FEASIBILITY OF IMPLEMENTING EPIC-CP

Recommendations to enhance the quality of person-centred clinical care of men with early-stage prostate cancer

Abstract

This report provides recommendations to improve the clinical care of men with prostate cancer by using a patient-reported outcome tool. The findings are based on clinician and patient descriptive data from a multi-center feasibility study of implementation, as well, as the participating cancer centres lessons learned.

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Executive Summary

The use of the Edmonton Symptom Assessment System – Revised Version (ESAS-r) in cancer centres is the current standard for symptom screening to inform clinical care and is an indicator for cancer program performance. While ESAS-r is a useful tool for generic symptom screening for cancer patients, it does not capture disease-specific concerns or the effects of specific treatments. In response to this gap, it was decided to identify and test a disease-specific Patient Reported Outcome Measure (PROM); the Extended Prostate Cancer Index Composite for Clinical Practice (EPIC-CP), was chosen to address the unique needs of men with prostate cancer. EPIC-CP is a16-item instrument specifically designed for men with prostate cancer that measures symptoms such as urinary incontinence, urinary irritation, bowel incontinence, sexual health dysfunction, hormonal, and Health-Related Quality of Life (HRQOL) domains.

Phase I of the Pilot Project was conducted in 2012 to test the long-form EPIC measure for feasibility and acceptability in one Ontario cancer centre. Results indicated that EPIC was endorsed and accepted by both patients and clinicians in radiation review clinics, and that the prostate-specific domains of EPIC were seen as a strength. In 2014, Cancer Care Ontario endorsed and funded a Phase II Pilot evaluation of EPIC-CP for early stage prostate cancer patients at four cancer centres across Ontario – The Princess Margaret Cancer Centre, the Cancer Centre of South Eastern Ontario, the Carlo Fidani Peel Regional Cancer Centre, and the Grand River Regional Cancer Centre. These centres represented both academic and community-based centres; these centres also have culturally diverse patient populations. Centres implemented EPIC-CP in clinical practice settings that included consultation and follow-up clinics in radiation oncology and surgical oncology, as well as treatment review.

A Patient Exit Survey (PES) was administered to every patient recruited in the study to evaluate the patient's experience with using the EPIC-CP measure and its acceptability for use in routine care. Qualitative semi-structured interviews were conducted with providers to capture their experience with the EPIC-CP and summary scores report, how they used it in practice, their perspectives on its value, and challenges or barriers encountered in the implementation process.

The main results of the phase II pilot are as follows:

- EPIC-CP administration and integration into practice was feasible in all centres. Overall, 90% of participating patients reported a favourable experience with the EPIC-CP.
- EPIC-CP fostered person-centred communication and the discussion of sensitive topics (i.e. sexual dysfunction). The PES highlighted that 71.4% of patients agreed or strongly agreed that questions regarding the impact of prostate treatment on sexual health were important to include in the EPIC-CP survey in order to facilitate discussion with clinicians.
- EPIC-CP assisted in standardizing the assessment of prostate cancer patients and facilitated customization of the treatment plan by targeting problems identified through the PROM.
- The use of EPIC-CP in clinic visits improved the patient experience of prostate cancer patients. Across the four centres, 62% of patients reported feeling more satisfied after their appointment with the addition of the EPIC-CP tool.

- Clinicians and prostate cancer patients both found the EPIC-CP to be more clinically meaningful and relevant than ESAS-r.

Accordingly, the recommendations from Phase II pilot are:

1. Implement EPIC-CP across Ontario in surgical and radiation outpatient consultation and follow-up clinics, as well as radiation review clinics.
    a. Both the PES and interviews suggest that the EPIC-CP was acceptable to patients and clinicians; EPIC-CP was shown to detect disease-specific symptoms and treatment effects for men with prostate cancer.
2. EPIC-CP was superior to ESAS-r in capturing prostate-specific symptoms and treatment impacts for the early stage prostate population. ESAS-r should not be used concurrently for early stage patients. A system should be designed through the technology platform that allows prostate patients to be directed to EPIC-CP in place of ESAS-r.
    a. Smart technology should be created through the Interactive Symptom Assessment and Collection (ISAAC) platform that allows prostate cancer patients to self-select their disease site and then be prompted to fill in the EPIC-CP survey. This would reduce the patient burden of completing both surveys and allow patients to take a survey that is more appropriate.
    b. To provide standardization, the EPIC-CP survey should be presented at the following time-points:
        i. At first consultation (i.e. baseline) for all early stage patients
        ii. At last review for radiation patients
        iii. At first follow-up for surgery patients
        iv. At every visit thereafter for both radiation and surgery patients (unless completed within the last four months)
    c. ESAS-r should be used routinely for patients with metastatic prostate cancer.
    d. EPIC-CP results should be integrated into electronic medical records.
3. Review and adapt (if necessary) clinic flow processes to integrate EPIC-CP into practice and facilitate its uptake for routine use.
4. Develop training and resources for patients and clinicians that facilitate the interpretation of PROMs and improve comfort with completing PROMs using technology.

The Phase II Pilot concluded that the EPIC-CP tool is highly endorsed by healthcare practitioners and prostate cancer patients across four diverse cancer centres. The EPIC-CP captures prostate-specific disease and treatment effects; this symptom information improves clinical care and symptom management for these patients. Provincial roll-out of EPIC-CP as a standard of care is recommended.

1.0 Introduction

Overview and Rationale

Patient self-reported health and well-being status through the use of validated patient-reported outcome measures (PROMs) is increasingly recognized as a key component of patient-centred care processes[1]. The use of PROMs allows each patient to reliably report his/her symptom experience and health status, thereby improving communication with health providers, and ultimately improving the quality of care[2,3]. Moreover, the use of PROMs in the clinical care encounter should improve management of treatment effects and consequently result in an improvement in symptoms and quality of life.

Cancer Care Ontario strongly endorses the use of PROMs for symptom screening and to inform clinical care; the organization requires the use of the Edmonton Symptom Assessment System – Revised version (ESAS-r) across the 13 regional cancer programs for this purpose. ESAS-r evaluates nine symptoms common to many cancer patients (e.g. appetite, pain, shortness of breath, or anxiety) using a single scale for each item. The use of ESAS-r in cancer centres is part of standard clinical symptom management and is a quality indicator for regional cancer program performance.

While the ESAS-r is suitable as a generic measure to screen for symptoms, condition-specific PROMs (also called disease-specific) are more sensitive to changes in health status that are related to a specific disease and treatments. The generic nature of the ESAS-r means that it does not capture specific disease concerns, such as bowel, bladder, or sexual issues, which often arise in men treated for prostate cancer. Jurisdictions, such as the United Kingdom, have developed recommendations to collect prostate cancer PROMs and have identified instruments to collect this data. There are a number of other jurisdictions exploring the use of prostate cancer-specific PROMs in collaboration with the International Consortium for Health Outcomes and/or funded by Prostate Cancer Canada.

Following an extensive review of the literature and content mapping of PROMs for prostate cancer, the Patient Reported Outcome Advisory Committee (2013) recommended testing a disease-specific measure for men treated for prostate cancer; the Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP). The EPIC-CP is a valid and reliable, 16-item, disease-specific PROM that targets the unique patient needs of men with prostate cancer and measures urinary incontinence, urinary irritation, bowel, sexual, and hormonal Health-Related Quality of Life (HRQOL) domains[4].

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[1] Tzelepis F, Rose SK, SansonFisher RW, Clinton-McHarg T, Carey ML, Paul CL. Are we missing the Institute of Medicine's mark? A systematic review of patient-reported outcome measures assessing quality of patient-centred cancer care. BMC Cancer 2014;14(1):41.

[2] Snyder CF, Aaronson NK, Choucair AK, et al.: Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. Quality of Life Research Nov 3. [Epub ahead of print], 2011

[3] Greenhalgh J: The applications of PROs in clinical practice: what are they, do they work, and why? Quality of Life Research 18:115-123, 2009

[4] Chang, P., Szymanski, K. M., Dunn, R. L., Chipman, J. J., Litwin, M. S., Nguyen, P. L., ... & Bubley, G. J. (2011). Expanded prostate cancer index composite for clinical practice: development and validation of a practical health related quality of life instrument for use in the routine clinical care of patients with prostate cancer. The Journal of urology, 186(3), 865-872.

Phase I Pilot Project Overview

The Phase I Pilot Project the EPIC-CP tool evaluated the feasibility of using EPIC-CP in clinical care in the Cancer Centre of South Eastern Ontario (CCSEO) in 2012. Evaluation was completed using clinician interviews and survey results; findings suggested that EPIC-CP was endorsed by both clinicians and patients. In addition, the prostate-specific domains of EPIC-CP were seen as an advantage over ESAS-r.

Based on the results of the Pilot Project Phase I from CCSEO, a Phase II multi-site feasibility and acceptability pilot study was developed for testing the EPIC-CP in four cancer centres with diverse characteristics. Sites that met diverse characteristics, such as community-based cancer programs and academic cancer centres, were invited to apply to be a test pilot site.

Objectives

The purpose of this study was to further evaluate the EPIC-CP measure, with regard to its feasibility, acceptability, and potential role in enhancing the clinical care of men with early-stage prostate cancer in four cancer centres. The specific objectives of the Phase II Pilot Project included:

1. Evaluate the feasibility of implementing EPIC CP-16 in both treatment review clinics and follow-up settings (radiation oncology and surgical oncology clinics).
2. Assess the acceptability of the EPIC-CP from both the patient and clinician perspective.
3. Develop and evaluate an EPIC-CP summary score data report that will be used by both clinicians and patients.
4. Identify clinician training and patient resources that would facilitate an appropriate response to EPIC-CP items.

2.0 Design & Methods

The pilot-test period of eight months was designated (from November 2014 to June 2015). The Phase II pilot study included both qualitative and quantitative methods to assess the feasibility and acceptability of the EPIC-CP measure in clinical practice, from both the patient and clinician perspectives. Experience with the EPIC-CP was evaluated from the patient perspective through a nine-item Patient Exit Survey (PES), and from the provider perspective through semi-structured qualitative interviews. Phase II of the Pilot Project was approved by the Ontario Cancer Research Ethics Board (OCREB) in 2014. Please see the Appendix for OCREB details.

Site Selection

Through a Request for Proposal (RFP) outlining pilot eligibility, four cancer centres volunteered and were selected as the phase II pilot sites:

1. Princess Margaret Cancer Centre (PMCC),
2. Cancer Centre of Southeastern Ontario (CCSEO),
3. Trillium Health Partners (THP), and
4. Grand River Regional Cancer Centre (GRRCC)

The above cancer centres are comprised of both academic and community-based settings and have varying access to surgical oncologists. The pilot sites also varied by size, partnering sites, and patient volumes.

Participant Inclusion and Exclusion Criteria

Patients

Eligibility criteria for prostate cancer patient participants included:

- In radiation or surgical oncology clinics (consultation or follow-up) or in radiotherapy treatment review clinics
- Receiving adjuvant hormone therapy
- Willing to sign a study consent form
- Able to read English sufficiently well to complete questionnaire (EPIC-CP tool was not translated to other languages)
- Has not received chemotherapy or palliative radiotherapy

Practitioners

Eligibility criteria for the practitioner interviews included the following:

- Must be exposed to EPIC-CP and resulting summary reports
- Must have used EPIC-CP as part of clinical appointment or interaction

Data Collection and Analysis

Interview methods

Semi-structured, qualitative interviews were conducted with a convenience sample of practitioners (i.e. urologists, radiation oncologists, and nurses), who were recruited utilizing email invitations. Interviews were audiotaped and were approximately 45 minutes in length.

All interviews were transcribed verbatim and thematic analysis was performed using qualitative, data-coding methodology based on the study by Graneheim and Lundman (2003). Qualitative data were analyzed as a whole data set and analysis stratified by site were not conducted.

Survey methods

Each patient recruited to use the EPIC-CP tool was also asked to evaluate their experience using the PES. In order to provide the patient with enough time to experience the EPIC-CP tool and its use with their providers, the PES was given to patients by the study coordinator during their final visit prior to the close of the study period. In some instances, due to scheduling conflicts, the patient was given the PES to take home to fill out, along with a return envelope. If surveys were not returned, a reminder phone call was made to the patient. For details regarding the take-home PES, please see Appendix 4.

Descriptive statistics were calculated to summarize demographic information and EPIC-CP scores. ESAS-r and EPIC-CP questionnaire data was collected electronically on a tablet at each cancer centre. ESAS-r and EPIC-CP scores were compared, specifically in the fields of vitality and depression, to determine if EPIC-CP could be used as a possible alternative to ESAS-r. EPIC-CP results were also compared to PES data in order to describe the extent of agreement or discordance between the two instruments.

3.0 Results

A total of 287 complete PES surveys were collected from the four cancer sites during the survey administration period. The majority of the sample of respondents were between the ages of 60 and 79 (77%) and had completed college, university or trade school (46%). Additionally, most respondents were not undergoing any hormone therapy (74%).

Table 1 - Overall demographic information for patients who completed the PES (n=287)

		Total n (%) (N=287)
Ages		
30-49		1.4% (4)
50-59		17.4% (50)
60-69		38.7% (111)
70-79		38.3% (110)
80 and above		4.2% (12)
Marital status		
Married/Life partner		78.0% (224)
Single, never married		4.5% (13)
Divorced/ Separated and Widowed		15.7% (45)
Other		1.7% (5)
Highest Education level		
Missing		0.3% (1)
No formal education		0.7% (2)
Completed public or grade school/Less than high school (some high school)		10.4% (30)
Completed high school		13.2% (38)
Some college (attended but not complete)		13.6% (39)
Completed college or university/Completed technical school (apprenticeships)		46% (132)
Post-graduate degree (i.e. PhD)		15.7% (45)
Hormone therapy		
Missing		1.4% (4)
No		74.2% (213)
Yes		24.4% (70)

Moreover, the majority of respondents (40%) were surveyed while in the radiation follow-up phase of their treatment journey (Table 2).

Table 2 – Patient visit type frequency for patients who completed the PES

Patient visit type		**Total n (%) (N=287)**
Missing		1.4% (4)
Radiation-consultation		5.6% (16)
Radiation-treatment		27.2% (78)
Radiation-follow-up		40.4% (116)
Surgical-consultation		3.8% (11)
Surgical-follow-up		21.6% (62)

Data was also collected on EPIC-CP survey completion rates, by question (more information on completion rates for individual cancer centres can be found in the Appendix). The overall percentage completion of all survey items was high, ranging from 90.5% to 99.5%. Sexual health completion rates were among the lowest scores, ranging from 90.5% to 92.0%, but far exceeded expectations (Table 3).

Table 3 - Percentage completion of the EPIC-CP survey items (all sites, N=937)

Questions on EPIC-CP	Total n (%) (N=287)
Ability to reach orgasm	90.5% (848)
Feeling depressed	98.9% (927)
Hot flashes or breast symptoms	96.9% (908)
Lack of energy	98.6% (924)
Number of pads or diapers used	98.9% (927)
Overall problem with bowel habit	99.5% (932)
Overall problem with sexual function	92.0% (862)
Overall urinary function	99.1% (929)
Problem with urinary leakage	99.1% (929)
Quality of erections	90.1% (852)
Rectal frequency	99.1% (929)
Rectal pain or urgency	99.3% (930)
Urinary control	99.1% (929)
Urinary frequency	99.0% (928)
Urinary pain or burning	98.5% (923)
Weak stream or bladder emptying	98.9% (927)

*Clarified at record level

Mixed Methods Results from the PES and Clinician Interviews

A total of 31 practitioners were selected for semi-structured interviews across the sites. A similar numbers of clinicians participated from each site (range 6-13):

- THP (n=7)
- PMCC (n=11)
- GRRCC (n=7)
- CCSEO (n=6)

Findings from both the survey results and qualitative interviews are outlined below.

EPIC-CP fostered person-centred communication and discussion of sensitive topics

Clinicians and patients both reported that the EPIC-CP tool facilitated discussions regarding sensitive treatment effects such as urinary and sexual dysfunction. The PES highlighted that 71.4% of patients agreed or strongly agreed that questions regarding the impact of prostate treatment on sexual health were important to include in order to facilitate discussion with clinicians. Additionally, 65.5% of patients agreed or strongly agreed that completing the EPIC-CP questionnaire helped them participate more in discussions regarding their care.

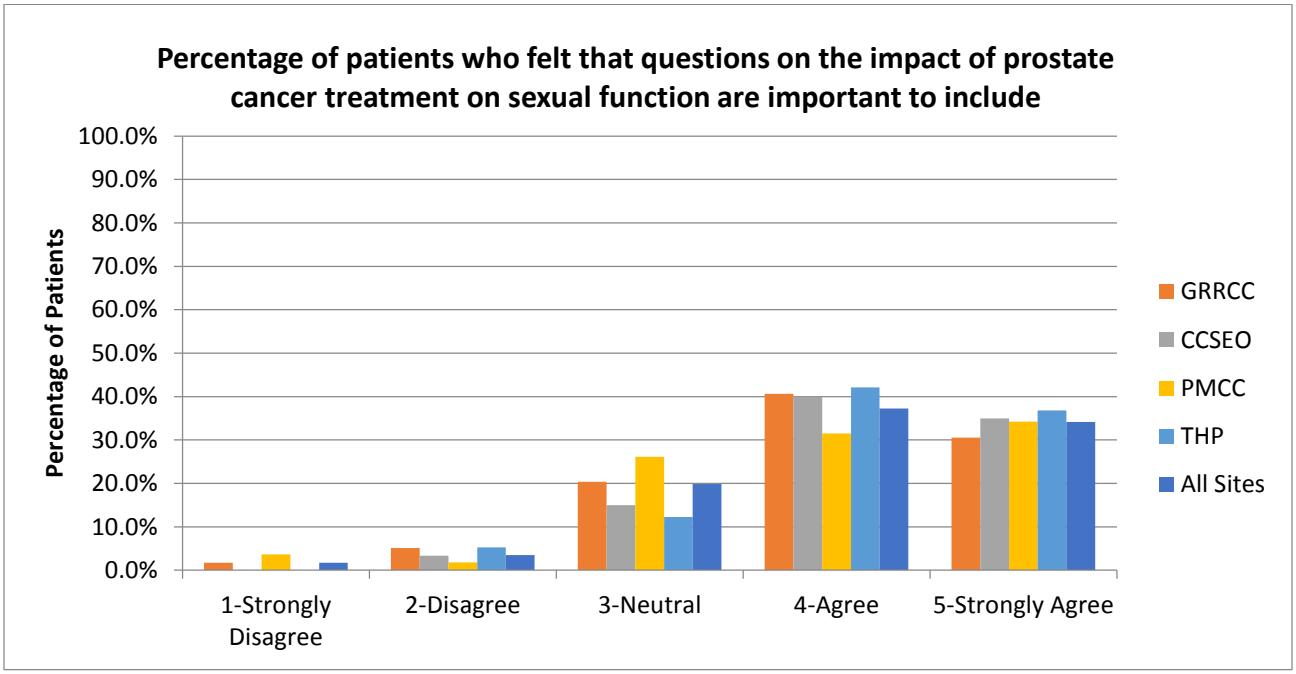
The completion of the EPIC questionnaire prior to the clinic visit helped the clinicians to structure their communication and facilitated open dialogue and discussion of sensitive topics. During the semi-structured interviews, many clinicians commented on how the completion of EPIC-CP made it less difficult to discuss the urinary and sexual dysfunction topics with patients, as well as created a safe environment for open communication. Clinicians described scanning the report either before they entered or as soon as they entered the clinic exam room, so that discussion about the scores could be part of the conversation with the patient. When asked if they used the EPIC-CP results to inform discussion, a clinician commented,

> "Oh, all the time. Absolutely. Every time it was a really good tool to sit down and actually focus the discussion on the things that were pertinent to their particular situation. And you could bring up

> stuff…because they had reported it I could say to them more easily, "I see you're having issues with…can you tell me about it" and then pull the information I needed to know how to treat them". - Clinician

Similarly, through the PES, 89.6% of patients agreed or strongly agreed that they felt comfortable talking about their EPIC-CP responses with clinicians (Figure 1). Fostering discussion around sensitive topics also provided clinicians with a deeper understanding of problems or symptoms from a patient's perspective, and what support or help patients would like as part of a shared treatment planning process. The EPIC tool was viewed as augmenting high-quality practice. Many clinicians felt that these conversations were already part of their current practice, but the standardization was seen as valuable for discussing treatment options/symptom management.

Figure 1 - The importance of including sexual function questions in the Patient Exit Survey



There were some men who reported that sexual dysfunction was no longer a concern to them as they did not feel it was important at their stage of life or did not have a partner. A few others explained that they did not expect sexual dysfunction to improve so did not think it was necessary to ask this at every visit.

EPIC-CP assisted in standardizing the assessment and facilitated customization of the treatment plan by targeting problems identified in the measure

In the semi-structured interviews, clinicians identified the subjective and self-reported nature of the EPIC-CP questionnaire as a strength, which provided an unbiased assessment of treatment impact by the patient. Clinicians felt that the tool empowered the patient to tell their story and experience.

> "Well, why (is it important) because I think that the patients are often more truthful. And sometimes I think they feel…I put them on the spot when I ask them the questions and they feel pressured to answer. But if they have time to think about it when it's on paper they may be more truthful or more willing to give that information out. The other thing is sometimes physicians may miss some questions or assume that the

> questions have been asked and they maybe haven't…like erectile function, not everybody is very keen on talking about erectile function…". – Clinician

Clinicians described that the EPIC-CP tool helped to tailor their visit according to the patient scores, as they focused their visit on the "red-flagged" items on the survey. For instance, if a patient did not trigger high symptom scores then the visit length might be five minutes, but if all domains were triggered with high scores then the visit might require 10-15 minutes.

> "I guess prior to EPIC, the questions I tended to ask patients are quite random…Now that there is EPIC we actually have something to go by and know that there are issues that we need to cover with them…it is helpful to remind us that we do have to see these patients that do have concerns or problems based on their scores…we have got the printout to see they do need something addressed". – Clinician

Furthermore, clinicians mentioned that having the EPIC-CP survey completed prior to the appointment, improved overall clinic efficiency. This meant that there was more time to focus the appointment on the patient and create a more person-centred environment. One clinician expressed,

> "I think actually it improves, you know, the efficiency overall because you end up have a more focused discussion with some clearer information than if you were to take this out…the patient at the time, they walk into the room. So you already have a starting point". - Clinician

EPIC-CP helped to inform the understanding of patient experience of prostate cancer treatment effects for routine care

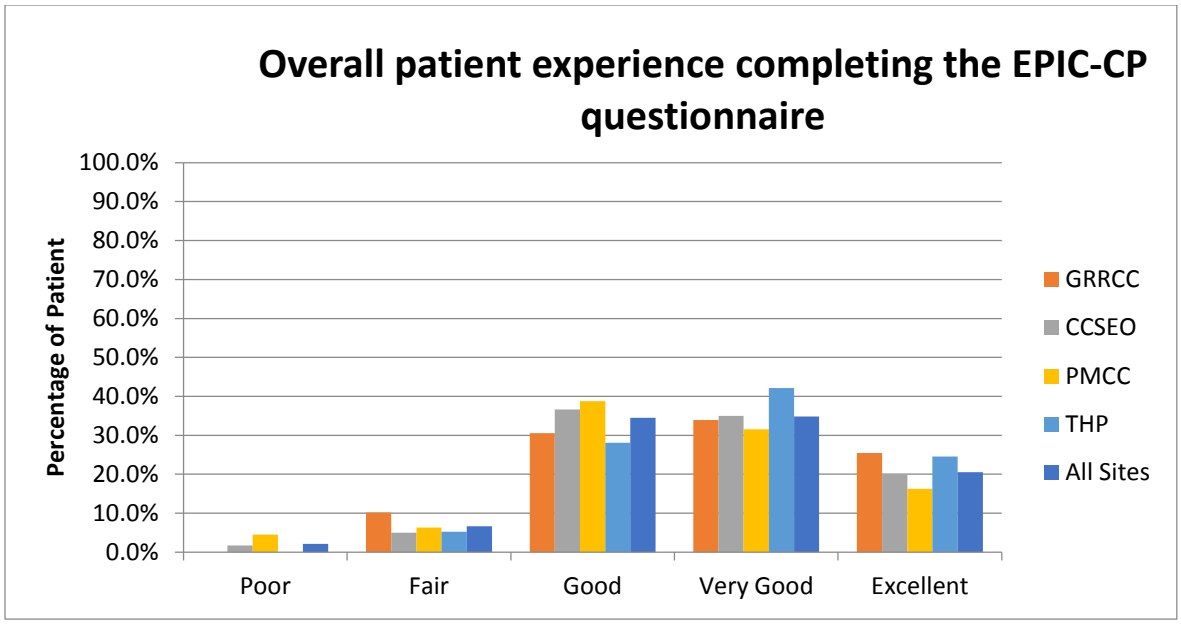
Overall, clinicians described receiving positive feedback from patients related to the use of EPIC-CP. Clinicians thought that the use of the PROM in routine care created a positive person-centred environment, which gave patients the opportunity to share their experiences about their cancer and treatment. Similarly, the PES reported that 34.5%, 34.8% and 20.6% of patients thought their experience completing the EPIC-CP questionnaire was good, very good and excellent, respectively (Figure 2). In addition, 62% of patients reported feeling more satisfied after their appointment with the addition of the EPIC-CP, while only 2.4% of patients voiced that they were annoyed that they had to complete the EPIC-CP questionnaire.

Although 81.6% of patients agreed and strongly agreed that they were willing to complete a similar questionnaire at future clinic visits, some patients did voice frustration with the technology. One clinician raised concerns about language and computer literacy by stating,

> "…so the gentlemen in their 50s and 60s are quite literate, they have iPads at home….use to a touch screen…they fly through those questions…other men are less comfortable…it took a long time… and that would be a whole other challenge if you've got someone for whom English is not their first language…they need someone to help them in the absence of a medical translator". - Clinician

Although responses were variable, the idea of education programs for clinicians and patients on EPIC-CP emerged during the interviews. Some clinicians felt that at a minimum, patients should be oriented to the measure the first time they complete the EPIC-CP and given specific education as to how to interpret the report and how it will be used by clinicians in patient care. In regards to clinician education, some practitioners thought that additional training on sexual health and the treatment strategies used for different stages of erectile dysfunction would be extremely beneficial.

Figure 2 - Overall patient experience with the EPIC-CP tool, by cancer centre



The comparison of EPIC-CP and ESAS-r in prostate cancer patient clinical practice

Since patients completed both the EPIC-CP survey and ESAS-r, this provided an opportunity to compare the results of the two PROMs. Items of interest for comparison included the scores on depression and vitality (See Appendix 3 for both EPIC-CP and ESAS-r surveys). A concordance approach was utilized in this analysis, seeking to describe the extent of agreement or discordance between the two instruments. We chose not to calculate Kappa statistics to determine the amount of chance concordance, but instead report the percent agreement not corrected for chance.

Depression

A comparison of depression scores from the EPIC-CP and ESAS-r is shown in Table 4. There was 92.5% concordance on the proportion of patients that were above or below a specified cut point on both instruments (cut points were 4+ for ESAS, 2+ for EPIC). However, for the discordant scores, a higher percentage of patients were above the cut point for EPIC-detected depression (7%) than were above the ESAS cut point (less than 1%), indicating that the EPIC-CP cut point detects a higher proportion of patients self-reporting depression than does ESAS. Only a very small proportion (less than 0.5%) of all patients (those with high ESAS depression scores but without high corresponding EPIC scores) would be missed if ESAS were not administered.

Table 4 - Comparison of EPIC-CP and ESAS-r depression scores

		EPIC Depression Scores		
ESAS Depression scores		**0 – 1**	**2- 4**	**Total**
	0 - 3	86.82% (718)	7.13% (59)	93.95% (777)
	4 +	0.36% (3)	5.68% (47)	6.05% (50)
	Total	87.18% (721)	12.82% (106)	100% (827)

Vitality

Similar to the depression scores, a comparison of the vitality scores from both EPIC-CP and fatigue from ESAS-r is shown in Table 5 below. There was an 88.1% concordance on the proportion of patients that were above or below a specified cut point on both instruments (cut points were 4+ for ESAS, 2+ for EPIC). For the discordant scores, a higher percentage of patients were above the cut point for EPIC-detected vitality (8.3%) than were above the ESAS cut point (3.7%), indicating that the EPIC-CP cut point detects a higher proportion of patients self-reporting fatigue/tiredness than does ESAS. Thus, only a very small proportion (3.7%) of all patients (those with high ESAS fatigue scores but without high corresponding EPIC vitality scores) would be missed if ESAS were not administered.

Table 5 - Comparison of EPIC-CP and ESAS-r vitality and fatigue scores

		EPIC vitality		
ESAS fatigue /tiredness scores		**0 - 1**	**2- 4**	**total**
	0 - 3	75.79% (623)	8.27% (68)	84.06% (691)
	4 +	3.65% (30)	12.29% (101)	15.94% (131)
	Total	79.44% (653)	20.56% (169)	100% (822)

Interviews with clinicians

Although not explicitly asked as a question, several clinicians mentioned that patients had been voicing their frustration with ESAS-r, particularly after completing the EPIC-CP questionnaire. The simple and straightforward wording of the EPIC-CP questionnaire and its relevance to prostate cancer patients was perceived as particularly valuable to both clinicians and patients. Clinicians relayed that often patients voiced being dissatisfied about completing ESAS-r at every visit because they did not find it relevant. Moreover, ESAS-r did not identify the impacts salient to prostate cancer treatment i.e. urine, bowel and sexual function. Clinicians also voiced concerns about the relevance of generic tools such as ESAS-r as many of the symptoms i.e. dyspnea or loss of appetite are only relevant to specific diseases. It was suggested,

"To be honest with you, I would rather it just replaced ESAS". - Clinician

Replacing ESAS with disease-specific PROs was raised as a potential solution to reduce patient burden and the need to track prostate-specific treatment effects from baseline to post treatment follow-up.

4.0 Implementation Lessons Learned

After the EPIC-CP pilot implementation, all four cancer centres were given an evaluation to provide an overview of their challenges, barriers and recommendations. For centre specific lessons learned, please see Appendix 5.

Human resourcing capacity

Two of the four cancer centres commented on the fast-paced nature of the clinics and the issue of competing priorities. With high patient volumes and an increased workload, it became difficult for the nurses to respond to the information in the EPIC-CP summary reports. After identifying this problem, both clinics provided extra support to the nursing educators and nursing leads to support the clinic workflow. Additionally, further human resources were required to manually select prostate patients to complete the EPIC-CP tool.

Technology

Three of the four cancer centres reported significant barriers with technology. Since the ISAAC system lacks the ability for patients to self-identify as having prostate cancer, the process of identifying prostate cancer patients to complete the EPIC-CP was done manually, causing human resource challenges. Using kiosks created longer wait times for both patients and clinicians. The number of printers, printer location, and printer functionality was also seen as a barrier. Both patients and clinicians were interested in a print-out of the scores, but this required staff to constantly find a free printer and locate the print-out, which caused several delays. Moreover, local firewall restrictions often prevented printing from tablets.

Patient and practitioner Education

All four cancer centres mentioned the lack of educational resources for both practitioners and patients. The sites felt that the EPIC-CP tool needed an introduction to explain its purpose, use and goals. Additionally, practitioners often felt "discomfort" or that they were "lacking in confidence" when reports pointed to discussions around sexual function and incontinence.

5.0 Recommendations

Through the quantitative and qualitative findings in the Phase II of the EPIC-CP Pilot Project, the recommendations below are suggested for the provincial implementation of EPIC-CP.

1. Implement EPIC-CP across Ontario in surgical and radiation outpatient consultation and follow-up clinics, as well as radiation review clinics.
    a. Both the PES and interviews suggest that the EPIC-CP was acceptable to patients and clinicians; EPIC-CP was shown to detect disease-specific symptoms and treatment effects for men with prostate cancer.
2. EPIC-CP was superior to ESAS-r in capturing prostate-specific symptoms and treatment impacts for the early stage prostate population. ESAS-r should not be used concurrently for early stage

patients. A system should be designed through the technology platform that allows prostate patients to be directed to EPIC-CP in place of ESAS-r.

   a. Smart technology should be created through the Interactive Symptom Assessment and Collection (ISAAC) platform that allows prostate cancer patients to self-select their disease site and then be prompted to fill in the EPIC-CP. This would reduce the patient burden of completing both surveys and allow patients to take a survey that is more appropriate.
   b. To provide standardization, the EPIC-CP survey should be presented at the following time-points:
      i. At first consultation (i.e. baseline) for all early stage patients
      ii. At last review for radiation patients
      iii. At first follow-up for surgery patients
      iv. At every visit thereafter for both radiation and surgery patients (unless completed within the last four months)
   c. ESAS-r should be used routinely for patients with metastatic prostate cancer.
   d. EPIC-CP results should be integrated into electronic medical records.

3. Review and adapt (if necessary) clinic flow processes to integrate EPIC-CP into practice and facilitate its uptake for routine use.
4. Develop training and resources for patients and clinicians that facilitate the interpretation of PROMs and improve comfort with completing PROMs using technology.

6.0 Conclusion

The Phase II Pilot Project concluded that the EPIC-CP tool is highly endorsed by healthcare practitioners and prostate cancer patients for use at clinic visits and follow-up visits, across four diverse cancer centres. The EPIC-CP tool captures prostate-specific symptom information that assists in enhancing clinical care and symptom management. Provincial roll-out of EPIC-CP as a standard of care is recommended.

6.0 Appendices

Appendix 1 – OCREB details

ocreb

Ontario Cancer Research Ethics Board
661 University Avenue, Suite 510
Toronto, Ontario Canada M5G 0A3
416-673-6649 | www.ocreb.ca

APPROVAL - AMENDMENT

The approval of this amendment applies to all participating centres (listed below) that have received OCREB approval to conduct the study. If this amendment or a portion of this amendment will not be implemented at your centre, please prepare a memo or Note-to-File explaining the opt-out details, to be stored with a copy of this letter in your study files.

To:	Colleen Graham (Grand River Hospital) Michael Brundage (Kingston General Hospital) Andrew Matthew (UHN-Princess Margaret Cancer Centre)
OCREB #:	14-046
Protocol ID:	EPIC-CP Pilot - Phase II
Study Title:	EPIC-CP Pilot - Phase II
Study Sponsor:	Cancer Care Ontario
Review Type:	Expedited Review
Date Approved:	27-Nov-2014
Date Approval Issued:	27-Nov-2014
Approval Expiry Date:	07-Oct-2015

Documents approved until the expiry date noted above:

- **Protocol:**
  EPIC Project Proposal (Administrative Amendment) Version November 20 2014
- **Consent:**
  EPIC Patient Consent - Version Nov 26 2014

All provincially approved OCREB study documents (including participant materials such as wallet cards and consent forms) are approved for use by participating centres with the application of centre specific 'administrative changes' to the document, without further OCREB review. Administrative changes include, for example, the addition to the document of centre contact information, centre letterhead, and any pre-approved centre-specific changes that have been authorized by OCREB.

Documents acknowledged:

- Provincial Application for OCREB Review of an Amendment to an Approved Protocol

- ***Note:This correspondence includes an electronic signature (validation and approval via an online system).***

The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the

requirements of: TCPS 2 - 2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. OCREB is registered with the U.S. Department of Health & Human Service under the IRB registration number IRB00003960.

Sincerely,

Richard Sugarman, MSW, RSW
Chair, Ontario Cancer Research Ethics Board

Mark Whissell, HBCom., CCPE
Vice-Chair, Ontario Cancer Research Ethics Board

Yoo-Joung Ko, MD, MMSc., SM, FRCP(C)
Vice-Chair, Ontario Cancer Research Ethics Board

Appendix 2 - Complete tables

Table 1 – Demographic information for all 287 PES, all four cancer centres

		GRRCC	CCSEO	PMCC	THP	Overall
Total N values		**59**	**60**	**111**	**57**	**287**
Age scores						
30-49		0%	1.7%	2.7%	0%	1.4%
50-59		13.6%	11.7%	22.5%	17.5%	17.4%
60-69		23.7%	36.7%	45.0%	43.9%	38.7%
70-79		54.2%	48.3%	27.9%	31.6%	38.3%
80 and above		8.5%	1.7%	1.8%	7.0%	4.2%
Marital status						
Married/Life partner		79.9%	80.0%	74.8%	80.7%	78.0%
Single, never married		1.7%	3.3%	8.1%	1.8%	4.5%
Divorced/ Separated and Widowed		17.0%	13.3%	15.3%	17.6%	15.7%
Other		1.7%	3.3%	1.85%	0%	1.7%
Highest Education level						
Missing		1.7%	0%	0%	0%	0.3%
No formal education		1.7%	0%	0%	1.8%	0.7%
Completed public or grade school		5.1%	8.3%	0%	1.8%	3.1%
Less than high school (some high school)		16.9%	11.7%	1.8%	3.5%	7.3%
Completed high school		15.3%	26.7%	1.8%	19.3%	13.2%
Some college (attended but not complete)		8.5%	11.7%	16.2%	15.8%	13.6%
Completed college or university		25.4%	20.0%	51.4%	40.4%	37.3%
Completed technical school (apprenticeships)		11.9%	13.3%	5.4%	7.0%	8.7%
Post-graduate degree (i.e. PhD)		13.6%	8.3%	23.4%	10.5%	15.7%
Patient visit type						
Missing		0%	5.0%	0.9%	0%	1.4%
Radiation-consultation		8.5%	0%	0%	19.3%	5.6%
Radiation-treatment		39.0%	20.0%	6.3%	63.2%	27.2%
Radiation-follow-up		52.5%	56.7%	45.9%	0%	40.4%
Surgical-consultation		0%	1.7%	0%	17.5%	3.8%
Surgical-follow-up		0%	16.7%	46.8%	0%	21.6%
Hormone therapy						
Missing		0%	5.0%	0.9%	0%	1.4%
No		57.6%	23.3%	82.0%	98.2%	74.2%
Yes		42.4%	41.7%	17.1%	1.8%	24.4%

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Table 3 – Percentage completion of the EPIC-CP survey items, all four cancer sites

	Grand River Hospital Completed Screens (n=257)	Grand River % Complete	Kingston General Hospital Completed Screens (n=145)	Kingston % Complete	Princess Margaret Hospital Completed Screens (n=334)	PMH % Complete	Trillium Completed Screens (n=201)	Trillium % complete	All sites completed Screens (n=937)	All Sites % Complete
Ability to reach orgasm	194	75.5%	142	97.9%	316	95%	178	88.6	848	90.5%
Feeling depressed	251	97.7%	144	99.3%	331	99%	198	98.5%	927	98.9%
Hot flashes or breast symptoms	242	94.2%	144	99.3%	329	99%	188	93.5%	908	96.9%
Lack of energy	249	96.9%	142	97.9%	332	99%	199	99%	924	98.6%
Number of pads or diapers used	252	98.1%	143	98.6%	311	93%	198	98.5%	927	98.9%
Overall problem with bowel habit	252	98.1%	145	100%	330	99%	201	100%	932	99.5%
Overall problem with sexual function	199	77.4%	142	97.9%	329	99%	187	93%	862	92.0%
Overall urinary function	254	98.8%	145	100%	333	100%	196	97.5%	929	99.1%
Problem with urinary leakage	252	98.1%	145	100%	331	99%	198	98.5%	929	99.1%
Quality of erections	192	74.7%	142	97.9%	320	96%	184	91.5%	852	90.9%
Rectal frequency	252	98.1%	144	99.3%	331	99%	199	99.0%	929	99.1%
Rectal pain or urgency	251	97.7%	145	100%	334	100%	200	99.5%	930	99.3%
Urinary control	254	98.8%	144	99.3%	330	99%	197	98.0%	929	99.1%
Urinary frequency	252	98.1%	144	99.3%	328	98%	198	98.5%	928	99%
Urinary pain or burning	249	96.9%	143	98.6%	330	99%	197	98.0%	923	98.5%
Weak stream or bladder emptying	252	98.1%	145	100%	328	98%	196	97.5%	927	98.9%

Appendix 3 - Surveys

EPIC-CP survey

Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) Prostate Cancer Quality of Life (QOL)

Patient Name:_____ Date of Birth: _____ Physician: _____ Date of Visit: _____ **Patients:**

Please answer the following questions by circling the appropriate answer. All questions are about your health and symptoms in the **LAST FOUR WEEKS.**

Select ONE answer for each question:

1. **Overall, how much of a problem has your urinary function been for you?**				
No Problem	Very small problem	Small problem	Moderate problem	Big problem

2. Which of the following best describes your urinary control?					
0-Total control	1-Occasional dribbling	2-Frequent dribbling	4- No urinary control		
3. How many pads or adult diapers per day have you been using for urinary leakage?					
0-None	1-One pad per Day	2-Two pads per Day	4- Three or more pads		
4. How big a problem, if any has urinary dripping or leakage been for you?					
0-No problem	1-Very small problem	2-Small problem	3-Moderate problem	4-Big problem	
***CLINICIANS**: Add the answers from questions **2-4** to calculate the **Urinary Incontinence Symptom Score** (out of 12)*					

5. How big a problem, if any, has each of the following been for you?						
	No problem	Very small problem	Small problem	Moderate problem	Big problem	
a. Pain or burning with urination	0	1	2	3	4	
b. Weak urine stream/incomplete bladder emptying	0	1	2	3	4	
c. Need to urinate frequently	0	1	2	3	4	

CLINICIANS: ADD *the answers from questions* ***5a-5c*** *to calculate the* ***Urinary Irritation/Obstructive Symptom Score*** *(out of 12)*	

6. How big a problem, if any, has each of the following been for you?						
	No problem	Very small problem	Small problem	Moderate problem	Big problem	
a. Rectal pain or urgency of bowel movements	0	1	2	3	4	
b. Increased frequency of your bowel movements	0	1	2	3	4	
c. Overall problems with your bowel movements	0	1	2	3	4	
CLINICIANS: ADD *the answers from questions* ***6a-6c*** *to calculate the* ***Bowel Symptom Score*** *(out of 12)*						

7. How do you rate your ability to reach orgasm (climax)?					
0- Very good	1-Good	2-Fair	3-Poor	4-Very poor to none	

8. How would you describe the usual quality of your erections?				
0- Firm enough for intercourse	1-firm enough for masturbation and foreplay	2-Not firm enough for any sexual activity	4-None at all	

9. Overall, how much of a problem has your sexual function or lack of sexual function been for you?					
0-No problem	1-Very small problem	2-Small problem	3-Moderate problem	4-Big problem	

10. How big a problem, if any, has each of the following been for you?						
	No problem	Very small problem	Small problem	Moderate problem	Big problem	
a. Hot flashes or breast tenderness/enlargement	0	1	2	3	4	
b. Feeling depressed	0	1	2	3	4	
c. Lack of energy	0	1	2	3	4	
CLINICIANS: ADD *the answers from question s* ***10a-10c*** *to calculate the* ***Vitality/Hormonal Symptom Score*** *(out of 12)*						

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***CLINICIANS: ADD** the five domain summary scores to calculate the Overall Prostate Cancer QOL Score (out of 60)*

ESAS-r survey

Cancer Care Ontario
Action Cancer Ontario

Edmonton Symptom Assessment System:
(revised version) (ESAS-R)

Please circle the number that best describes how you feel NOW:

No Pain	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Pain
No Tiredness *(Tiredness = lack of energy)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Tiredness
No Drowsiness *(Drowsiness = feeling sleepy)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Drowsiness
No Nausea	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Nausea
No Lack of Appetite	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Lack of Appetite
No Shortness of Breath	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Shortness of Breath
No Depression *(Depression = feeling sad)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Depression
No Anxiety *(Anxiety = feeling nervous)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Anxiety
Best Wellbeing *(Wellbeing = how you feel overall)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Wellbeing
No _____ Other Problem *(for example constipation)*	0	1	2	3	4	5	6	7	8	9	10	Worst Possible _____

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Patient's Name _____

Date _____ Time _____

Completed by (check one):
- ☐ Patient
- ☐ Family caregiver
- ☐ Health care professional caregiver
- ☐ Caregiver-assisted

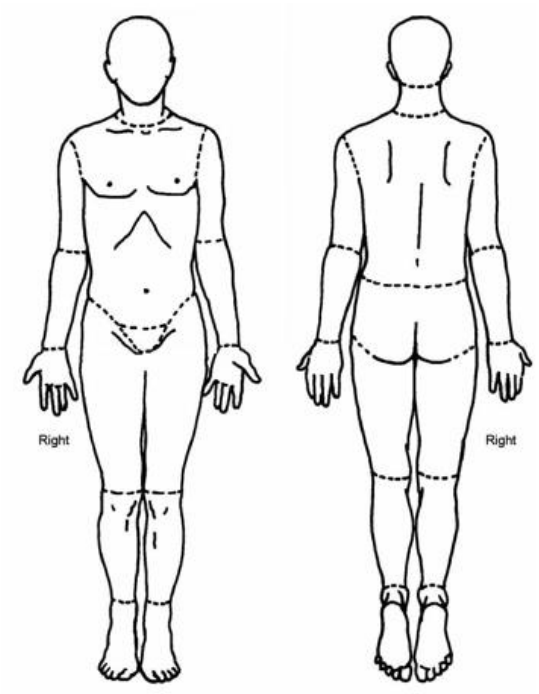
BODY DIAGRAM ON REVERSE SIDE

ESAS-r

Revised: November 2010

Cancer Care Ontario

Please mark on these pictures where it is that you hurt:



Ontario

Appendix 4 – Patient Exit Survey

Study ID Number: _____

Patient Survey about EPIC-CP

Introduction

Thank you for participating in this pilot study and taking the time to tell us about your experience with prostate cancer treatment. We are interested in your feedback about the Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) questionnaire. Your comments will assist us as we try to make improvements to the patient experience. Please note that your responses will be kept confidential and will only be seen by the study coordinator and members of the research team. Your responses will not be discussed with your health care team.

Part 1. Background Information

What is your current age (check box):

☐ 30-39

☐ 40-49

☐ 50-59

☐ 60-69

☐ 70-79

☐ 80 and above

Present marital status (please check one):

☐ Married / Life Partner

☐ Single, never married

☐ Divorced/Separated

☐ Widowed

☐ Other, please specify _____

Education: What is the highest level of education you have completed (check all that apply)?

- ☐ No formal education
- ☐ Completed Public or Grade School
- ☐ Less than high school (some high school)
- ☐ Completed high school
- ☐ Some College (attended but not complete)
- ☐ Completed College or University
- ☐ Completed Technical School (apprenticeships)
- ☐ Post-Graduate Degree (e.g. PhD)

At which clinic visit did you complete the EPIC-CP (check all that apply):

- ☐ At a follow-up appointment
- ☐ Before I started my radiotherapy treatment
- ☐ During my radiotherapy treatment
- ☐ After I completed my radiotherapy treatment
- ☐ Before my surgery
- ☐ After my surgery
- ☐ Other (please specify): _____

Part 2. Completing Questionnaire and Engaging with the Health Care Team

How much do you agree with the following statements? (Please place an X in the box)

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
Completing the EPIC-CP helped me to tell my clinicians about how I have been feeling					
I felt comfortable talking about my answers to the questionnaire with my doctor or nurse.					
Completing the questionnaire helped me participate more in discussions about my care.					
The questions about the impact of prostate treatment on my sexual life were important to include.					
The questionnaire helped me feel more satisfied after my appointment.					
The questionnaire made it possible to discuss more issues than if I hadn't completed it.					
I was annoyed that I had to complete the questionnaire.					
I am willing to complete similar questionnaires at future clinic visits.					

Part 3. Using the Touchscreen Computer to Complete the Questionnaire

2. How much do you agree with the following statements?

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
I was comfortable with completing the questionnaire on a touchscreen computer.					
Completing the questionnaire was time consuming.					
The questionnaire software was easy to use.					
The font size was easy to read.					
I would have liked more pictures or images in the questionnaire.					
I felt comfortable completing the questionnaire in the clinic.					
I felt I had enough privacy when I completed the questionnaire.					
I would have preferred completing this questionnaire at home.					
I had no difficulty printing the summary report.					
I received the help I need to complete the questionnaire.					
I would like to have a print out of the questionnaire results to take with me.					

3a) Did you review the summary report with your doctor during your clinic appointment?

1) ☐ Yes

0) ☐ No

3b) Did you review the summary report with your nurse during your clinic appointment?

1) ☐ Yes

0) ☐ No

Part 4. Overall Impressions

4. How would you rate your overall experience completing this questionnaire?

☐ Poor

☐ Fair

☐ Good

☐ Very Good

☐ Excellent

5. Do you have any other comments you would like to make?

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Appendix 5 – Cancer Centre Feedback

Technical Feedback Regarding EPIC Pilot Project

Trillium Health Partners

Challenges

- Printing functionality was disabled due to firewall
- ISAAC technology was not compatible with tablets
- EPIC and Electronic Medical Record (EMR) did not merge successfully
- More human resources were required to troubleshoot problems with tablets, printers, networking and printing

Recommendations:

- ISAAC should be tablet friendly
- Design ISAAC so that the prostate population can be self-selected

Grand River Regional Cancer Centre

Challenges

- ISAAC technology was not compatible with tablets
- ISAAC did not work well with EMR
- High patient volume

Recommendations:

- ISAAC should be tablet friendly
- Need a dedicated Project manager

Princess Margaret Cancer Centre

Challenges

- Fast paced clinics required additional human resources – not enough time for clinician to review patient responses
- Required educational resources for clinicians
- Several competing research interests
- Nurses required support for increased workload
- Patient population did not know how to work the tablets properly, patients requested papers
- More volunteers needed

Recommendations:

- Clinic flow needs to be developed
- Dedicated project coordinator

Cancer Centre of Southeastern Ontario

Challenges

- Patients were taking too long filling out EPIC-CP survey – delayed clinic flow
- Clinic flow should be clearly defined
- Printer functionalities need to be addressed

Recommendations:

- ISAAC should be tablet friendly
- Educational resources required for staff and patients
- Utilize patient brochures/posters to engage patients
- Ensuring clear champion would assist in clinic flow

Appendix 6.0 – EPIC Leads

List of EPIC-CP leads at each site:

Overall leads:

- Dr. Michael Brundage and Dr. Doris Howell

Credit Valley:

- Virginia Boquiren, Alexander Lim, Trish Lymburner, Gwen Burrows, Jo-Anne Billings, Terry Lord and Noel Skinner and Luiz Costa, Dr. Munir Jamal

Grand River Regional Cancer Centre:

- Dr. Ramana Rachakonda, Colleen Graham, Sheeba Thallury and Carol Ballantyne

Princess Margaret Cancer Centre:

- Dr. Andrew Matthew, Alyssa Macedo, Anika Petrella, Michael Lima, Dr. Charles Catton, Dr. Girish Kulkarni, Dr. Anthony Joshua, Dr. Tony Finelli, Dr. Neil Fleshner