Prospective, Randomized Evaluation of Patient Reported Knowledge and Satisfaction Following the Use of an Enhanced Gynecologic Brachytherapy-Specific Educational Video

NCT04363957

Document Date: 1/18/2019

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Prospective, Randomized Evaluation of Patient Reported Knowledge and Satisfaction Following the Use of an Enhanced Gynecologic Brachytherapy-Specific Educational Video

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Study Agent: Brachytherapy video consent

Protocol	Date
Original (v 1.0)	18Jan2019

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

UCSD Principal Investigator / Study Chair

Jyoti S. Mayadev

Printed Name

2/6/2018

Signature Date

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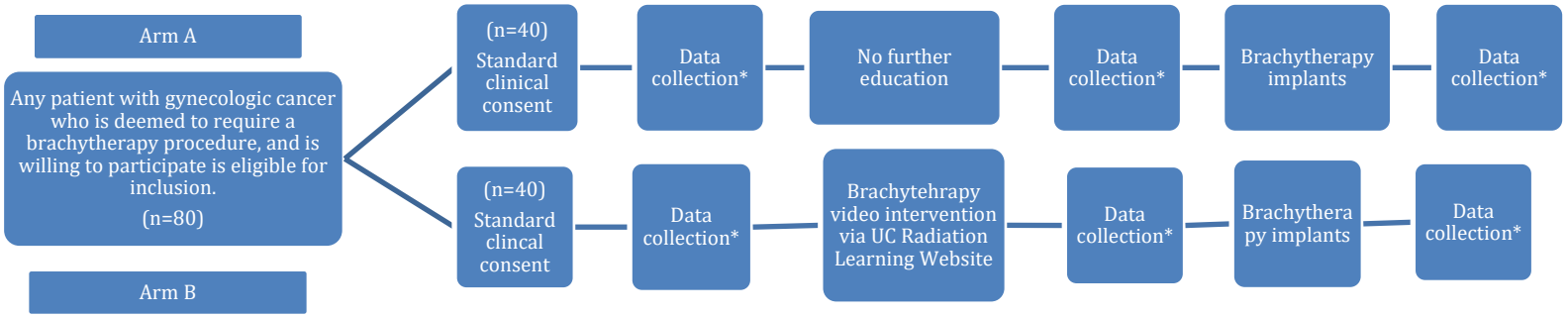
LIST OF ABBREVIATIONS

AE	Adverse Event
CTCAE	Common Terminology Criteria for Adverse Events
ECOG	Eastern Cooperative Oncology Group
HIPAA	Health Insurance Portability and Accountability Act
HPV	Human Papillomavirus
IRB	Institutional Review Board
NCI	National Cancer Institute

STUDY SCHEMA



*Data collection. Prospective data collection includes: age, performance status, TMN staging, tumor histology, use and type of systemic therapy, brachytherapy dose volume histogram information, treatment-specific dosimetric and quality assurance information. Validated data includes: NCCN distress score, and brachytherapy-specific survey [3].

STUDY SUMMARY

Title	Prospective, Randomized Evaluation of Patient Reported Knowledge and Satisfaction Following the Use of an Enhanced Gynecologic Brachytherapy-Specific Educational Consent Video.
Short Title	Brachytherapy video consent
Phase	Phase III
Methodology	Randomized
Study Duration	12 months
Study Center(s)	Single-center
Objectives	**Primary Objective:** To evaluate the impact of a gynecologic brachytherapy-specific educational consent video in patients receiving brachytherapy on patient reported satisfaction **Secondary Objectives:** Evaluate the integration of the brachytherapy-specific consent video on patient treatment-related anxiety
Number of Subjects	80
Diagnosis and Main Inclusion Criteria	Any patient with gynecologic cancer who is deemed to require a brachytherapy procedure, and is willing to participate is eligible for inclusion.
Study Product(s), Dose, Route, Regimen	Gynecologic brachytherapy video consent.
Duration of administration	Prior to consent for the gynecologic brachytherapy procedure.
Reference therapy	None.
Statistical Methodology	1:1 block randomization between standard and enhanced video consent. To address the study hypotheses, we will use two-sample t-test to compare satisfaction score in two groups (patients provided with standard of care verbal consent (arm A) vs. enhanced online accessible brachytherapy educational video (Arm B)).

STUDY TABLE

	Consult	Pre-Informed consent	Intervention	Post Informed Consent	Post Brachytherapy
History (Medical/Oncology)	X				
Demographics	X				
Eligibility criteria	X				
Physical exam	X				
Vital Signs	X				
Height, weight	X				
Performance status	X				
TNM stage	X				
Tumor histology	X				
Use/type of systemic therapy	X				
Brachytherapy dose/volume information					X
Physician workflow data			X		
Informed Consent			A, B		
NCCN distress score		X		X	X
Brachytherapy-specific survey		X		X	X
Brachytherapy educational video			B		

Arm A: Standard consent process
Arm B: Video consent process

1.0 BACKGROUND AND RATIONALE

1.1 Background

High dose-rate brachytherapy is a highly technical and integral component of the definitive treatment of gynecologic cancers. Gynecologic brachytherapy requires a skillfully coordinated team approach with a focus on the patient experience[1].

Patients associate high-quality care with the ability to participate in decision making and obtain reliable information about their health and treatment [3,4].

Provider explanation of these complex information processes can be overwhelming despite a well-documented informed consent [9]. Prior work from our group explored enhanced patient consent material on gynecologic brachytherapy understanding and patient satisfaction and quality of life (rash Mayadev). We found that brachytherapy specific take home materials in supplement to a standard verbal consent process resulted in high patient treated related satisfaction (Rash D, Mayadev, J. Prospective Evaluation of Patient Satisfaction Following the Use of Visual Brachytherapy-Specific Educational Materials for Cervical Cancer. Brachytherapy. 2016 Jan-Feb;15(1):65-70. doi: 10.1016/j.brachy.2015.09.007).

This study seeks to engage and educate the patient regarding the expected treatment trajectory using audiovisual mixed multimedia that comprehensively discusses the entire brachytherapy procedural process. We hypothesize there will be a significant improvement in all evaluable metrics in the cohort of patients receiving the brachytherapy video which would translate into improved quality of delivered care, patient understanding, increased treatment compliance, and enhancement in provider-patient communication.

1.2 Study Intervention

This study uses a gynecologic brachytherapy specific patient education video for the consent process in radiation oncology. All patients will meet with the radiation oncologist and have the standard of care procedure consent performed. Arm B (intervention arm) will have the access to view the brachytherapy educational video via the UCSD radiation learning center (https://ucsd.radonclearningcenter.org/ucsdradonclearningcenter) after the standard consent, study consent, and prior to the first brachytherapy procedure.

1.3 Rationale

Brachytherapy is a highly technical and integral component of the definitive treatment of gynecologic cancers [1]. To enhance provider communication and patient engagement, our study investigates a video consent on impact of patient treatment-related outcomes.

We will use a detailed brachytherapy video in addition to the standard brachytherapy verbal consent to evaluate patient-reported satisfaction and patient anxietyfor gynecologic high-dose rate brachytherapy (a radiation procedure).

2.0 STUDY OBJECTIVES

2.1 Primary Objectives

To evaluate the impact of a gynecologic brachytherapy-specific educational video in patients receiving brachytherapy on patient reported satisfaction

2.2 Secondary Objectives

To evaluate the use of the brachytherapy-specific educational video on patient treatment-related anxiety

2.3 Exploratory Objectives

To evaluate the number of views and completeness of views of the brachytherapy video by the patients. To examine the patient radiation doses, treatment planning aspects, and normal tissue doses on brachytherapy completion.

2.4 Endpoints:

2.4.1 Primary:

Using the brachytherapy specific questionnaire, we will collect three patient reported time points for impact: baseline, after the consent process and before the first brachytherapy procedure (both arms have the standard consent at the consultation, and arm B will have access to the brachytherapy video online), and prior to the last brachytherapy procedure. For primary outcome we will examine satisfactory scores assessed by the brachytherapy-specific survey at two time points: baseline and following consent.

2.4.2 Secondary:

We will examine satisfactory scores at three patient reported time points: baseline, after the consent process and before the first brachytherapy procedure, and prior to the last brachytherapy procedure.

Using the NCCN distress scale, we will examine patient treatment-related anxiety at three patient reported time points: baseline, after the consent process and first brachytherapy procedure, and prior to the last brachytherapy procedure.

2.4.3 Exploratory:

The view number and completeness will be recorded from the UCSD radiation oncology learning website. The dose distribution of the target volume, normal tissue volumes and doses, and treatment planning goals will be explored.

3.0 PATIENT ELIGIBILITY

3.1 Inclusion Criteria

Subjects must meet all of the inclusion criteria to participate in this study.

1. Patient has the ability to understand and the willingness to sign a written informed consent.

2. Patient must be female, all races and ethnic groups are eligible.

3. Must be > 18 years of age, or have parental approval for inclusion.

4. Must carry a diagnosis of gynecologic malignancy.

5. Is deemed to require high-dose rate gynecologic brachytherapy procedure (intracavitary, hybrid intracavitary/interstitial, or interstitial).

6. Any prior external beam radiation therapy is allowed.

7. Any performance status is allowed.

8. Women of child-bearing potential and men with partners of child-bearing potential must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study participation, and for # days following completion of therapy. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately.
    - A woman of child-bearing potential is any female (regardless of sexual orientation, having undergone a tubal ligation, or remaining celibate by choice) who meets the following criteria:
        - Has not undergone a hysterectomy or bilateral oophorectomy; or
        - Has not been naturally postmenopausal for at least 12 consecutive months (i.e., has had menses at any time in the preceding 12 consecutive months)

3.2 Exclusion Criteria

Subjects meeting any of the exclusion criteria at baseline will be excluded from study participation.

1. Patient has had prior high-dose rate gynecologic brachytherapy at any point in the past.
2. . Patient is a non English speaker

3. Patient is unable to watch the video

4. Patient declines consent to the study

5. Study-specific exclusion criteria.

6. Patient has a severe or uncontrolled medical disorder that would, in the investigator's opinion, impair ability to receive study treatment (i.e., uncontrolled diabetes, chronic renal disease, chronic pulmonary disease or active, uncontrolled infection, psychiatric illness/social situations that would limit compliance with study requirements).

4.0 TREATMENT PLAN

4.1 Study Design

1:1 randomized trial using blocked randomization based on chronologic arrival in clinic, a group of patients will be randomized to the standard of care verbal consent (Arm A), or the standard of care consent plus the online brachytherapy informed video (Arm B). There will be three time points for the collection: After the standard consent process as the baseline, following the standard only vs standard and educational video consent process prior to the first brachytherapy procedure, and prior to the last brachytherapy procedure. The patients in the brachytherapy video consent process will be watching this online via the UCSD Radiation Oncology Learning Center Website https://ucsd.radonclearningcenter.org/ucsdradonclearningcenter. The patient will be given a specific log in to use, and we will be able to track the number of times the patient watches the video and the completion of the video view. The patient is allowed to watch the video as many times as desired.

4.2 Duration of Study Treatment

In the absence of treatment delays, the treatment will continue through the end of the completion of the necessary external beam radiation therapy treatments, or conclusion of all gynecologic brachytherapy procedures.

4.3 Duration of Follow Up

The study intervention with conclude after completion of the final brachytherapy implantation and prior to discharge from clinic.

Discontinuation from Study Participation
Patients may be removed from study participation for the following reasons (in addition to those listed for discontinuation of study treatment):

- The patient or legal representative withdraws consent;
- The patient is lost to follow-up;
- The patient dies;
- It is the decision of the investigator.

5.0 Measurement of Effect

5.1 Brachytherapy-specific outcomes

Primary outcome of this trial will be change in patient satisfaction scores (difference of baseline and following the video consent) as assessed by the brachytherapy-specific survey. Secondary outcomes will include patient treatment-related anxiety(NCCN distress score).

6.0 ADVERSE EVENTS

6.1 An adverse event (AE) is any untoward medical occurrence in a patient receiving study treatment and which does not necessarily have a causal relationship with this treatment. We do not anticipate AE on this video study. Gynecologic Brachytherapy Video Consent

7. Product description:

We developed a novel gynecologic brachytherapy-specific video. Due to clinical time constraints, it is often not feasible to comprehensively cover the full expanse of a brachytherapy

procedure with the patient; however, this is a crucial part of the treatment process. The video and associated multimedia educational materials will be used to enhance patient education and understanding, and provider-patient communication.

Video weblink: https://chtapps-prod.ucdmc.ucdavis.edu//VideoConf/VCVideo/BRACHYSixthCut.mp4 will be posted to the UCSD Radiation Oncology Learning Center Website https://ucsd.radonclearningcenter.org/ucsdradonclearningcenter

Availability: Supplied by UCSD PI, Dr. Jyoti S. Mayadev.

How supplied: Audiovisual digital multimedia.

Storage and stability: On UCSD computing devices, behind institutional firewall, and subject to computing and technology requirements.

Route of administration for this study: Patient views video prior to gynecologic brachytherapy.

Side effects: There are no anticipated side effects.

8.0 SAMPLE SIZE AND STATISTICAL PLAN

This is a single site, randomized, open-label trial comparing the effect of the branchytherapy specific video versus verbal standard consent in patients receiving gynecologic brachytherapy(N=80).

8.1

Study Design/Study Endpoints

In this open-label study design, eligible participants will be randomized using a simple 1:1 schedule to either brachytherapy verbal standard consent (Arm A), or the brachytherapy specific video (Arm B), based on chronological arrival in clinic. There will be three time points for the collection: after the standard verbal consent process at baseline, following the standard vs video brachytherapy education, and prior to the last brachytherapy procedure.

Primary outcomes will be judged from a Likert-scale questionnaire. Patients will be given a Likert-scale questionnaire to assess their satisfaction with the information provided about the brachytherapy procedure which was adapted from a previously-published, validated instrument, and was published by our brachytherapy group[2] . We will also assess the reduction in procedure-related anxiety based on the video intervention using the validated National Comprehensive Cancer Network patient anxiety screening tool.

8.2 Power and Sample Size Determination

Study Power: Estimates of study power are based on two-sample t-tests comparing outcomes between patients provided with brachytherapy informed video versus standard of care verbal consent. We based power estimates on a sample-size of 80 participants (40 pts with brachytherapy informed video and 40 with standard of care verbal consent). We used PASS 14 (NCSS Statistical Software). Assuming a two-sided test with alpha=0.05, we have 80% power to detect a 3.2 mean difference between armse.g., 57.5 mean score in patients with brachytherapy informed video versus a 54.3 mean score in patients with standard of care verbal consent, assuming SD of 2.7 and 6.4, respectively.

Accrual will be based on chronological arrival in clinic. Approximately 250 brachytherapy gynecologic procedures are performed at UCSD and collaborating sites annually. Accrual of 80 participants could occur over 2 years. Annual target accrual will be 40 participants per year.

8.3 Evaluable Subjects and Subject Replacement

The intent-to-treat (ITT) data set will include all eligible individuals who are randomized.
The per-protocol (PP) data set will include all patients having completed all three data collection time points as assessed by the brachytherapy-specific survey, and NCCN distress score.

Data will not be analyzed until we have reached target accrual. Given the short duration of the intervention to the end of treatment we do not anticipate any issues with the number of evaluable subjects. Should a subject withdraw an additional subject would be randomized and enrolled. A slight imbalance is accepted.

8.4 Efficacy Analysis

8.4.1 Analysis of Primary Endpoint

The primary analysis will be based on the Intention-to-Treat population, defined as all individuals who were randomized to arm A or arm B. A Likert-scale questionnaire is used to calculate satisfaction score.
Using the brachytherapy specific questionnaire, we will examine three patient reported time points for impact: baseline, after the consent process, and prior to the last brachytherapy procedure. For primary endpoint, we will use a two-sample t-test to compare differences of satisfaction scores at two time points (baseline and following consent process) between groups. We do not anticipate any possible confounders, if any we will include it in the secondary analysis.

8.4.2 Handling of missing data

In primary analysis, outcome values will not be imputed. Further sensitivity analysis for the impact of potential missing data will be conducted following study completion using multiple imputation analysis.

8.4.3 Analysis of Secondary Endpoints

Satisfactory scores at three time points will be analyzed using a mixed effect model for repeated measures (MMRM) to assess satisfactory scores trajectories between two arms. The MMRM model will include terms for time, consent arm, baseline score, arm-by-time interaction, baseline score by time interaction, plus covariates that include age, stage. Time will be treated as categorical.

If values of last two time points are similar, analysis of covariance model (ANCOVA) will be used to model the change in satisfactory scores. The mean of the last two time points will be calculated. That is, the after consent score (mean values) will be regressed upon baseline score and consent arms. Patient treatment-related anxiety between groups, defined as NCCN distress score, are also collected at three time points and will be analyzed using the same strategy.

9 STUDY MANAGEMENT

9.1 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed according to UCSD conflict of interest policy.

9.2 Institutional Review Board (IRB) Approval and Consent

The IRB should approve the consent form and protocol prior to any study-related activities. It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form.

Prior to a patient's participation in the trial, the written informed consent form should be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

Any recruitment materials developed for this project will be submitted for IRB review prior to their use.

9.3 Subject Data Protection

In accordance with the Health Information Portability and Accountability Act (HIPAA), subjects who have provided written informed consent must also sign a subject authorization to release medical information to the study Sponsor and allow a regulatory authority, or Institutional Review Board access to subject's medical information relevant to the study.

9.4 Data and Safety Monitoring/Auditing

In addition to adverse event monitoring and clinical oversight by Jyoti S. Mayadev, UCSD

principal investigator and co-investigators, quality assurance of the study will be performed by the UCSD Moores Cancer Center Clinical Trials Office internal monitor. Monitoring intervals will be dependent upon the number of patients enrolled and the complexity of the study.

This study will also use the UCSD Moores Cancer Center Data Safety and Monitoring Board (DSMB) to provide oversight in the event that this treatment approach leads to unforeseen toxicities. Data from this study will be reported when<minimum annually, frequency related to risk; can ask for recommendations from DSMB> and will include:

1) the protocol title, IRB protocol number, and the activation date of the study.
2) the number of patients enrolled to date
3) the dates of patient enrollment
4) a summary of all adverse events regardless of grade and attribution
5) a response evaluation for evaluable patients when available
6) a summary of any recent literature that may affect the ethics of the study.

9.5 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, investigators are required to conduct their research according to the plans reviewed and approved by the IRB.

9.6 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Study Chair. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to the IRB for approval prior to implementation.

9.7 Record Retention

Study documentation includes all Case Report Forms, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that the study investigator must retain all study documentation pertaining to the conduct of a clinical trial. In the case of a study with a drug seeking regulatory approval and marketing, these documents shall be retained for at least two years after the last approval of marketing application in an International Conference on Harmonization (ICH) region. In all other cases, study documents should be kept on file until three years after the completion and final study report of this investigational study.

9.8 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki.

The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator at each institution or site will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

10.0 REFERENCES

1. Mayadev J, Qi L, Lentz S, et al. Implant time and process efficiency for CT-guided high-dose-rate brachytherapy for cervical cancer. *Brachytherapy.* 2014;13(3):233-239.
2. Rash D, Hess C, Lentz S, Tait L, Michaud A, Mayadev J. Prospective evaluation of patient satisfaction after the use of brachytherapy specific educational materials for cervical cancer. *Brachytherapy.* 2016;15(1):65-70.
3. Colosia AD, Peltz G, Pohl G, et al. A review and characterization of the various perceptions of quality cancer care. *Cancer.* 2011;117(5):884-896.
4. Watson DE MD, Peterson S. Patient experiences with Ambulatory Cancer Care in British Columbia, 2005/06. 2007; http://www.health.gov.bc.ca/library/publications/year/2007/OncologySurvey/UBC_OncologyReport.pdf. Accessed 4/11/15, 2015.
5. Rainey LC. Effects of preparatory patient education for radiation oncology patients. *Cancer.* 1985;56(5):1056-1061.
6. van der Molen B. Relating information needs to the cancer experience: 1. Information as a key coping strategy. *European journal of cancer care.* 1999;8(4):238-244.
7. Hess CB, Chen AM. Measuring psychosocial functioning in the radiation oncology clinic: a systematic review. *Psycho-oncology.* 2014;23(8):841-854.
8. Dutta S, Nguyen NP, Vock J, et al. Image-guided radiotherapy and -brachytherapy for cervical cancer. *Frontiers in oncology.* 2015;5:64.
9. LE L. Being informed: undergoing radiation therapy. *Cancer Nursing.* 2001;24(6):5.
10. Jacobsen PB, Donovan KA, Trask PC, et al. Screening for psychologic distress in ambulatory cancer patients. *Cancer.* 2005;103(7):1494-1502.

11 APPENDICES

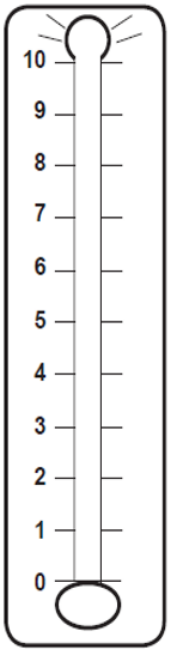
Appendix A. Performance Status

ECOG Performance Status Scale		Karnofsky Performance Scale	
Grade	Descriptions	Percent	Description
0	Normal activity. Fully active, able to carry on all pre-disease performance without restriction.	100	Normal, no complaints, no evidence of disease
		90	Able to carry on normal activity; minor signs or symptoms of disease.
1	Symptoms, but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work).	80	Normal activity with effort; some signs or symptoms of disease.
		70	Cares for self, unable to carry on normal activity or to do active work
2	In bed < 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	60	Requires occasional assistance, but is able to care for most of his/her needs.
		50	Requires considerable assistance and frequent medical care
3	In bed > 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	40	Disabled, requires special care and assistance.
		30	Severely disabled, hospitalization indicated. Death not imminent
4	100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	20	Very sick, hospitalization indicated. Death not imminent.
		10	Moribund, fatal processes progressing rapidly
5	Dead.	0	Dead.

Appendix B. NCCN Distress Tool

Instructions: Below, circle the number (0-10) that best describes how much distress or anxiety you have been experiencing as it relates to your planned brachytherapy procedure.

Extreme distress or anxiety



No distress or anxiety

Instructions: Below, circle the number (0-5) that best describes how much the following problems have been affecting you.

	None at All	Rarely Ever	Not Very Much	Some	Often	Very Much
Depression	0	1	2	3	4	5
Fear	0	1	2	3	4	5
Nervousness	0	1	2	3	4	5
Sadness	0	1	2	3	4	5
Worry	0	1	2	3	4	5
Loss of interest in activities	0	1	2	3	4	5
Changes in urination	0	1	2	3	4	5
Constipation	0	1	2	3	4	5
Diarrhea	0	1	2	3	4	5
Nausea	0	1	2	3	4	5
Getting around	0	1	2	3	4	5
Indigestion	0	1	2	3	4	5
Pain	0	1	2	3	4	5

Appendix C. Patient Reported Satisfaction

Appendix C: Treatment Specific Patient Reported Satisfaction

Question	Strongly disagree (1)	Disagree (2)	Uncertain (3)	Agree (4)	Strongly agree (5)	
I am satisfied with:						
The information I have been given about my cancer treatment						
The information I have been given about possible side effects						
The information I have been given on what to do if side effects happen						
Explanations about possible interactions between my prescribed cancer treatments and other treatments I am thinking about using						
The way treatment information is presented to me, it is clear and easy to understand						
I get enough opportunity to ask questions about my cancer treatment						
I get enough opportunity to ask questions about how to manage side effects						
Available information resources such as handouts and staff						
The manner in which the information is provided. It is friendly, respectful, non judgmental						
To make informed choices about my cancer treatment						
To make informed choices about how to manage side effects						