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To: Office of Management and Budget (OMB)

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Subject: Bundled Generic Sub-study, "Examining the Management of Muscle Invasive Bladder Cancer (MISC) by Medical Oncologists" **under "Formative Research, Pretesting, and Customer Satisfaction of NCI's Office of Communication and Education," OMB No. 0925-0046-12, Expiration Date 2/28/2013**

The Center for Cancer Research, National Cancer Institute (CCR, NCI) in collaboration with members of the Bladder Cancer Advocacy Network (BCAN) Bladder Cancer Think Tank Meeting in 2010, proposes conducting research to determine the patterns of practice in the management of patients with muscle-invasive bladder cancer (MIBC) by medical oncologists in the United States. This is an initiative developed during the BCAN Bladder Cancer Think Tank Meeting in 2010. The goal of this formative research is to highlight the patterns of practice and need to delineate guidelines for clinical practice.

Background

The CCR, NCI in collaboration with the Standardization of Treatment working group of BCAN, is working to improve the quality of care provided to bladder cancer patients by finding ways to better standardize the treatment given. Their challenge is to determine what care is being given now, what the appropriate care is, and what can be done to make sure that doctors then give that care.

In bladder cancer patients, perioperative chemotherapy refers to chemotherapy that is administered before or after radical cystectomy. Current guidelines recommend that doctors consider administering perioperative chemotherapy to most patients with MIBC either before (neoadjuvant chemotherapy) or after (adjuvant chemotherapy) radical cystectomy. Although it is not appropriate in all cases, clinical trials have shown that chemotherapy provides an overall survival benefit for survivors with MIBC.^{1,2}

1 Grossman HB, Natale RB, Tangen CM, et al: Neoadjuvant chemotherapy plus cystectomy compared with cystectomy alone for locally advanced bladder cancer. *New Eng J Med* 349:859-66, 2003

2 Vale C.L.: Neoadjuvant Chemotherapy in Invasive Bladder Cancer: Update of a Systematic Review and Meta-Analysis of Individual Patient Data: Advanced Bladder Cancer (ABC) Meta-analysis Collaboration. *Eur Urol* 48:202-206, 2005

Recently, BCAN researchers reviewed 4,541 patient records from fourteen institutions to see whether these patients received adjuvant or neoadjuvant chemotherapy, or if they did not receive any chemotherapy. They found that only 34% of patients were given perioperative chemotherapy. However, since they were just reviewing patient records, researchers could not see the reasons that so few patients were given perioperative chemotherapy. Potential reasons could be that patients decided against the chemotherapy offered by their doctor, or that doctors assumed that older patients would not want chemotherapy.³

As the timing of these treatments has not been standardized, the primary aim of this formative study is to examine the patterns of practice in the management of patients with MIBC by medical oncologists in the United States in order to highlight the need to delineate guidelines for clinical practice. Results from this study, along with other studies similar in nature, will be used in support of improving existing service delivery.

Participants

Participants will be registered medical oncologists who participated in BCAN's Bladder Cancer Think Tank Meeting in 2010 and medical oncologist affiliated with US Oncology. To ensure a mix of experiences and perspectives, participants from larger academic/medical centers as well as smaller community-based settings will be included, and efforts will also be made to include individuals from a mix of urban and rural locations.

BCAN's mission is to increase public awareness about bladder cancer; to advance bladder cancer research; and to provide educational and support services for the bladder cancer community. More than 90 leading physicians, researchers, and advocates attended the Bladder Cancer Think Tank Meeting in 2010. This included urologists, pathologists, basic scientists, oncologists, radiation oncologists, and survivors.

US Oncology's mission is to expand patient access to high-quality, advanced cancer care. Through nearly 1,400 physicians, US Oncology unite the nation's largest network of community oncologists and cancer researchers. Physicians affiliated with US Oncology care for more than 850,000 patients in communities throughout the nation.

Methodology

Participants affiliated with the BCAN network will be contacted through an e-mail invitation (**Attachment 12A**) from the CCR, NCI which will include a secure, non-identifiable link to the web-based survey (**Attachment 12B**). In addition, for those participants affiliated with US Oncology, a link to the survey will be posted on the "The Oncology Portal".⁴ The Oncology Portal is a web-based community that allows remote network physicians to collaborate in real time to handle tough cases, discuss new treatments, and receive expert insight from leaders in oncology sub-specialties.

Recruitment will continue until the target sample size for completed surveys is reached. The collection tool has been automatically setup to prevent participants from completing the survey

³ Feifer A., Taylor J. M., Shouery M., Steinberg G. D., Stadler W. M., Schoenberg M., Zlotta A., Lerner S. P., Bajorin D. F., Bochner B.; B.C.A.N. Muscle-invasive Bladder Cancer Quality of Care Consortium; Memorial Sloan-Kettering Cancer Center, New York, NY; The University of Chicago, Chicago, IL; The University of Chicago Medical Center, Chicago, IL; Johns Hopkins Medical Institutions, Baltimore, MD; Princess Margaret Hospital, Toronto, ON, Canada; Baylor College of Medicine, Houston, TX. Multi-institutional quality-of-care initiative for nonmetastatic, muscle-invasive, transitional cell carcinoma of the bladder: Phase I. *J Clin Oncol* 29: 2011 (suppl 7; abstr 240).

⁴ www.theoncologyportal.com

once the goal is met. A representative from the CCR, NCI will collect and analyze the data.

The survey will inquire about the type of chemotherapy given in the perioperative setting, including doses, cycle length and duration of treatment, the imaging schedule and the type of practice. The survey has been developed to focus on the following categories:

- Bladder Cancer Referral Information,
- Perioperative Chemotherapy- General Staging/ Goals of Care,
- Neoadjuvant Chemotherapy- Patient Characteristics,
- Neoadjuvant Chemotherapy- Staging,
- Neoadjuvant Chemotherapy- Regimen,
- Neoadjuvant Chemotherapy- Staging and Follow-up,
- Post Cystectomy Treatment

Participants responding to this questionnaire will not receive remuneration for their participation.

A similar effort was conducted with Canadian medical oncologists who primarily treat bladder cancer. The results from this study indicated that the majority of physicians who were emailed the invitation completed the web-based survey.⁵ As such, it is not uncommon for response rates on web-surveys to be notably higher than comparable studies conducted through a random-digit phone survey for example. Final results of the Canadian study along with the data collected in this USA study will be presented at the Bladder Cancer Advocay Network (BCAN) Think Tank meeting in San Diego, California on August, 4-8, 2011. It will be clear that we are not making recommendations based on the study results. It is hoped that this formative study, along with similar research, will be used to highlight the current patterns of practice in the management of MIBC by medical oncologists and the need to standardize these practices.

Participants will not be provided consent forms. However, the following language will be added to the invitation email and prior to the link in “The Oncology Portal” as an alternate for the consent form: “By clicking on the link below, you are consenting to participate in this survey. Cumulative results of the survey will be known after the completion of the survey.”

All information provided by participants will be kept secure to the extent permitted by law. The operating settings for the web-survey will be set-up to only accept one response (i.e. one survey) from one computer. The only identifiable information that will be collected is the IP address which will allow us to track prevent participants from completing the survey multiple times on the same computer.

An Office of Human Subjects Research (OHSR) exemption request has been submitted.

Burden

We expect a total of 100 participants to participate in the web-survey. The average total participation time will be 10 minutes per participant. This time includes reviewing the instructions for completing the survey; and getting online and completing the survey. The total burden requested for this sub-study is estimated to be 17 hours. This effort will account for less than 1 percent of the total burden hours granted in the full generic OMB clearance package. To

5 Hsu T., North S., Eigel B. J., Chi K. N., Canil C. M., Wood L., Lau A., Panzarella T., Sridhar S. S.; University of Toronto, Toronto, ON, Canada; Cross Cancer Institute, Edmonton, AB, Canada; Tom Baker Cancer Centre, Calgary, AB, Canada; British Columbia Cancer Agency, Vancouver, BC, Canada; Ottawa Regional Cancer Center, Ottawa, ON, Canada; Queen Elizabeth II Health Sciences Centre, Halifax, NS, Canada; Princess Margaret Hospital, Toronto, ON, Canada; Department of Biostatistics, Princess Margaret Hospital and University of Toronto, Toronto, ON, Canada, The neoadjuvant management of bladder cancer in Canada: A survey of genitourinary medical oncologists. J Clin Oncol 29: 2011 (suppl 7; abstr 285)

date, a total of 1758 burden hours have been used of the 7050 hours that were requested.

Table 1: Estimates of Hour Burden for Web Survey

Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time (Minutes/Hour)	Annual Hour Burden
Medical Oncologist from BCAN Bladder Cancer Think Tank Meeting 2010 and US Oncology	100	1	10/60 (0.1667)	17
<i>Totals</i>	100			17

List of Attachments (Attached below)

12A: Invitation Email

List of Attachments (Attached separately)

12B: Web-based Survey

Attachment 12A: Invitation Email

Recruitment Email

Subject Line: Examining the Management of Muscle Invasive Bladder Cancer by Medical Oncologists.

Dear Colleagues,

This is an initiative developed during the Bladder Cancer Advocacy Network (BCAN) think tank session in 2010. Currently medical oncologists administer a variety of cisplatin and non-cisplatin-based regimens to this patient population. Our goal is to examine the patterns of practice in the management of patients with muscle invasive bladder cancer by medical oncologists in the United States.

It is our hope that detailing patterns of practice will facilitate the development of clinical trials incorporating novel treatment approaches and/or new targeted agents and help delineate guidelines for clinical practice.

The survey consists of 26 questions and takes about 5-10 minutes. The information you provide will be kept secure to the extent permitted by law.

By clicking on the link below, you are consenting to participate in this survey. Cumulative results of the survey will be known after the completion of the survey.

Link to the survey:

<https://www.surveymonkey.com/s/PerioperativeBCAN2>

We greatly appreciate your time and effort in filling out this survey. If you have additional questions, do not hesitate to contact me.

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