**The development of the C-PAT: a concise tool to assess the quality of care in the cystectomy pathway**

**Abstract**

Objectives

To develop and test the psychometric properties of a concise, patient reported questionnaire, designed to assess key aspects of the radical cystectomy (RC) patient pathway that are important to both patients and clinicians.

Subjects/Patients and Methods

Draft items were developed by a consultation with a 13 member expert clinical panel, and the in-depth qualitative analysis of 14 semi-structured interviews with patients who had received RC within the previous eighteen months. A further 9 cognitive interviews with patients refined the items and ensured they were easy to complete. Pilot testing in 122 patients recruited from five hospitals in England tested the properties of validity and reliability of the resulting 17-item questionnaire.

Results

Patients and clinicians identified the following aspects as important for the delivery of quality patient care. These included timely referral and initial test results; an explanation of risk/benefits of treatment; access to a cancer nurse specialist; training and support in stoma management; timely surgery, surgical complications, and timely follow-up. Pilot testing showed missing data was low (≤3% for all items), and between 73% and 89% of the responses to items were the most positive about their care (indicating ceiling effects). 5 items were identified using factor analysis as being statistically related (Cronbach’s alpha 0.76, ICC test-retest reliability of 0.95) and formed the scored part of the tool ‘care and support’, scored 0-16. There was insufficient evidence at this stage to show the tool was capable of measuring differences between cancer centres.

Conclusion

We have developed a questionnaire which captures aspects of quality of care within the cystectomy patient pathway. The results support the validity and reliability of the 17-item Cystectomy-Pathway Assessment Tool (C-PAT). We envisage the tool can be the basis for audit of the patient reported assessment of the quality of care for individual cancer centres.

 Key words: Bladder cancer, cystectomy, PREM, PROM, questionnaire

**Introduction**

There are more than 10,000 bladder cancer diagnoses in the UK (1) and over 1500 radical cystectomies (RC) performed in England every year (2). The Bladder Cancer (BC) patient pathway is complex and usually begins in primary care, where multiple visits to the general practitioner may often be necessary (3), before referral to a urologist. Patients may also have to travel long distances for appointments at different hospitals for a variety of tests and procedures, before undergoing RC. The complex scheduling process is complicated further by some patients receiving neo-adjuvant chemotherapy or radiotherapy prior to undergoing a salvage RC. An analysis of the National Cancer Experience Survey (NCPES) showed that BC patients report some of the poorest experiences of care among patients with cancer of different characteristics and diagnoses (4). Delays along the patient pathway (3,5), alongside unmet informational and supportive needs (6–8), are some of the known aspects of the BC patient pathway that can adversely affect the patient’s experience and survival. As highlighted by the recent Get Things Right First Time (GRIFT) report (2018), there are often substantial delays between referral and cystectomy, with patients waiting an average 144 days to have their cystectomy (data from April 2013 to March 2016) (9).

Since 2004, the British Association of Urological Surgeons (BAUS) has collected, and published on their website, complex outcome data (such as 30 and 90 day mortality and length of stay) submitted by urologists performing cystectomy (10). Mandatory surgical outcome reporting since 2013 has improved reporting to >93% of all performed operations (11), and has allowed the comparison of RC outcomes by region, centre and surgeon, thereby improving our understanding of the standards of current care. In addition, a growing number of patient reported outcome measures (PROMs) have been developed for the assessment of outcomes and health related quality of life (HRQL) after bladder cancer treatment (12–14). However, although attractive to measure as an indication of performance, the measurement of outcomes do not always directly identify ways of improving care quality, and can be out of the control of the care provider (due to case-mix for example) (15). Patient reported experience measures (PREMs), are related but are distinct from PROMs: PREMS are concerned with measuring particular aspects of the patient’s care, as well as the service provided (16). This method of measuring a care process (such as timely referral and early communication of test results) can be particularly useful, as it can allow comparisons between centres, capturing good or poor practice, and inform improvements to care pathways (4). Existing questionnaires and PREMs are generally lengthy and generic to all cancers (17), for example, the NCPES (18) and the European Cancer Consumer Quality Index (ECCQI) (19) are respectively 59 items and 45 items in length.

Therefore, the aim of this study is to develop a concise tool that can assess aspects of the RC pathway that are important to both patients and clinicians. In order to have confidence in the measurements made, and for it be useful in practice, the instrument must be shown to be valid (appropriate and acceptable to the population of interest) and reliable (with consistent and stable measurements over time) (20). The objective is to develop a concise instrument for the patient assessment of the quality of care by audit, to allow the comparisons across cancer centres, and to drive measureable improvements of care for patients on the RC pathway.

**Methods**

**Initial item development**

A review of the qualitative literature exploring the patients’ experience of cystectomy, alongside existing PROMs and PREMS, resulted in an initial conceptual framework of domains that were important to both patients and clinicians in the RC pathway. This was refined by a thirteen member multidisciplinary clinical panel, and informed the basis of an interview schedule for further in-depth exploration of the concepts with patients. Semi-structured qualitative (concept elicitation) interviews were carried out with patients who had RC and urinary diversion over the previous 18 months at Southmead Hospital, Bristol, England. Interviews were recorded following patient consent and transcribed verbatim. Thematic analysis of the transcripts was used to categorise the experiences of the patients (21). All interviews and the analysis were conducted by the first author. Further consultation with the expert panel, alongside the patient interviews, resulted in candidate items based on the patients’ experiences and the phrases they preferred to use. These items with response scales were refined by rounds of cognitive interviews with individual patients, to ensure they were completed as intended, and were easy to complete. This process resulted in the developmental Cystectomy-Pathway Assessment Tool: ‘dC-PAT’. Figure 1 outlines the major steps in the process.

**Psychometric testing**

A non-interventional multi-site pilot study, with an embedded test-retest element, was designed to assess the dC-PAT’s psychometric properties of validity and reliability in the target population.

Patients at five tertiary NHS hospitals, located in different areas of England, who had received a cystectomy over the last 18 months, were identified using their medical records by the local clinical team. Eligible patients were sent a study package containing the dC-PAT, a demographic survey and two other questionnaires of known validity. These were the ICIQ-Satisfaction for the measurement of satisfaction after urological surgery (22) , and the Bladder Utility Symptom Scale (12) which measures aspects of quality of life in bladder cancer patients after cystectomy.

All the Bristol respondents to the first administration were sent a second questionnaire pack containing the same questionnaires after a period of two weeks in order for test-retest reliability to be assessed. A single phone call reminder was made after a further two weeks if the pack was not returned.

**Statistical analysis**

The Statistical Package for the Social Sciences (SPSS Inc., IBM Corp., Armonk, NY, USA) was used for the analysis. Items were considered to have a floor effect or ceiling effect if the frequency of responses were found to be, for the majority, of either the ‘most negative’ or the ‘most positive’ options respectively.

*Reliability*

Instrument reliability was evaluated by the measurement of internal consistency; the extent to which the questionnaire items measure the same underlying concept. The calculation of Cronbach’s α gives a statistical indication of this by returning a value between 0 and 1. A value of zero means the items are entirely unrelated to one another and 1 means that they are measuring the exact same concept. A value of ≥0.7 is considered acceptable, and >0.9 to indicate possible item redundancy (23).

Exploratory factor analysis was used to identify items which could be grouped together conceptually and statistically by their common variance, and informed how the instrument could be scored (24). Summing the scores of items within a domain gives a more interpretable estimate of an underlying concept than the individual standalone items, and is potentially more sensitive to differences between centres or change over multiple administrations.

Test-retest reliability was assessed by calculating the percentage perfect agreement between the first and second administration for each item. The Kappa statistic was calculated to indicate the extent to which any item agreement may be due to chance (Kappa statistic (κ): 0 = poor, 0.01-0.20 = slight, 0.21-0.40 = fair, 0.41-0.6 = moderate, 0.61-0.8 = substantial, and 0.81-1 = almost perfect agreement (25). Test-retest reliability of item aggregate scores was evaluated using the intraclass correlation coefficient (ICC); a coefficient (ICC) of >0.7 is considered an indicator of sufficient test-retest reliability (23).

*Construct validity*

The ability of the dC-PAT to reflect known theories, relating to patient satisfaction with care and improvements in quality of life, were examined by correlation with the ICIQ-S and BUSS scores. The ICIQ-S has an outcome score of 0-24, and the BUSS is scored from 0-100. For each of these PROMs, a higher score indicated a higher satisfaction or higher quality of life respectively.

Convergent validity was investigated using Pearson’s correlation coefficient to examine hypothesised relationships with these scores (26). Hypotheses were that the dC-PAT scores should be positively correlated with high patient satisfaction with outcome (ICIQ-S outcome score) and reduced impact on quality of life post-surgery (BUSS). Moderate correlations were expected as these were best-fit comparisons due to scores measuring related, but non-identical constructs.

*Sensitivity*

The ability of the dC-PAT to detect any potential differences in the quality of care between different hospitals was evaluated using the Kruskal-Wallis test (non-parametric ANOVA). This tests whether each of the sites had a significantly different item distribution of responses.

The study was approved by the South Central – Hampshire B Research Ethics Committee REC reference: 19/SC/0366.

**Results**

**Qualitative interviews**

Interviews with fourteen patients (12 male, 2 female, aged 52-79 years) highlighted the importance of a timely referral and rapid availability of initial test results, an explanation of the risk/benefits of treatment, training in stoma management, timely surgery, and the impact of surgical complications. Patients also said that the involvement in treatment decision making, preparedness for surgery, sensitive manner of healthcare staff, post-operative support, and the concept of returning to ‘normal life’ after treatment, were important to them. Evidence from in-depth cognitive interviews with a further 7 male, and 2 female patients, (aged 54-79) made iterative modifications to the draft questionnaire until all the included items were confirmed to be completed easily and interpreted as intended (Appendix 1 details the clinical and demographic information of the qualitative participants).

**Psychometric testing**

A total of 261 eligible patients were identified across the included sites and were sent a questionnaire pack (see Appendix 2 for full demographic and recruitment information). A total of 122 (48%) returned the questionnaires. The overall sample was 81% male, 61% aged 70 years or over, 97% white, 61% left school before 17, 73% were married and 74% retired. From the 44 Bristol responders who returned the first questionnaires, 35 (80%) of these patients returned the second questionnaires for the test-retest analysis.

The C-PAT first four questions were unscored and collected data on the bladder cancer specific type and location of treatment (see Appendix 3 for summary statistics by site for Q1-4). In response to Q1, the sample was evenly distributed in terms of number of months since respondents had received a RC (range 0-18 months). 98% of patients had a cystectomy with a stoma, two patients (1.6%) had a neobladder, 42% had received chemotherapy, and 4% had received radiotherapy prior to their cystectomy. One third (33%) of patients had their ‘first tests and scans’ in the same hospital in which they had an RC, and two-thirds received these at a different hospital from their RC.

**Item response distribution**

Missing data was low (≤3%), suggesting all of the items were understood and completed without difficulty (table 1). The percentage responses given as ‘I don’t know/can’t remember’ were low for all items (≤4%). All the items exhibited ceiling effects (the majority of responses were highly positive about their care). The percentage responses given for the most positive option ranged from 73% for item 16 ‘overall care’, to 89% for the item 11 ‘prepared what to expect’. The percentage of the responses given for the most negative option ranged from 0% for item 10a ‘rate hospital care’ to 15% for item 14 ‘complications’. Items 10b and 17 were ‘free text’ items to allow comment on elements of their hospital care, and overall care and were used by 32% and 42% of patients respectively. The free-text comments were reviewed to ensure there were no comments that would influence the addition or removal of items. These allowed respondents to provide more detailed descriptions of specific incidents or issues that were generally specific to an individual within a centre.

Table ? Item response distribution of the BC-PREM 1st administration (N=122).

**Reliability analysis**

The overall Cronbach’s alpha for the 12 scored items (Q5-16) was 0.640 so did not reach the threshold of 0.7 to be considered a reliable overall score. Hence, all items were retained for further exploration by factor analysis.

**Factor analysis**

Four factors were identified by exploratory factor analysis (table 2). Five of the items: 10 ‘rate hospital care’, 11 ‘prepared expect’, 13 ‘support stoma’, 15 ‘recommend friends’ and 16 ‘overall care’ loaded strongly onto a single factor 1 (Cronbach’s alpha 0.76) All these items were correlated (all significant at p≤0.05 except between Q11 and q15 p=0.058), however no item correlations were above 0.6 to warrant item removal (due to possible redundancy). Factor 1 items were related conceptually by the measurement of what we have called ‘care and support’, so these were subjected to further statistical tests to further explore the validity and reliability of Factor 1 as a scored part of the questionnaire.

Items 7 ‘delay results’, 9 ‘delay operation’ and 12 ‘delay follow-up’ loaded onto a second factor (Cronbach’s alpha 0.56) and items 5 ‘delay referral’ and 6 ‘delay seen hospital’ loaded onto a third factor. Despite the conceptual relatedness of Factors 2 and 3 to ‘delays in the pathway’, a further reliability analysis, when the items from factor 2 and 3 were combined, returned a Cronbach’s alpha of <0.6. This was not sufficiently reliable to consider using these five delay items for scoring purposes. Item 8 ‘contact CNS’ loaded strongly onto a further fourth factor but as correlations with the other items were low (0.18- 0.348), this item was also not included in the scoring system.

**Construct (convergent) validity**

The dC-PAT domain ‘care and support’ was moderately correlated with the ICIQ-Satisfaction outcome score (0.31) and BUSS score (0.28) (P<0.002), as hypothesised.

**Test-retest reliability**

A total of 44 participants at the Bristol site returned the first set of questionnaires (n=44) and 35 (80%) patients returned the second set of questionnaires. The percentage of patients reporting identical responses for each item administration ranged from 84 to 100% (table 3). The Kappa statistic showed substantial agreement for seven of the items (between 0.61 and 0.8) (25) and item 12 ‘delay follow-up’ moderate agreement (between 0.41 and 0.6). Item 7 ‘delay results’, item 8 ‘contact CNS’ and item 9 ‘delay operation’ showed fair agreement (between 0.21 and 0.4). All P values were significant at P≤0.05.

The test-retest ICC for the factor 1 ‘care and support’ score was calculated to be 0.95 (CI 0.90-0.97).

**Sensitivity**

The Kruskal-Wallis test (non-parametric ANOVA) was employed to test whether each of the sites had had the same item distribution of responses. For all items, the test was not significant, P> 0.05 so there was no evidence that different sites performed differently on the measured concepts. There was also no evidence that the domain score ‘care and support’ and other concurrent PROM scores detected any statistical difference in the distribution of scores between sites (table 4).

**Discussion**

Using qualitative methods and psychometric testing, we have developed a concise patient reported experience questionnaire which captures the aspects of the cystectomy patient pathway, deemed important by both patients and clinicians. The findings provided evidence of validity and reliability of a scored 5-item domain for ‘care and support’, alongside 12 other unscored items. The final C-PAT is included as Figure 2.

Evidence from qualitative interviews during item development were consistent with a recent qualitative synthesis of the experiences of a bladder cancer diagnosis (27)**.** In addition to the findings of this review, our interviews highlighted the importance during the pathway of a timely referral, early availability of diagnostic results, timely treatment, and the impact of surgical complications. Although considered important by patients in the interviews, ‘the sensitivity of delivery of the diagnosis’, and the ‘manner of healthcare staff’ were not included as items in the dC-PAT. The interviews revealed that isolated incidents of poor communication between specific members of staff, rather than systemic underperformance across the pathway, made the validity of any associated items questionable. Patients were unsure how to respond to a more general question, when on the whole, their experience of the manner and sensitivity of the staff was good. The decision was made to focus the questionnaire on operational factors, including delays within the pathway and follow-up, which we envisage could be highlighted, monitored and addressed by a more in-depth review of care. For example, the item 14 post-operative ‘complications’ is designed with the intention of identifying clusters of serious adverse events at centres (those requiring interventional surgery), rather than the assessment of the management or experience of any complications, which are known to be relatively common after cystectomy. Lengthier general cancer questionnaires such as the NCPES or the EORTC PATSAT C-33 are designed to cover issues of patient experience and management within the hospital environment, including the experience of radiotherapy and chemotherapy. The two free-text items in the C-PAT provide space for patients to make further detailed comments about specific incidents that happened during their care, and allow further issues to be reported. In practice, we hope that the free-text boxes will facilitate conversations and provide pointers to specific issues occurring at centres which require addressing.

Psychometric testing of the dC-PAT in five tertiary cancer centres in England showed that missing data was low, suggesting the items were understood and completed without difficulty. The ‘I don’t know/can’t remember’ response options were not used in more than 4% of responses, so the decision was made not to include these options in the final version. All the items exhibited ceiling effects (the majority of responses were highly positive). However, this is not unusual for a questionnaire that measures concepts related to satisfaction with care (22,28). Further study is required to determine whether this may indicate a potential lack of sensitivity of the items (29) or is a reflection of the likely ‘true’ levels of care quality in the sampled hospitals. It is also possible that when the C-PAT is completed at other centres, these may not perform as highly, and that the performance at a centre will change over time. Regular audit by C-PAT can be used for high standards to be maintained.

Exploratory factor analysis resulted in four factors, indicating the items were neither unidimensional, nor all sufficiently related in order to provide a reliable overall score including all scored items. This was not unexpected, considering the breadth of concepts which the questionnaire covers. However, Factor 1 included five related items that contributed strongly to the perceived overall quality of the provision of hospital care and stoma support. Cronbach’s alpha was 0.76 and the test-retest ICC was 0.95, so these items were considered a reliable domain termed ‘care and support’. Moderate convergent validity was demonstrated as hypothesised with the ICIQ-S outcome score and BUSS scores for this domain. Factors 2, and 3, consisted of related items which measured the extent of delay in the hospital patient pathway, but were not domains with sufficient reliability to justify being scored. Only one third of patients received their ‘first scans and results’ in the same hospital as where they received their cystectomy, so the cause of delays reported at different stages of the pathway are likely to be complex. For this reason, these items are unscored and included as standalone items.

The majority of the items showed good test-retest reliability, as demonstrated by high identical percentage agreement and chance corrected kappa statistics. Three items showed ‘fair’ agreement as interpreted by chance corrected agreement (κ: 0.21-0.40), however, these items still had over 84% identical agreements and were retained for their clinical value.

Neither the individual dC-PAT items nor the scored domain ‘care and support’, detected any statistically significant differences in responses between hospital sites. However, as the other questionnaires of known validity (ICIQ-S and BUSS) also did not detect any differences in outcomes, this could suggest that the sample size was not large enough, or any true differences between sites were not sufficient to be detected. The sites were chosen carefully to be in different parts of England, and to be different in annual numbers of RCs. However, the sample size or response rate of the smaller site samples, at Medway and Cheltenham in particular, may have introduced bias or reduced sensitivity. For example , although not detected in this study, a reduced risk of perioperative complications has been associated with higher hospital patient and individual surgeon procedure volumes (30).

BAUS registry data from the referenced study submitted in the two years 2014-15 showed 73.6% of radical cystectomies were in male patients (2). Our sample of 81% male was not dissimilar but the predominant white British sample (97%) may be considered a limitation if any non-respondents from non-white British groups differed in their demographic characteristics. In the same BAUS database, 86.4% of cystectomies received an ileal conduit, 5.3% orthoptic neobladders, 1.9% cutaneous pouches, and 6.5% had other form of diversion or was missing data (2). We were not able to test with a large sample of patients with continent diversions due to their infrequency, however, one patient with a neobladder was included in the patient interviews and two responded during the pilot testing. Although we acknowledge that other types of continent diversionhave not been explicitly tested, we are confident that the wording of the items is sufficiently inclusive to ensure their applicability across these different patient groups. Further validation work in demographically diverse patient populations and those that have a greater diversity of type of urinary diversion is required, to explore the comprehensiveness of the C-PAT when completed by these different patient groups. The main limitation to this study was that the questionnaire return rate was relatively low at 48%, whereas a typical response rate of a salient questionnaire survey such as this may be more like 65% (31). This may introduce bias if the non-responders differed systematically from the responders. However, it was not possible to collect demographic data for the non-respondents, as this was collected on return of the questionnaire pack and we were restricted by our ethics approvals on receiving patient identifiable data from external sites. The lower response rate may be due to there being no follow-up or phone contact with the recipients, and the relatively large number of questions that had to be answered in the questionnaire packs. We would expect this response rate to improve if the C-PAT is routinely administered as part of the follow-up assessment of the care pathway, as intended. Next steps could include exploratory work to improve response rates by including telephone or text reminders, greater support from the CNSs, or through electronic administration.

**Conclusion**

We consider that if a patient reports positively to the items of the C-PAT then they are likely to have received high quality care. In particular, they have received good care and support throughout the pathway, a prompt referral and early availability of investigation results, had timely treatment, had no significant surgical complications, and timely follow-up. We recommend the C-PAT as a concise audit tool to be included as part of routine follow-up to assess the quality of the cystectomy care pathway, alongside data collected from other sources, such as the NCPES, and length of stay and mortality from HES. Other PROMs such as the BUSS may also be used to assess specific outcomes such as the impact on quality of life. Further research and use in practice is required to determine whether the C-PAT is a tool capable of detecting differences in the quality of care between cancer centres.

**Acknowledgements**

This study was funded by the Bristol Urological Institute Oncology Fund and a grant from Action Bladder Cancer UK. The authors would like to thank the clinical panel and the patients who participated in this study.

**Conflicts of Interest**

Professor James Catto reports personal fees from Astra Zeneca, Janssen, Roche, Ferring, MSD, Bristol-Myers Squibb and a grant from Roche, outside the submitted work. All other authors report no conflict interest.

**References**

1. Cumberbatch MGK, Jubber I, Black PC, Esperto F, Figueroa JD, Kamat AM, et al. Epidemiology of Bladder Cancer: A Systematic Review and Contemporary Update of Risk Factors in 2018. Eur Urol. 2018;74(6):784–95.

2. Jefferies ER, Cresswell J, McGrath JS, Miller C, Hounsome L, Fowler S, et al. Open radical cystectomy in England: the current standard of care - an analysis of the British Association of Urological Surgeons (BAUS) cystectomy audit and Hospital Episodes Statistics (HES) data. BJU Int. 2018;121(6):880–5.

3. Santos F, Dragomir A, Kassouf W, Franco E, Aprikian A. Urologist referral delay and its impact on survival after radical cystectomy for bladder cancer. Curr Oncol. 2015 Feb;22(1):e20–6.

4. Saunders C, Abel G, Lyratzopoulos G. Inequalities in reported cancer patient experience by socio-demographic characteristic and cancer site: evidence from respondents to the English Cancer Patient Experience Survey. Eur J Cancer Care (Engl). 2015 Jan;24(1):85–98.

5. Russell B, Liedberg F, Khan MS, Nair R, Thurairaja R, Malde S, et al. A Systematic Review and Meta-analysis of Delay in Radical Cystectomy and the Effect on Survival in Bladder Cancer Patients. Eur Urol Oncol. 2020;3(2):239–49.

6. Mohamed NE, Pisipati S, Lee CT, Goltz HH, Latini DM, Gilbert FS, et al. Unmet informational and supportive care needs of patients following cystectomy for bladder cancer based on age, sex, and treatment choices. Urol Oncol Semin Orig Investig. 2016 Dec;34(12):531.e7-531.e14.

7. Bessa A, Martin R, Häggström C, Enting D, Amery S, Khan MS, et al. Unmet needs in sexual health in bladder cancer patients: a systematic review of the evidence. BMC Urol [Internet]. 2020 Jun 3 [cited 2020 Oct 8];20. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7268732/

8. Gore JL, Lai J, Setodji CM, Litwin MS, Saigal CS, Urologic Diseases in America Project. Mortality increases when radical cystectomy is delayed more than 12 weeks: results from a Surveillance, Epidemiology, and End Results-Medicare analysis. Cancer. 2009 Mar 1;115(5):988–96.

9. Simon H. GIRFT Programme National Specialty Report [Internet]. [cited 2020 Dec 3] p. 23–4. Available from: https://www.gettingitrightfirsttime.co.uk/surgical-specialty/urology-surgery/

10. BAUS. Cystectomy Outcomes Data [Internet]. BAUS website. [cited 2020 Sep 15]. Available from: https://www.baus.org.uk/patients/surgical\_outcomes/cystectomy/

11. Joseph John, John P, Sarah F, Alexandra C, Edward R, Benjamin C, et al. Benchmarking radical cystectomy – analysis of the British Association of Urological Surgeons national database. Submitt Publ. 2020;

12. Perlis N, Krahn MD, Boehme KE, Alibhai SMH, Jamal M, Finelli A, et al. The Bladder Utility Symptom Scale: A Novel Patient Reported Outcome Instrument for Bladder Cancer. J Urol [Internet]. 2018 Mar [cited 2018 Aug 29]; Available from: https://linkinghub.elsevier.com/retrieve/pii/S0022534718424986

13. Leung T-M, Benn EKT, Galsky M, Latini DM, Goltz HH, Lee CT, et al. Examining the Psychometric Properties of the Bladder Cancer Needs Assessment Survey. 2017;14.

14. Mason SJ, Catto JW, Downing A, Bottomley SE, Glaser AW, Wright P. Evaluating Patient Reported Outcome Measures (PROMs) for bladder cancer: a systematic review using the COSMIN checklist. BJU Int [Internet]. 2018 [cited 2018 May 23];0(ja). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/bju.14368

15. Hollenbeck BK, Montie JE, Wei JT. Radical Cystectomy and Surgical Quality of Care. J Natl Compr Canc Netw. 2005 Jan 1;3(1):37–42.

16. Weldring T, Smith SMS. Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs). Health Serv Insights. 2013 Aug 4;6:61–8.

17. Saunders C, Carter DJ, Jordan A, Duffield C, Bichel-Findlay J. Cancer patient experience measures: An evidence review. J Psychosoc Oncol. 2016 May 3;34(3):200–22.

18. Abel GA, Saunders CL, Lyratzopoulos G. Cancer patient experience, hospital performance and case mix: evidence from England. Future Oncol Lond Engl. 2014;10(9):1589–98.

19. Wind A, Roeling MP, Heerink J, Sixma H, Presti P, Lombardo C, et al. Piloting a generic cancer consumer quality index in six European countries. BMC Cancer [Internet]. 2016 Sep 2 [cited 2018 Sep 19];16(1). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5010728/

20. Beattie M, Murphy DJ, Atherton I, Lauder W. Instruments to measure patient experience of healthcare quality in hospitals: a systematic review. Syst Rev [Internet]. 2015 Jul 23 [cited 2019 Jan 4];4. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4511995/

21. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006 Jan;3(2):77–101.

22. Uren AD, Cotterill N, Hashim H, Worthington J, Kapoor D, Abrams P. International Consultation on Incontinence Questionnaire-Satisfaction: psychometric testing of a new patient-reported outcome measure for the evaluation of satisfaction after urological surgery. BJU Int. 2020 Apr 22;

23. Nunnally J, Bernstein I. The assessment of reliability. In: Psychometric theory. Third ed. McGraw-Hill Inc; 1994. p. 248–92.

24. Yong AG, Pearce S. A beginner’s guide to factor analysis: Focusing on exploratory factor analysis. Tutor Quant Methods Psychol. 2013;9(2):79–94.

25. Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. Biometrics. 1977 Mar;33(1):159.

26. Hays RD, Anderson R, Revicki D. Psychometric considerations in evaluating health-related quality of life measures. Qual Life Res Int J Qual Life Asp Treat Care Rehabil. 1993 Dec;2(6):441–9.

27. Edmondson AJ, Birtwistle JC, Catto JWF, Twiddy M. The patients’ experience of a bladder cancer diagnosis: a systematic review of the qualitative evidence. J Cancer Surviv. 2017 Aug 1;11(4):453–61.

28. Yellen E, Davis GC, Ricard R. The measurement of patient satisfaction. J Nurs Care Qual. 2002 Jul;16(4):23–9.

29. FDA. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. U.S. Department of Health and Human Services; 2009.

30. Moschini M, Simone G, Stenzl A, Gill IS, Catto J. Critical Review of Outcomes from Radical Cystectomy: Can Complications from Radical Cystectomy Be Reduced by Surgical Volume and Robotic Surgery? Eur Urol Focus. 2016 Apr;2(1):19–29.

31. Nakash RA, Hutton JL, Jørstad-Stein EC, Gates S, Lamb SE. Maximising response to postal questionnaires – A systematic review of randomised trials in health research. BMC Med Res Methodol. 2006 Feb 23;6(1):5.

|  |  |  |
| --- | --- | --- |
| **dC-PAT item (no. of response options)** | **Missing data (%)** | **Response option (%)** |
| **Most positive**  | **Middle response(s)** | **Least positive** | **I don’t know/can’t remember** |
| Q5 Was there a delay from when you first saw your GP, until you were referred to your local hospital? (3) | 3 | 75 | 11 | 10 | 1 |
| Q6 Was there a delay from when your GP said they had referred you, until you were seen at your local hospital? (3) | 3 | 86 | 8 | 2 | 1 |
| Q7 Was there a delay from when you had your first tests and scans, until you received the results? (3) | 2 | 82 | 10 | 4 | 2 |
| Q8 Were you given the name and telephone number of a cancer nurse specialist who you could contact if needed? (3)  | 0 | 73 | 18 | 5 | 4 |
| Q9 After the decision was made to remove your bladder, was there a delay before you received the operation? (3) | 0 | 84 | 13 | 3 | 0 |
| Q10 How would you rate the care you received whilst in hospital for the operation to remove your bladder? (5) | 1 | 78 | 21 | 0 | 0 |
| Q11 Do you feel like the hospital prepared you for what to expect after your operation? (3) | 0 | 89 | 9 | 2 | 0 |
| Q12 After you left hospital, was there a delay before you received an appointment or phone-call to discuss any future follow-up? (3) | 1 | 84 | 12 | 1 | 2 |
| Q13 After you left hospital, do you feel like you had enough support to manage with your new stoma or new bladder at home? (3) | 1 | 86 | 10 | 3 | 0 |
| Q14 In the first three months after your operation to remove the bladder... Did you have any complications that required further treatment with a local or general anaesthetic at the hospital? (2) | 2 | 83 | n/a  | 15 | 0 |
| Q15 Overall, how likely would you be to recommend the hospital where you had your bladder removed to friends or family, if they needed similar care or treatment? (5) | 1 | 81 | 16 | 2 | 0 |
| Q16 Overall, how would you rate all of the care you have received? (5) | 1 | 73 | 26 | 0 | 0 |

Table 1. Item response distribution of the dC-PAT scored items.

|  |
| --- |
| Table 2. Exploratory factor analysis of the scored dC-PAT items. |
|  C-PAT item | Factor |
| 1 | 2 | 3 | 4 |
|  Q5 delay referral |  |  | .809 | -.151 |
|  Q6 delay seen hospital |  |  | .761 | .316 |
| Q7 delay results |  | .755 | .379 | .248 |
| Q8 contact CNS | .129 | .235 | .151 | .731 |
| Q9 delay operation |  | .561 | -.144 | .348 |
| Q10 rate hospital care | .774 |  |  |  |
| Q11 prepared expect | .585 | -.138 |  | .468 |
| Q12 delay follow-up |  | .825 |  | -.178 |
| Q13 support stoma | .625 |  | -.103 | .159 |
| Q15 recommend friends | .696 | .200 |  | -.455 |
| Q16 overall care | .794 | .205 | .306 |  |
| Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Small coefficients of an absolute value under 0.1 are not shown. |

Table 3. Reliability (stability) of the dC-PAT scored items and percentage perfect agreement between test and retest (n=35).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **dC-PAT item** | **Number of response options** | **Perfect agreement %** | **Kappa statistic** | **P value** |
|  Q5 delay referral | 3 | 87.5 | 0.68 | >0.001 |
|  Q6 delay seen hospital | 3 | 87.5 | 0.61 | >0.001 |
| Q7 delay results | 3 | 84.4 | 0.23 | 0.05 |
| Q8 contact CNS | 3 | 85.7 | 0.23 | 0.01 |
| Q9 delay operation | 3 | 85.7 | 0.31 | 0.04 |
| Q10 rate hospital care | 5 | 91.2 | 0.77 | >0.001 |
| Q11 prepared expect | 3 | 100 | 1 | 0 |
| Q12 delay follow-up | 3 | 91.2 | 0.54 | >0.001 |
| Q13 support stoma | 3 | 88.6 | 0.61 | >0.001 |
| Q14 complications | 2 | 91.4 | 0.62 | >0.001 |
| Q15 recommend friends | 5 | 88.6 | 0.61 | >0.001 |
| Q16 overall care | 5 | 91.4 | 0.79 | >0.001 |

Table 4. Mean scores of the concurrent questionnaires and dC-PAT ‘care and support’ domain at each hospital.

|  |  |  |
| --- | --- | --- |
| Questionnaire or domain (score range) | Mean scores | P value  |
| All sites (N=122) | Bristol (N=44) | Exeter (N=26) | Gloucester (N=13) | Medway (N=10) | Sheffield (N=29) |
| dC-PAT – ‘care and support’ (0-16) | 14.9 | 14.9 | 14.5 | 15.2 | 14.3 | 15.4 | 0.74 |
| ICIQ-S outcome score (0-24) | 20.7 | 20.8 | 20.2 | 21.0 | 20.5 | 20.9 | 0.90 |
| BUSS score (0-100) | 73.6 | 75.7 | 72.2 | 70.0 | 74.1 | 73.1 | 0.40 |

Figure 1. Development process of the C-PAT.



Cystectomy Pathway Assessment Tool (C-PAT)

**CONFIDENTIAL**

**Today’s date**

You are being asked to complete this questionnaire as you have recently had surgery to remove your bladder (cystectomy) as a treatment for bladder cancer. We would be grateful if you could answer the following questions, thinking about your experience. This will help us in improving and providing better services for patients.

|  |  |
| --- | --- |
| **1.** | **How many months ago did you receive your surgery to remove the bladder?** |
|  0-3 months |  |  |
|  |  |  |
|  4-6 months |  |  |
|  |  |  |
|  7-11 months |  |  |
|  |  |  |
|  Longer than 12 months |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **2.** | **What type of treatment did you receive for bladder cancer?***(Tick all that apply)* |
|  Intravesical therapy (BCG) |  |  |
|  |  |  |
|  Chemotherapy |  |  |
|  |  |  |
|  Radiotherapy |  |  |
|  |  |  |
|  Bladder removal (cystectomy) with a stoma |  |  |
|  |  |  |
|  Bladder removal (cystectomy) with a neobladder |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **3.** | **In which hospital did you receive your first tests and scans?** |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **4.** | **In which hospital did you receive your surgery to remove the bladder (cystectomy)?** |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **5.** | **Was there a delay from when you first saw your GP, until you were referred to your local hospital?** |
|  No, it was an acceptable length of time  |  |  |
|  |  |  |
|  Yes, I could have been referred sooner |  |  |
|  |  |  |
| Yes, I could have been referred much sooner |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **6.** | **Was there a delay from when your GP said they had referred you, until you were seen at your local hospital?** |
|  No, it was an acceptable length of time  |  |  |
|  |  |  |
| Yes, I could have been seen sooner  |  |  |
|  |  |  |
| Yes, I could have been seen much sooner |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **7.** | **Was there a delay from when you had your first tests and scans, until you received the results?** |
|  No, it was an acceptable length of time |  |  |
|  |  |  |
| Yes, I could have had the results sooner  |  |  |
|  |  |  |
| Yes, I could have had the results much sooner |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **8.** | **Were you given the name and telephone number of a cancer nurse specialist who you could contact if needed?** |
|  Yes, it was easy to contact them |  |  |
|  |  |  |
| Yes, but it was difficult to contact them |  |  |
|  |  |  |
|  Yes, but I did not need to contact them |  |  |
|  |  |  |
| No, I was not assigned a clinical nurse specialist |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **9.** | **After the decision was made to remove your bladder, was there a delay before you received the operation?** |
|  No, it was an acceptable length of time  |  |  |
|  |  |  |
| Yes, I could have had the operation sooner  |  |  |
|  |  |  |
| Yes, I could have had the operation much sooner |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **10a.** | **How would you rate the care you received whilst in hospital for the operation to remove your bladder?** |
|  Excellent |  | 4 |
|  |  |  |
|  Good  |  | 3 |
|  |  |  |
|  Average |  | 2 |
|  |  |  |
| Poor |  | 1 |
|  |  |  |
| Extremely poor |  | 0 |
|  |  |  |
| **b.** | **Please provide any further explanation of your answer in the space below:** |  |  |

|  |  |
| --- | --- |
| **11.** | **Do you feel like the hospital prepared you for what to expect after your operation?** |
|  Yes, I felt well prepared  |  | 2 |
|  |  |  |
| No, I could have felt more prepared |  | 1 |
|  |  |  |
| No, I could have felt a lot more prepared |  | 0 |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **12.** | **After you left hospital, was there a delay before you received an appointment or phone-call to discuss any future follow-up?** |
|  No, it was an acceptable length of time |  |  |
|  |  |  |
|  Yes, I could have had the discussion sooner  |  |  |
|  |  |  |
| Yes, I could have had the discussion much sooner |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **13.** | **After you left hospital, do you feel like you had enough support to manage with your new stoma or new bladder at home?** |
|  Yes, I had enough support  |  | 2 |
|  |  |  |
|  No, I could have had more support  |  | 1 |
|  |  |  |
| No, I could have had much more support |  | 0 |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **14a.** | **In the first three months after your operation to remove the bladder...****Did you have any complications that required further treatment with a local or general anaesthetic at the hospital?** |
|  Yes |  |  |
|  |  |  |
|  No  |  |  |
|  |  |  |
|  |  |  |
| **b.** | **If yes, please provide details in the space below:** |  |  |

|  |  |
| --- | --- |
| **15.** | **Overall, how likely would you be to recommend the hospital where you had your bladder removed to friends or family, if they needed similar care or treatment?** |
|  Extremely likely |  | 4 |
|  |  |  |
| Likely  |  | 3 |
|  |  |  |
|  Neither likely nor unlikely |  | 2 |
|  |  |  |
| Unlikely |  | 1 |
|  |  |  |
| Extremely unlikely |  | 0 |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| **16.** | **Overall, how would you rate all of the care that you have received?** |
|  Excellent |  | 4 |
|  |  |  |
|  Good  |  | 3 |
|  |  |  |
|  Average |  | 2 |
|  |  |  |
| Poor |  | 1 |
|  |  |  |
| Extremely poor |  | 0 |
|  |  |  |

|  |  |
| --- | --- |
| **17.** | **Please use the box below to make any further suggestions or comments about** **your care.** |
|  |  |  |
|  |  |  |  |

**Thank you very much for answering these questions**.

Appendix 1. Qualitative interviews demographic and recruitment information.

|  |  |
| --- | --- |
| Participant characteristic | Percentage % (n=23)  |
| Gender (%) | Female | 17 |
| Male | 83 |
| Age (%) | 50-59 | 13 |
| 60-69 | 35 |
| 70-79 | 52 |
| Treatment type (%) | Ileal conduit (stoma) | 91 |
| Neobladder | 9 |
| Chemotherapy | 22 |
| Radiotherapy | 4 |
| Ethnicity (%) | White British | 100 |
| Living arrangements (%) | Living with partner | 4 |
| Married | 74 |
| Single | 17 |
| Missing | 4 |
| Employment (%) | Employed | 26 |
| Retired | 74 |

Appendix 2. Demographic and recruitment information.

|  |  |
| --- | --- |
|  | **Hospital site** |
| **All sites**  | **Bristol**  | **Exeter**  | **Cheltenham**  | **Medway**  | **Sheffield**  |
| Recruitment (n, %) | No. of eligible patients sent questionnaire packs | 261 | 83 | 52 | 33 | 33 | 60 |
| No. returned 1st admin. | 122 (48) | 44 (53) | 26 (50) | 13 (39) | 10 (29) | 29 (48) |
| Gender (%) | Female | 18 | 20 | 15 | 15 | 0 | 24 |
| Male | 81 | 80 | 85 | 85 | 100 | 76 |
| Age (%) | 40-49 | 1 | 0 | 0 | 8 | 0 | 0 |
| 50-59 | 10 | 11 | 12 | 15 | 10 | 3 |
| 60-69 | 29 | 27 | 31 | 23 | 10 | 38 |
| 70-79 | 48 | 48 | 50 | 54 | 70 | 34 |
| 80 or over | 13 | 14 | 8 | 0 | 10 | 24 |
| Ethnicity (%) | Asian or Asian British | 1 | 2 | 0 | 0 | 0 | 0 |
| Black or Black British | 1 | 2 | 0 | 0 | 0 | 0 |
| White | 97 | 95 | 96 | 100 | 100 | 97 |
| Other  | 1 | 0 | 4 | 0 | 0 | 3 |
| Education (%) | Left school at 17 or before | 61 | 66 | 50 | 46 | 70 | 69 |
| College or further education | 24 | 18 | 38 | 23 | 20 | 21 |
| Graduated from university | 13 | 16 | 8 | 31 | 0 | 10 |
| Other | 2 | 0 | 4 | 0 | 10 | 0 |
| Living arrangements (%) | Living with partner | 5 | 7 | 12 | 0 | 0 | 0 |
| Married | 73 | 66 | 69 | 92 | 80 | 76 |
| Single | 15 | 20 | 19 | 8 | 10 | 7 |
| Other | 7 | 7 | 0 | 0 | 10 | 17 |
| Employment (%) | Employed | 16 | 16 | 23 | 22 | 10 | 7 |
| Retired | 74 | 77 | 65 | 70 | 80 | 82 |
| Other | 10 | 7 | 12 | 8 | 10 | 10 |

Appendix 3. Summary statistics by site of dC-PAT Q1-4.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Item** | **Response option (%)** | **All sites (N=122)** | **Bristol (N=44)** | **Exeter (N=26)** | **Cheltenham (N=13)** | **Medway (N=10)** | **Sheffield (N=29)** |
| Q1 ‘How many months ago did you receive your surgery to remove the bladder?’ | 0-3 months | 16 | 27 | 12 | 8 | 10 | 10 |
| 4-6 months | 28 | 18 | 50 | 15 | 30 | 28 |
| 7-11 months | 29 | 27 | 19 | 54 | 40 | 24 |
| 12-18 months | 26 | 27 | 19 | 23 | 20 | 34 |
| Missing | 1 | 0 | 0 | 0 | 0 | 3 |
| Q2 ‘What type of treatment did you receive for bladder cancer?’ | Cystectomy with stoma  | 98 | 93 | 100 | 100 | 100 | 97 |
| Neobladder | 2 | 7 | 0 | 0 | 0 | 0 |
| Chemotherapy | 42 | 30 | 62 | 23 | 60 | 44 |
| Radiotherapy | 4 | 7 | 4 | 0 | 0 | 0 |
| Intravesical therapy (BCG) | 19 | 23 | 31 | 16 | 10 | 6 |
| Missing | 1 | 0 | 0 | 0 | 0 | 3 |
| Q3 ‘In which hospital did you receive you first tests and scans’? | % first tests and scans received at main site hospital | 33 | 36 | 31 | 38 | 30 | 41 |
| Q4 ‘In which hospital did you receive your surgery to remove the bladder (cystectomy)’? | % cystectomy reported to be at main site hospital  | 100 | 100 | 100 | 100 | 100 | 100 |