4. Discussion

The results of the two formats (electronic and paper) agreed well with each other. There was good correspondence for the average (mean and median) toxicity scores for the entire questionnaire and individual subsite scores between the electronic and paper formats. The overall pattern of subsite scores was very similar for the two formats of questionnaire for the prostate and gynaecological patients at all time points at the start and end of the treatment and at 12 months generally with no significant differences ($p>0.05$). Intra-class correlation (ICC) coefficients based on each patient's average scores and individual items demonstrated that the repeatability was generally high with values >0.8.

Since we have initially used these questions, we have taken comments from patients and we have adapted the questions to improve their understanding based on these comments. Because of the need to record the change in patients' symptoms with time (as stated in the CTCAE), a number of questions were amended to allow patients to state their symptoms at the start of the treatment and avoid comparison. As one of the patients mentioned that he/she had problems with reading the questionnaire content survey, the font size used was 12pt as a standard size but this could be increased if necessary. The subsite questions were in a different colour to indicate to patients that they were in a different section. The background colour for each question changed with each question to alert the patients of a change. Again in response to the questionnaire content survey, radiobuttons which could be used to answer the questions were used with the help of the function keys on the keyboard as it was thought that this would be a way of avoiding difficulty with controlling a mouse for older patients in particular. The question regarding weight was omitted on the paper version since this caused some concern and was omitted by many patients. It was felt to be most appropriate to be added to the physician questionnaire. The programme for the electronic version could allow for subsequent irrelevant questions to be omitted which would address the criticism of some patients in the patient survey that there was a repetition of questions. In this study however, it was thought that the two formats should be comparable and this facility was not employed, but the computer program does allow this option. Work has also been carried out to look at the data from prostate and gynaecological cancer patients who used these questionnaires in a previous study (with paper format) to refine the questionnaires and omit questions that were less useful in scoring patient symptoms following the treatment.

The two formats of questionnaires (i.e. electronic and paper) gave consistent and reliable results. The patients found the questionnaires in either format to be clear, not too onerous, and straightforward to complete. Patients generally had no preference regarding format. As shown in the previous QoL and PRO studies [14-18], the electronic version was accepted by patients. We plan to use the electronic questionnaire in clinic. The electronic questionnaire allows us to immediately create a report to summarise patients' symptoms and this could inform a patient/doctor consultation. Indeed, a few patients had commented that they have found that completing the symptom questionnaire helped them to articulate their concerns during the consultation.

Our study showed that the patients' compliance and quality of recorded data is identical for both methods of data capture. We recommend electronic capture in future because of the advantages of this approach. For example, it would lessen the risk of input errors because there is no need for transcription (i.e. there is no need to make a re-entry of those data on a computer). Although it is not shown conclusively here, we believe that electronic capture might be a considerable time-saving procedure in future. Furthermore, electronic versions of the questionnaire ought to use less paper and so should be 'greener' than the alternative. This is important for large studies involving many patients over many years. Indeed, we note that such questionnaires are to be repeated for years during patient follow-up; they also could be completed at home and be transmitted electronically before follow-up. However, some patients were clearly not confident with the use of electronic media, and so patients ought also to be given the option to fill out a paper copy of the questionnaire, if desired. Help should be available for the patients if they need it, especially when completing the questionnaire for the first time.

Conflict of Interest Statement

None declared.

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